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The Permanente Journal

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ON THE COVER

"Dead Vlei, Namibia 2009" by Stuart Hahn, MD, is a photograph taken at a salt/clay pan or dry lake bed at Sossusvlei, Namibia called "Dead Vlei." The word "Vlei" refers to a shallow grass depression or small valley. The trees are Camel Thorn Trees that died when the water vanished. Dr Hahn can see a number of symbolic interpretations of these long dead trees.

Dr Hahn retired from The Permanente Medical Group in 2010. He previously was the Clinical Director at the Sacramento Regional Appointment and Advice Call Center. He has been seriously exploring photography since 2000 and has an interest in both wildlife and landscape photography.

For more information about this or other published photographs please feel free to E-mail him at hahnsk@sbcglobal.net

Dr Hahn has been published in *The Permanente Journal* and *leaflet*.

95 CME EVALUATION FORM

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ORIGINAL RESEARCH & CONTRIBUTIONS

4 Predicting Poor Outcomes in Heart Failure. David H Smith, RPh, PhD; Eric S Johnson, PhD; Micah L Thorp, DO, MPH; Xiuhai Yang, MS; Amanda Petrik, MS; Robert W Platt, PhD; Kathy Crispell, MD

Using data from electronic health records from a large health maintenance organization, the authors developed a model to predict the 5-year mortality or hospitalization risk for heart failure among 4696 patients who had an echocardiogram and a heart failure diagnosis from 1999 to 2004. They observed a 56% five-year risk of death or hospitalization for heart failure. The simple model includes demographic characteristics, blood pressure, renal function, and anemia status. The observed risk was three times higher in the highest-risk quintile than in the lowest-risk quintile.

CME **12 Napa Immunization Study: Immunization Rates for Children with Publicly Funded Insurance Compared with Those with Private Health Insurance in a Suburban Medical Office.** James C Cotter, MD, MPH

The immunization rates and health-access measures of 109 children ages 24 to 48 months, who had publicly funded health insurance (PFI) were compared with 300 children of the same age with private health insurance in the same medical practice. Children with PFI had lower rates of immunization and fluoride prescriptions; however the differences were only significant in the cohort of children age 2 years, and became similar by age 3 years.

23 A Single-Blinded, Direct Observational Study of PGY-1 Interns and PGY-2 Residents in Evaluating their History-Taking and Physical-Examination Skills. Sandeep Sharma MD, DrPH(c)

An independent medical observer used a yes/no checklist with 60 variables in a single-blinded observational study. Frequency tables were generated and results were based on descriptive statistics. In 7 categories aimed at chart review for accuracy, discrepancies were found between what medical interns and residents recorded in the patient's chart and the observed actions during the patient encounter. In 64%, the time spent on history taking was <7 minutes. In 72%, patients were not asked about family medical history.

CME **30 Early Detection of Colon Cancer—The Kaiser Permanente Northwest 30-Year History: How Do We Measure Success? Is It the Test, the Number of Tests, the Stage, or the Percentage of Screen-Detected Patients?** David Moiel, MD; John Thompson, MD

This historical review of 5458 patients summarizes colorectal cancer screening strategies for 3 decades. The number of exams and disease-stage does not accurately reflect the effectiveness of screening efforts. A better measure is the percentage of screen-detected cases. Using a good test able to reach more people rather than the "perfect test" that reaches fewer transforms an ineffective program to a successful one when the strategy moves from testing to screening.

40 Centering Parenting: Pilot Implementation of a Group Model for Teaching Family Medicine Residents Well-Child Care. Pooja Mittal, DO

Leaders in child health care recommend primary care physicians use a parent-centered approach, with a focus on the parent–child relationship in the context of family, culture, and community. The family medicine residency program at the University of California, San Francisco is testing a parent-centered group-care model that over a year allows residents to experience comparative development as well as interactions among a group of parents and children, and forges a stronger bond between physician and parent.

Implementation Study

CME **42 Regional Expansion of Minimally Invasive Surgery for Hysterectomy: Implementation and Methodology in a Large Multispecialty Group.** Esteban Andryjowicz, MD; Teresa Wray, MD

In the US each year, hysterectomy is the second most common major operation performed in women (600,000). This article reviews the steps that a large multispecialty group used to teach non-open hysterectomy methods to improve the quality of care and decrease inpatient procedures, and therefore costs. A structured educational intervention was delivered to 350 obstetrician/gynelcologists at 12 medical centers, and their 26,055 hysterectomies (2005-2010) were studied. The rate of non-open hysterectomies increased 120% (from 38% to 78%) and the average length of stay decreased 31%.

REVIEW ARTICLES

48 Quality Measurement and Improvement in General Surgery.
Marisa Cevasco, MD, MPH; Stanley W Ashley, MD

Several sophisticated quality-measurement and outcomes systems have been developed including the National Surgical Quality Improvement Program, the use of selective referral and centers of excellence, the Surgical Care Improvement Project, and the World Health Organization Surgical Safety Checklist. This article reviews each of these initiatives, highlights their contributions, and discusses future directions within general surgery.

54 New Technology Review Process: The Laparoscopic Adjustable Gastric Band. Sandra Arthurs, MS, BME; Yerado Abrahamian, MHS; Elizabeth L Loughren, MPH; Jo Carol Hiatt, MD; Robin Cisneros; Jed Weissberg, MD

The Interregional New Technologies Committee (INTC) considers all available published evidence on a particular technology, surgical technique, or implantable device for a specific clinical indication and provides a recommendation on the sufficiency of the evidence for determining net medical benefit. This overview illustrates the INTC process and how it supports clinical decision making.

CASE STUDIES

61 A Case of an Abdominal Mass: Follicular Lymphoma. Tina L Walker, MD; Gabriel E Lopez, MD

Follicular lymphoma (FL) the second most common subtype of non-Hodgkin lymphoma usually affects older individuals (average 63.5 years). This report describes FL in a 38-year-old woman. These patients will likely first present to their primary care physicians.

66 Does My Patient Have Asthma?
Eric Macy, MD, MS

A 57-year-old woman, initially seen in primary care, had diagnoses of steroid-dependent "asthma," obesity, depression, reflux, sleep apnea, pollen allergy, hypertension, hyperlipidemia, and prediabetes. The diagnosis of asthma should be confirmed by pulmonary function tests before and after bronchodilator use to document reversible airflow obstruction or should undergo a methacholine or mannitol challenge.

70 Suppressed Wound Healing In a Patient with Rheumatoid Arthritis Taking Leflunomide (Arava).
CME
D Miller Wise, MD

Although patients with rheumatoid arthritis taking disease-modifying antirheumatic drugs (DMARDs) are monitored for various medication adverse events, DMARDs, and leflunomide in particular, have effects that are not observed clinically, specifically adverse effects on wound healing.

CLINICAL MEDICINE

75 ECG Diagnosis: Pulmonary Embolism.
Joel T Levis, MD, PhD, FACEP, FAAEM

The S1Q3T3 sign (prominent S wave in lead I, Q wave and inverted T wave in lead III) is a sign of acute corpulmonale (acute pressure and volume overload of the right ventricle because of pulmonary hypertension) and reflects right ventricular strain.

76 Dermatology Image: Erythema Multiforme.
Joel T Levis, MD, PhD, FACEP, FAAEM

Erythema multiforme is a type of delayed hypersensitivity skin reaction triggered by infection or by certain drugs. It consists of a polymorphous eruption of macules, papules, and characteristics target lesions (central bullae or vesicle with surrounding concentric rash) distributed with a propensity for the distal extremities, and minimal mucous membrane involvement with less than 10% epidermal detachment.

77 Image Diagnosis: Ultrasound in Right Lower Quadrant Pain.
L Paige Sokolsky, MD; Gus M Garmel, MD, FACEP, FAAEM

Doppler ultrasound is the imaging modality of choice as an enlarged, torsed ovary with peripherally displaced follicles because of vascular congestion. Because the ovary is supplied by both the ovarian and uterine arteries, a torsed ovary may have arterial flow, and medial displacement of the ovary compresses the uterus and bladder.

COMMENTARY

79 Physician-Assisted Suicide and Euthanasia: Can You Even Imagine Teaching Medical Students How to End Their Patients' Lives?
J Donald Boudreau, MD

In the peer-reviewed literature there is a paucity of commentary on the interface of euthanasia and physician-assisted suicide with medical education. This paper explores potential implications for medical education of a widespread sanctioning of physician-inflicted and physician-assisted death. Through a consequential-basis analysis, the author concludes that euthanasia, when understood to include physician aid in hastening death, is incommensurate with humanism and the practice of medicine.

85 Bridging Physician-Patient Perspectives Following an Adverse Medical Outcome.
Mark Montijo, PhD; Kathleen Nelson, RN, MPA; Mark Scafidi, JD; Dave St Pierre, MHROD; Dorothy Tarrant, LCSW, MPA; Jocelyne Vistan, MA; Maureen Whitmore, MA

During the course of physician-patient interactions in today's increasingly complex health care environment, conflict inevitably arises. Physicians are held to very high standards, sometimes leaving them and their patients ill-equipped to cope with medical complications and unexpected outcomes. In the aftermath of an unanticipated adverse outcome, how health care professionals deal with errors has gained greater importance and attention.

EDITORIAL

89 Patient-Centered Research from Electronic Medical Records.
Mikel Aickin, PhD

Currently, perhaps the largest collection of unresolved or poorly resolved medical issues are the kinds patients present in primary care. A new electronic section of the journal, dedicated to publication of EMR-based research, is now open for article review. Encouraged article characteristics include: assessment of therapies as they are actually provided, inclusion of all relevant patients, and new analytic methods.

NARRATIVE MEDICINE

92 Humanity before Science: Narrative Medicine, Clinical Practice, and Medical Education.
Samir Johna, MD; Simi Rahman, MD

It appears from the available literature that Narrative Medicine may be the answer to the current crisis in the physician-patient relationship. Its impact extends well into physicians' own wellness. Medical educators should consider incorporating narrative writings as early as medical school education and all the way into residency and fellowship education.

CME credits are available online at www.thepermanentejournal.org. The mail-in CME form can be found on page 95.

SOUL OF THE HEALER

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leaflet

medical lit-art e-journal

leaflet:
a thin triangular flap of a heart valve
a small book usually having a paper cover
the medical lit-art e-journal from The Permanente Press

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.

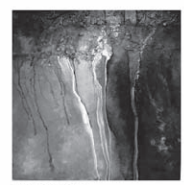
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Questions may be directed to: Ms Max McMillen, ELS, Editor *leaflet,* e-mail: max.l.mcmillen@kp.org.

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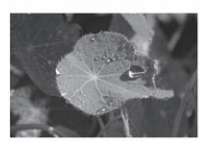

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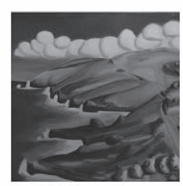

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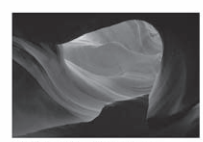

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Tuscan Twilight
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Tranquility
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Predicting Poor Outcomes in Heart Failure

David H Smith, RPh, PhD
Eric S Johnson, PhD
Micah L Thorp, DO, MPH
Xiuhai Yang, MS
Amanda Petrik, MS
Robert W Platt, PhD
Kathy Crispell, MD

Abstract

Background: Health plans must prioritize disease management efforts to reduce hospitalization and mortality rates in heart failure patients.

Methods and Results: We developed a risk model to predict the 5-year risk of mortality or hospitalization for heart failure among patients at a large health maintenance organization. We identified 4696 patients who had an echocardiogram and a heart failure diagnosis from 1999 to 2004.

We observed a 56% five-year risk of hospitalization for heart failure or death (95% confidence interval, 54% to 58%). The hazard ratios for echocardiogram data contributed statistically significantly to the model, but echocardiogram findings did not improve our ability to predict risk *accurately* once we had accounted for demographic characteristics and clinical findings. A more complex model demonstrated a modest capacity to accurately predict risk. Our risk model discriminated the highest- and lowest-risk patients with limited success–the observed risk was 3 times higher in the highest risk quintile, compared with the lowest-risk quintile.

Conclusions: Using data available from electronic health records, we developed a series of risk-prediction models for poor outcomes in patients with heart failure. We found that a relatively simple model is as effective as a more complex model, but that all the models predict with only modest accuracy. Until better prediction variables are available for heart failure patients, our prediction model may be valuable for prioritizing centralized disease management program efforts by stratifying patients according to their absolute risk of poor outcomes.

Introduction

Investigations into risk factors for poor outcomes in patients with heart failure have included patient-reported symptoms, comorbid conditions, and laboratory findings.[1,2] These studies show that increases in patient-reported symptoms, extreme hemoglobin values, and poor renal function are important risk factors for poor outcomes. However, findings from echocardiogram data, an important diagnostic tool in heart failure, have been less well studied for their predictive value across the spectrum of heart failure. In those with systolic dysfunction (<50%), lower ejection fraction values are associated with worse survival.[3] Other studies, however, have demonstrated that higher ejection fraction values are associated with worse outcomes than lower values among patients with preserved left ventricular function.[4] In this study, we examine the predictive value of echocardiogram measurements, including both ejection fraction and left ventricular wall thickness so as to further clarify these risks.

We stress prediction in the analysis and interpretation. Our interest is predicting the outcomes among heart failure patients using information that providers and health plans collect routinely, not hypothesis testing[5p1-9] (eg, does low ejection fraction cause mortality). This is an important distinction because although every causal factor is a predictor, not every predictor is a cause,[6] suggesting that some variables included in a prediction model, including the order of their entry into model building, may differ from a causal model. This study sought to predict outcomes among heart failure patients and to develop a prognostic risk model that could separate the higher- and lower-risk patients and determine how effectively ejection fraction and left ventricular wall thickness

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improved predictions. Whereas other investigators have examined prediction rules in the inpatient setting and for patients with severe heart failure,[7,8] we included patients more representative of those in a community-based setting.

Methods

Population

We conducted a retrospective study on a prevalence cohort of patients. Patients included in the study were adult (age 18 years and older) members of Kaiser Foundation Health Plan of the Northwest (Health Plan) who had an echocardiogram completed between 1999 and 2004 and a diagnosis of heart failure. Patients were followed for up to 5 years or until April 1 2005, death, or disenrollment from the Health Plan (whichever came first). The patient's first echocardiogram served as the index date. Patients were required to have at least 1 year of Health Plan membership (and prescription benefit coverage) before their index echocardiogram. All patients had 1 to 3 years of baseline data from which baseline covariates were extracted. We included patients with a diagnosis of heart failure (International Classification of Diseases, Ninth Revision [ICD-9] 428) from the inpatient or outpatient setting during the baseline period—or up to 30 days after their index echocardiogram (to account for diagnoses assigned after an echocardiogram, presumably on the basis of the echocardiogram findings). Others have found that ICD-9 428 has a predictive value positive of 82%[9] for heart failure, but the test performance of that characteristic may not be the same in our setting. However, in order to mimic the data readily available (eg, without chart review) to a centralized population management department we were

Table 1. Baseline characteristics of sample and event rates (heart failure hospitalization or death) by baseline characteristics

Characteristics	Eligible patients N = 4696 (%)	Number of events	Crude event rate (per 100 person-years)
Demographic			
Age			
20 to 59 years	875 (18.6)	177	8.28
60 to 64 years	443 (9.4)	122	11.63
65 to 69 years	551(11.7)	184	14.08
70 to 74 years	667 (14.2)	252	15.92
75 to 79 years	792 (16.9)	344	19.25
80 to 84 years	689 (14.7)	379	28.04
85 +	679 (14.5)	401	35.29
Sex			
Men	2284 (48.6)	916	18.64
Women	2412 (51.4)	943	17.34
Race			
White	4439 (94.5)	1741	18.78
Nonwhite	257 (5.5)	87	15.14
Body mass index			
<25	1117 (23.8)	580	27.54
25-34	2550 (54.3)	994	17.21
35+	1029 (21.9)	285	11.62
Current smoking			
Yes	456 (9.7)	174	18.28
No	4240 (90.3)	1685	17.92
Clinical			
Ejection fraction percentage			
>65	371 (7.9)	170	19.93
50-65	2500 (53.2)	891	15.84
40-49	593 (12.6)	225	16.31
30-39	550 (11.7)	246	20.93
20-29	472 (10.1)	216	22.93
<20	210 (4.5)	111	29.50
Posterior wall thickness			
≥11	2779 (59.2)	1146	18.93
<11	1917 (40.8)	713	16.59
Coronary artery disease			
Yes	2402 (51.1)	1059	21.07
No	2294 (48.9)	800	15.02
Diabetes			
Yes	1582 (33.7)	721	22.54
No	3114 (66.3)	1138	15.91
Systolic blood pressure			
<120	1393 (29.7)	562	19.46
120-140	1786 (38.0)	681	17.06
140+	1517 (32.3)	616	17.74
Blood pressure treatment			
Yes	4370 (93.1)	1740	18.09
No	326 (6.9)	119	17.46

Table continued on next page.

interested in that pragmatic patient inclusion strategy. The Kaiser Permanente Northwest (KPNW) institutional review board approved this study.

Covariates

The most current covariate baseline value (before the index date) was extracted from KPNW's electronic medical record (EMR) (including laboratory data from inpatient or outpatient visits, patient registries, and echocardiogram findings; see Table 1 for listing). Covariate laboratory findings were obtained from outpatient laboratory data only because outpatient values are less likely to be influenced by acute events. Glomerular filtration rate (eGFR) was estimated using the four-variable Modification of Diet in Renal Disease equation.[10]

Table 1. *Continued*

Dyslipidemia			
Yes	2191 (46.7)	819	17.29
No	2505 (53.3)	1040	18.52
Ischemic stroke			
Yes	511 (10.9)	284	31.45
No	4185 (89.1)	1575	16.67
Transient ischemic attack			
Yes	321 (6.8)	152	24.26
No	4375 (93.2)	1707	17.55
Hypothyroidism			
Yes	773 (16.5)	359	22.87
No	3923 (83.5)	1500	17.08
Chronic lung disease			
Yes	2143 (45.6)	917	20.08
No	2553 (54.4)	942	16.28
Aortic/mitral valvular disease			
Yes	1495 (31.8)	673	23.07
No	3201 (68.2)	1183	15.95
Depression			
Yes	1042 (22.2)	435	21.12
No	3654 (77.8)	1424	17.17
Known ventricular tachycardia or fibrillation			
Yes	210 (4.5)	83	19.27
No	4486 (95.5)	1776	17.90
Atrial fibrillation/flutter			
Yes	1726 (36.8)	806	22.20
No	2970 (63.2)	1053	15.67
Peripheral vascular disease			
Yes	752 (16.0)	425	32.21
No	3944 (84.0)	1434	15.88
Laboratory			
Hemoglobin			
<11	508 (10.8)	294	34.54
≥11	4188 (89.2)	1565	16.47
Baseline eGFR			
≥60	2650 (56.4)	821	13.18
<60 to 45	1036 (22.1)	458	19.05
<45 to 30	706 (15.0)	379	29.85
<30	304 (6.5)	201	44.88

eGFR = estimated glomular filtration rate.

Outcomes

Our outcome of interest was a composite of all-cause mortality or hospitalization (whichever came first) with a primary discharge diagnosis of heart failure.

Statistical Methods

We used Cox regresssion to predict the combined endpoint of all-cause mortality or first cardiovascular hospitalization. Patients were required to have a measured ejection fraction. As recommended by experts,[5p41-5] we required at least 20 endpoint events for each degree of freedom reflected in candidate variables. We included candidate variables with <15% missing data in the model and used single imputation on missing data.

We included covariates if they were prevalent in at least 10% of patients. When deciding the variables to include in our model, we tried to balance each variable's ease of electronic extraction and measurement error. To do this we fit a series of models starting with easily obtainable demographic characteristics (ie, Model 1, including age, gender, race, body mass index [BMI]), then added variables readily measured at a primary care office visit (Model 2, adding eGFR, hemoglobin, blood pressure to Model 1 variables). In the next model we added echocardiogram data (Model 3, adding ejection fraction and posterior heart wall thickness, plus an interaction with wall thickness and BMI to standardize for body mass to Model 2 variables). These clinical measures are more expensive to measure, but

are thought to be closely related to heart failure prognosis. Our next model added a set of comorbid conditions (Model 4, adding smoking, diabetes, dyslipidemia, and hypothyroidism to Model 3 variables) that were readily diagnosed by patient inquiry or laboratory tests (ie, minimal measurement error). Model 5 added comorbid conditions (transient ischemic attack, chronic lung disease, heart valve disease, atrial fibrillation/flutter, depression, coronary artery disease, peripheral vascular disease, and stroke) that required complex clinical interaction to diagnose.

Model fit was assessed using Bayes Information Criterion (BIC). We calculated the concordance statistic[5p465-507] (C-statistic = 1 is perfect prediction; C-statistic = 0.5 is equal to chance prediction) to evaluate each prediction model's accuracy. Some readers may be more familiar with the Area under the Receiver Operating Curve (AUROC) in logistic regression, which is the analog to Cox regression's C-statistic. To determine the added predictive value of each model's set of additional variables, we evaluated the marginal relative change (%) in the C-statistic in accuracy between models.[11] Patients were categorized into quintiles of predicted risk. The mean predicted risk (overall and per quintile) was then compared with the mean observed risk to examine the model calibration (predicted risk/observed risk). A perfectly calibrated model would have the same observed and predicted risk. We plotted the observed risk and the predicted risk (within quintiles of predicted risk) to evaluate the risk model's calibration (ie, the extent to which the predicted risks over- or underestimate the observed risks).[12] We assessed the model's discriminative ability by dividing the predicted risk in the highest quintile by the predicted risk in the lowest quintile.[12]

We used Stata 9.2 (College Station, Texas, USA) and R (version 2.4), an open source software from the R Foundation for Statistical Computing (www.R-project.org).

The authors had full access to the data and take responsibility for its integrity. All authors have read and agree to the manuscript as written.

Results

Among 519,383 adults aged 18 years and older, we found 10,265 with a diagnosis of heart failure—8291 of whom had an echocardiogram. Our analysis dataset included 4696 of those patients with at least one year of Health Plan membership and pharmacy coverage before their echocardiogram. Table 1 shows the baseline characteristics and event rates. Older age, low ejection fraction, and cardiovascular disease were associated with higher death rates, while increasing BMI, blood pressure, and dyslipidemia were associated with lower event rates. The overall observed 5-year risk was 56%; 95% Confidence Interval (CI), 54% to 58%.

… easily accessible data from EMRs can be combined to predict patients at risk of poor outcomes from heart failure …

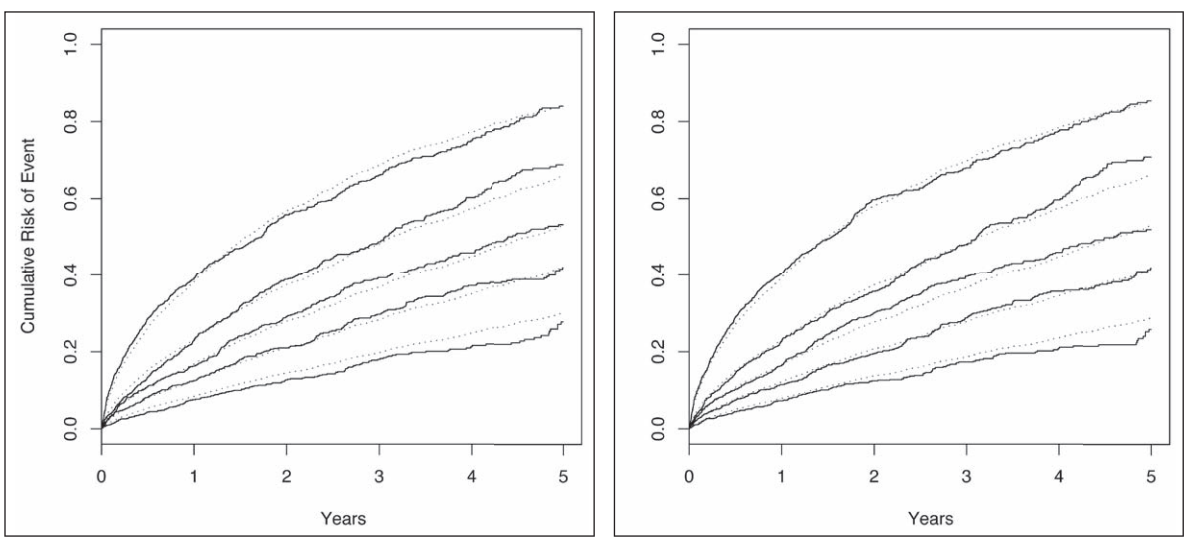


Figure 1. Calibration Plot for Model 2 (Panel A) and Model 3 (Panel B).
The curves show the observed risk (solid lines) and predicted risk (dotted lines) of outcome (death or heart failure hospitalization) according to quintiles of predicted risk based on the risk score.

Table 2 shows the main results for the prediction models. The first model, with demographic characteristics only, had a C-statistic of 0.63, suggesting accuracy that is 13% better than chance prediction. In Model 2 (demographics along with hemoglobin, eGFR, and blood pressure), the C-statistic shows a 31% relative improvement: from 0.63 to 0.67. Adding echocardiogram data in Model 3 showed a 6% relative improvement to 0.68. Adding diagnoses that are readily measured in Model 4 improved the accuracy to 0.69 (6% relative improvement), and adding further comorbidities raised the C-statistic to 0.71 (an 11% relative improvement). The hazard ratios (HRs) on baseline characteristics were consistent across models and model fit is improved (ie, lower BIC), but not appreciably, with added characteristics. Few hazard ratios exceeded 1.5, except older age, anemia, low eGFR, and low ejection fraction. Ejection fraction <20%, however, was a characteristic of <5% of the population. No HRs exceeded 2.5. No interactions were significant at $p < 0.05$.

As discussed above, the results from the C-statistic show that Models 2 and 3 have similar discriminatory power. Another dimension of discrimination is the ratio of observed risks across the highest and lowest quintiles predicted risk. The risk model from Model 2 showed that patients in the highest quintile were about 3 times more likely to have the outcome as patients in the lowest quintile of risk: 84% (highest quintile); 66% (60th to 79th percentiles); 53% (middle quintile); 42% (20th to 39th percentiles); 30% (lowest quintile). Similar results were found for Model 3 (see Figure 1).

Table 2. Cox model results of heart failure hospitalization or death adjusting using baseline characteristics[a]

Characteristic	Model 1 HR; 95% CI	Model 2 HR; 95% CI	Model 3 HR; 95% CI	Model 4 HR; 95% CI	Model 5 HR; 95% CI
Age					
20 to 59 years	0.54 (0.44 to 0.65)	0.60 (0.49 to 0.73)	0.57 (0.47 to 0.69)	0.57 (0.46 to 0.69)	0.58 (0.49 to 0.72)
60 to 64 years	0.75 (0.60 to 0.93)	0.79 (0.64 to 0.97)	0.75 (0.61 to 0.94)	0.76 (0.61 to 0.95)	0.75 (0.60 to 0.94)
65 to 69 years	0.89 (0.74 to 1.08)	0.93 (0.77 to 1.13)	0.93 (0.77 to 1.13)	0.92 (0.76 to 1.11)	0.93 (0.77 to 1.13)
70 to 74 years (reference)					
75 to 79 years	1.18 (1.00 to 1.39)	1.21 (1.02 to 1.42)	1.21 (1.02 to 1.42)	1.25 (1.06 to 1.47)	1.19 (1.01 to 1.40)
80 to 84 years	1.64 (1.40 to 1.93)	1.64 (1.39 to 1.93)	1.67 (1.42 to 1.97)	1.85 (1.57 to 2.18)	1.82 (1.54 to 2.14)
85 plus years	1.96 (1.66 to 2.30)	1.87 (1.59 to 2.20)	1.92 (1.63 to 2.27)	2.16 (1.82 to 2.55)	2.16 (1.82 to 2.56)
Sex					
Men	1.16 (1.05 to 1.27)	1.24 (1.13 to 1.36)	1.15 (1.04 to 1.26)	1.14 (1.04 to 1.26)	1.14 (1.03 to 1.26)
Race					
Non-white (white reference)	0.99 (0.80 to 1.23)	0.91 (0.73 to 1.13)	0.92 (0.74 to 1.14)	0.90 (0.72 to 1.12)	0.93 (0.75 to 1.16)
BMI					
<25 (reference)					
25-34	0.73 (0.68 to 0.84)	0.76 (0.69 to 0.85)	0.81 (0.69 to 0.95)	0.80 (0.68 to 0.94)	0.81 (0.69 to 0.95)
>34	0.70 (0.60 to 0.81)	0.72 (0.61 to 0.84)	0.82 (0.63 to 1.08)	0.76 (0.58 to 1.00)	0.80 (0.60 to 1.05)
	C=0.63 BIC=29066				
Baseline eGFR					
≥60 (reference)					
<60 to 45		1.25 (1.11 to 1.40)	1.22 (1.09 to 1.37)	1.18 (1.05 to 1.33)	1.14 (1.01 to 1.28)
<45 to 30		1.66 (1.46 to 1.89)	1.59 (1.40 to 1.81)	1.51 (1.33 to 1.71)	1.43 (1.26 to 1.63)
<30		2.60 (2.22 to 3.06)	2.50 (2.13 to 2.93)	2.34 (1.99 to 2.75)	2.22 (1.88 to 2.61)
Baseline anemia					
Hemoglobin <11		1.70 (1.49 to 1.93)	1.75 (1.54 to 1.99)	1.71 (1.50 to 1.94)	1.59 (1.40 to 1.82)
Systolic blood pressure					
<120 (reference)					
120-140		0.82 (0.52 to 1.29)	0.81 (0.52 to 1.28)	0.81 (0.51 to 1.28)	0.84 (0.53 to 1.33)
>140		0.67 (0.41 to 1.08)	0.68 (0.42 to 1.10)	0.65 (0.40 to 1.05)	0.67 (0.41 to 1.08)
BP treatment (90 days prior to BP)		0.84 (0.58 to 1.22)	0.80 (0.55 to 1.15)	0.78 (0.54 to 1.13)	0.73 (0.50 to 1.06)
BP treatment x systolic blood pressure (p value)		0.44	0.40	0.34	0.29
		C=0.67 [relative improvement = 31%] BIC=28893			

The calibration of Models 2 and 3 were also very similar, as shown in Figure 1. Specifically, the calibration was excellent at the highest level of predicted risk (ie, 84% observed vs 84% predicted for Model 2 and 85% observed vs 85% predicted for Model 3), and was within 5% for all quintiles in both Model 2 and Model 3.

Discussion

We found that easily accessible data from EMRs can be combined to predict patients at risk of poor outcomes from heart failure, and that they predict as well as models using less easily accessible clinical data. From the perspective of the Health Plan, our prediction model may be most valuable for prioritizing centralized disease management program efforts by stratifying patients according to their absolute risk of poor outcomes. Care Managers might then use that risk data to focus coordination of care efforts on those at highest risk, or perhaps to deliver specific health prevention information to patients not yet at the highest risk. Information on individual patient risk level could also be provided to physicians as part of their decision making as they identify patients most likely to benefit from case management, a complex patient medical home or referral for other heart failure specific services. Unlike many previous efforts at risk prediction for patients with heart failure, our analysis was not restricted to any particular subgroup of patients; instead, the population we used is representative of the community setting. This is an important point for disease management efforts because those responsible for population man-

Table 2. *Continued*

Characteristic	Model 1 HR; 95% CI	Model 2 HR; 95% CI	Model 3 HR; 95% CI	Model 4 HR; 95% CI	Model 5 HR; 95% CI
Ejection fraction					
>65%			1.17 (0.99 to 1.38)	1.14 (0.96 to 1.34)	1.10 (0.93 to 1.30)
50-65 (reference)					
40-49			1.00 (0.86 to 1.16)	0.99 (0.85 to 1.14)	0.98 (0.84 to 1.14)
30-39			1.30 (1.13 to 1.51)	1.26 (1.09 to 1.46)	1.29 (1.12 to 1.50)
20-29			1.54 (1.32 to 1.81)	1.50 (1.28 to 1.76)	1.56 (1.32 to 1.83)
<20			2.18 (1.77 to 2.68)	2.09 (1.70 to 2.58)	2.31 (1.87 to 2.84)
Posterior wall thickness			1.29 (1.10 to 1.53)	1.27 (1.07 to 1.50)	1.23 (1.04 to 1.45)
Posterior wall thickness x BMI (p value)			0.74	0.63	0.75
			C=0.68 [relative improvement = 6%] BIC=28879		
Current Smoking				1.46 (1.24 to 1.72)	1.34 (1.14 to 1.58)
Diabetes				1.55 (1.40 to 1.71)	1.46 (1.32 to 1.61)
Dyslipidemia				0.97 (0.88 to 1.07)	0.90 (0.81 to 1.00)
Hypothyroidism				1.19 (1.06 to 1.34)	1.13 (1.00 to 1.27)
				C=0.69 [relative improvement = 6%] BIC=28816	
Transient ischemic attack					0.97 (0.81 to 1.15)
Chronic lung disease					1.24 (1.13 to 1.36)
Aortic/mitral valvular disease					1.14 (1.04 to 1.26)
Atrial fibrillation/flutter					1.18 (1.06 to 1.30)
Depression					1.32 (1.18 to 1.48)
Coronary artery disease					1.07 (0.97 to 1.19)
Peripheral vascular disease					1.41 (1.26 to 1.59)
Ischemic stroke					1.40 (1.23 to 1.61)
					C=0.71[relative improvement = 11%] BIC=28736

[a] The concordance statistic (C=) shows the overall accuracy of the prediction as sets of characteristics were evaluated cumulatively. Bayes Information Criterion (BIC) was used to evaluate model fit.

BIC = Bayes Information Criterion, BMI = body mass index, BP = blood pressure, C = concordance statistic, CI = Confidence Interval, eGFR = estimated glomular filtration rate, HR = hazard ratio

agement are concerned with the totality of the Health Plan members with heart failure. We also purposefully focused on demographic and clinical findings that are available from routinely collected EMR data, making our results more immediately applicable to centralized care management programs.

Some data like ejection fraction measurements are inconvenient to obtain from automated data sources because they don't exist in easily extractable data fields. However, our analysis showed that there was little increase in predictive ability when we added increasingly complex clinical measurements. Our findings illustrate that the added predictive ability of knowing ejection fraction is small when compared with a model that includes demographics, blood pressure, renal function and anemia status. The small increase in accuracy apparent when measurements from echocardiogram were added is particularly interesting and has potentially significant implications for disease management prioritization efforts. Specifically, whereas ejection fraction was available to us electronically at KPNW, not all managed care environments enjoy such access.

… predicting absolute risk requires a clinician to balance competing risk factors simultaneously … an extremely difficult cognitive challenge.

Some may find it surprising that ejection fraction did not add more predictive ability in our study. To put this into context, previous investigations have shown that each 10 point decrease in ejection fraction below 45% is related to a 30% increase in death rate (HR 1.31, 95% CI, 1.24 to 1.38), after adjusting for other potent risk factors (including, for example, the New York Heart Association heart failure classification) over a median of 38 months of follow-up.[3] However, it is important to note that our findings do confirm this strong relation between ejection fraction and increasing poor outcomes. Additionally, our findings are dependent on the specific time frame of prediction (ie, 5 years) that we used; a shorter time frame may have suggested stronger predictive value for echocardiogram findings. The HR for individuals with poor ejection fraction was greater than 2.0 (eg, Model 3, HR = 2.18, 95% CI, 1.77 to 2.68)—meaning that they were twice as likely to suffer the outcome as patients with better ejection fraction—so we found that ejection fraction does have *independent* predictive ability. Thus, taken on its own, ejection fraction is an important risk factor, but as pointed out by Guyatt,[13] predicting absolute risk requires a clinician to balance competing risk factors simultaneously. Doing so is an extremely difficult cognitive challenge. A regression-based approach like the one taken here can help providers and health plans avoid problems with double-counting the contribution of correlated risk factors. It should be noted that we used ejection fraction findings from a specific point in time, and that additional prognostic value may be available for example, from serial ejection fraction findings. We purposefully included the entire spectrum of heart failure patients (ie, both preserved and reduced systolic function) in our model. Thus, our findings do not speak to the issue of whether ejection fraction measurements would add to predictive ability if stratified models were built for patients with preserved systolic function, and, separately, patients with systolic dysfunction.

A study[8] of four clinical prediction rules in hospitalized heart failure patients examined the predictive ability related to outcomes of inpatient death, complications, and 30-day mortality. The measure of accuracy used in that study (area under the receiver operating characteristic (ROC) curve, analogous to the C-statistic used in our study) was below 0.62 for inpatient death or complications, and went as high as 0.74 for inpatient death. Our study is different in important ways: 1) we used outpatient instead of inpatient characteristics; 2) we were able to assess the usefulness of echocardiogram data instead of physical examination findings such as pulse and respiratory rate; and 3) we had a 5-year follow-up period, not a 30-day period. In spite of these differences, however, 2 studies have remarkably similar findings and illustrate the difficulty in predicting outcomes in patients with heart failure. They further suggest investigators are missing important characteristics in existing models of heart failure prognosis. For example, prognosis may depend on a patient's willingness to adhere with medications and other daily disease management efforts that are difficult to capture at baseline.

Our study's main limitation is the lack of a protocol for measuring the characteristics completely and reliably. We had to impute 11% of BMI values, for example, because BMI was not collected during the baseline period. It is possible that BMI would be a stronger predictor if we had measured it more completely, instead of assigning patients' values according to their other (known) characteristics. The other characteristics that contributed to the risk prediction model had far less missing data (for example, 99.8% of patients had a recorded systolic blood pressure value), but may have been measured unreliably

on the basis of a single value. Other investigators have shown that predicting cardiovascular events on the basis of a single baseline value for blood pressure underestimates the strength of the relation by as much as 60%, a statistical problem known as regression dilution bias.[14] The characteristics that we evaluated might have discriminated patients' risk more effectively if we were able to reduce regression dilution bias through repeated baseline measurements. Although a prognostic risk model based on repeated baseline measurements would be better in theory, it would be impractical for most health plans, as they lack repeated baseline measures collected according to a protocol. Our findings should be subject to validation efforts in other cohorts.

We suggest that Model 2 could be used for disease management prioritization efforts, provided that patients who are included in the population to be stratified all have a recent echocardiogram and a diagnosis of heart failure. We feel this is important because all patients who contributed to our risk model had an echocardiogram, which may have influenced the spectrum of heart failure patients. Patients without an echocardiogram, for example, may have been less severe or at least less symptomatic compared with patients who had an echocardiogram. Because we excluded patients without an echocardiogram, we cannot evaluate how the effectiveness of our risk model predictions varies across the entire spectrum of patients with a diagnosis of heart failure.[15] So decision makers who use our risk model to prioritize patients for disease management in their populations may elect to only calculate predictions for patients who have had an echocardiogram. Including lower-risk heart failure patients would probably compromise the risk model's accuracy and reduce its transportability, as successful transportability of a risk model to other clinical populations depends on the comparability of their disease spectrum.[16] ❖

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

References

1. Go AS, Yang J, Ackerson LM, et al. Hemoglobin level, chronic kidney disease, and the risks of death and hospitalization in adults with chronic heart failure: the Anemia in Chronic Heart Failure: Outcomes and Resource Utilization (ANCHOR) Study. Circulation 2006 Jun 13;113(23):2713-23.
2. Felker GM, Shaw LK, Stough WG, O'Connor CM. Anemia in patients with heart failure and preserved systolic function. Am Heart J 2006 Feb;151(2):457-62.
3. Solomon SD, Anavekar N, Skali H, et al; Candesartan in Heart Failure Reduction in Mortality (CHARM) Investigators. Influence of ejection fraction on cardiovascular outcomes in a broad spectrum of heart failure patients. Circulation 2005 Dec 13;112(24):3738-44.
4. Ahmed A, Aronow WS, Fleg JL. Higher New York Heart Association classes and increased mortality and hospitalization in patients with heart failure and preserved left ventricular function. Am Heart J 2006 Feb;151(2):444-50.
5. Harrell FE. Regression Modeling Strategies: Introduction. New York: Springer; 2001.
6. Moons KG, Royston P, Vergouwe Y, Grobbee DE, Altman DG. Prognosis and prognostic research: what, why, and how? BMJ 2009 Feb 23;338:b375.
7. Frankel DS, Piette JD, Jessup M, Craig K, Pickering F, Goldberg LR. Validation of prognostic models among patients with advanced heart failure. J Card Fail 2006 Aug;12(6):430-8.
8. Auble TE, Hsieh M, McCausland JB, Yealy DM. Comparison of four clinical prediction rules for estimating risk in heart failure. Ann Emerg Med 2007 Aug;50(2):127-35.
9. Roger VL, Weston SA, Redfield MM, et al. Trends in heart failure incidence and survival in a community-based population. JAMA 2004 Jul 21;292(3):344-50.
10. Levey AS, Bosch JP, Lewis JB, Greene T, Rogers N, Roth D. A more accurate method to estimate glomerular filtration rate from serum creatinine: a new prediction equation. Modification of Diet in Renal Disease Study Group. Ann Intern Med 1999 Mar 16;130(6):461-70.
11. Royston P, Altman DG. Risk stratification for in-hospital mortality in acutely decompensated heart failure. JAMA2005 May 25;293(20):2467-8.
12. Lumley T, Kronmal RA, Cushman M, Manolio TA, Goldstein S. A stroke prediction score in the elderly: validation and Web-based application. J Clin Epidemiol 2002 Feb;55(2):129-36.
13. Guyatt GH. Determining prognosis and creating clinical decision rules. In: Haynes RB, Sackett DL, Guyatt GH, Tugwell P, eds. Clinical Epidemiology. 3rd ed. Philadelphia: Lippincott Williams & Wilkins; 2006. p 323-55.
14. MacMahon S, Peto R, Cutler J, et al. Blood pressure, stroke, and coronary heart disease. Part 1, Prolonged differences in blood pressure: prospective observational studies corrected for the regression dilution bias. Lancet 1990 Mar 31;335(8692):765-74.
15. Mulherin SA, Miller WC. Spectrum bias or spectrum effect? Subgroup variation in diagnostic test evaluation. Ann Intern Med 2002 Oct 1;137(7):598-602.
16. Justice AC, Covinsky KE, Berlin JA. Assessing the generalizability of prognostic information. Ann Intern Med 1999 Mar 16;130(6):515-24.

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ORIGINAL RESEARCH & CONTRIBUTIONS

Napa Immunization Study: Immunization Rates for Children with Publicly Funded Insurance Compared with those with Private Health Insurance in a Suburban Medical Office

James C Cotter, MD, MPH

Abstract

Introduction: Healthy People 2020 set a goal to increase the proportion of children who receive the recommended doses of Diphtheria Tetanus and Pertussis, polio, measles mumps and rubella, Haemophilus influenzae type b, hepatitis B, varicella and pneumococcal conjugate vaccines to 80% from the 2009 baseline rate of 69%. The purpose of this study is to compare the recommended immunization rates for low-income children insured through publicly funded health insurance (PFI) to the rates for children with private health insurance (PHI) in a suburban medical office.

Methods: The immunization rates and health access measures of 109 children ages 24 to 48 months who had PFI were compared with 300 children of the same age with PHI in the same medical practice.

Results: Overall immunization rates for the study population were very high and exceeded the Healthy People 2020 goals for full immunization. Children with PFI had lower rates of immunization and fluoride prescriptions; however the differences were only significant in the cohort of children age two years. By three years of age, the immunization rates and the fluoride prescription rates were similar. There were no significant differences in health outcomes for Spanish-speaking compared with English-speaking children.

Discussion: Barriers to successful immunization practices and strategies to overcome those barriers are discussed.

Conclusion: The successful immunization practices and secondary outcomes in this study are a reflection of the integrated care model in this practice that facilitates comprehensive, coordinated, and accessible care for patients and allows physicians and support staff to practice culturally sensitive and compassionate care—the definition of a medical home.

Introduction

Healthy People 2020 set a goal to: "Increase the proportion of children aged 19 to 35 months who receive the recommended doses of DTaP, polio, MMR, Hib, hepatitis B, varicella and PCV vaccines."[1] The target for full immunization with the recommended doses of each vaccine was set at 90% and for the complete series of all of these immunizations at 80%. The most recent data from 2009 as reported by the National Immunization Survey showed that only 69% of US children received the full set of recommended immunizations—well below the Healthy People 2020 target.[2]

The primary goals of the Children's Health Initiative (CHI)-Napa County are that every child in Napa County has health insurance and that every child in Napa County has access to comprehensive health care and a primary care home. CHI-Napa County has enrolled virtually every low-income child in Napa County up to age 18 with health insurance (Mark Diel, MPH, personal communication; 2011 Jan 18).[a] However, insuring a child and providing access to health care may not be sufficient to assure comprehensive health care for children. Childhood immunization is a good proxy for access to health care.[3] This study examines the immunization rates and preventive care of low-income children compared with those with employer-based and/or private health insurance (PHI) in a suburban group medical practice. The benefits of a medical home to facilitate childhood immunization are discussed.

The Uninsured Child

Children without health insurance have poor access to health care. The National Health Interview Survey in 2002 reported "Fifteen percent of uninsured children had not had contact with a doctor or other health professional in more than 2 years (including those who never had a contact) compared with 3% for

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children with private insurance coverage or children with Medicaid."[4p5] Children who are uninsured are significantly more likely to have unaddressed health care needs and to have delays in needed care.[5] The same study showed uninsured children to be far less likely to have a usual place of care and much less likely to have well-child care visits.

The 2003 report on Health Insurance Coverage in America reported that 64% of the uninsured are in low-income families.[6] The report showed that in 2002, 21% of children younger than age 19 years were uninsured and the numbers of the uninsured were rising 10% per year from 2000 to 2003. Significant ethnic disparities were seen in the uninsured; for example, although Hispanics made up 15% of the population, they accounted for 29% of the uninsured. The numbers of uninsured dropped over the next 3 years, nonetheless, by 2006, nearly 12% of US children younger than age 18 years still lacked health insurance. There were also significant disparities in the uninsured child. In 2006, 19.3% of poor children were uninsured and 22.1% of Hispanic children were uninsured.[7]

State Children's Health Insurance Program and Children's Health Initiatives

In 1997, in response to rising numbers of uninsured children, the US Congress passed the State Children's Health Insurance Program (S-CHIP) to extend health insurance coverage to children beyond the limits of the federal Medicaid program. In response to this new funding source, California developed the Healthy Families program to provide medical coverage to children up to 250% of the federal poverty level (FPL). Through additional funding from the California Endowment, pilot projects were created to extend health insurance coverage to undocumented children, resulting in the formation of the first CHI in Santa Clara County in 2000.[8] As of 2008, there were over 30 county CHI programs throughout California coordinating health coverage to children who lack health insurance.

CHIs in California enroll low-income children in publicly funded health insurnce (PFI) and dental insurance through a number of programs on the basis of income and legal status. Medi-Cal, the California version of the federal Medicaid program, provides care to children up to 133% of the FPL. Healthy Families is a program that is funded through the S-CHIP program and is designed for legal residents up to 250% of the FPL. Healthy Kids and the Kaiser Permanente (KP) Child Health Plan are privately funded programs that extend health and dental insurance to children up to 250% of the Federal Poverty Level and who do not qualify for Medi-Cal or the Healthy Families programs.

Provision of stable health insurance coverage has been shown to benefit children. Children are more likely to receive proper preventive services and to be up to date for their immunizations when they have stable health coverage.[9] Children with stable health insurance have been shown to be more likely to have a regular clinician and to have a marked decrease in unmet needs and delayed care.[10]

Publicly funded health insurance programs often have cumbersome enrollment processes and retention of coverage may be difficult, particularly for those who are socioeconomically challenged. Disruptions in health insurance for children have been shown to result in lower immunization status, postponed care, and a decrease in medication prescriptions.[11] County-based CHIs have been formed to assist in outreach, enrollment and retention of health insurance status for low-income children in California.

Napa County Children's Health Initiative

The CHI-Napa County was established in 2005. Initial funding was provided by the Blue Shield of California Foundation, First Five Napa County, First Five California, KP, Napa Valley Vintners, Queen of the Valley Hospital, St Joseph's Health System Foundation, the California Endowment, the County of Napa, and the United Way of the Bay Area. Initial estimates provided by the 2005 California Health Interview Survey indicated between 736 to 3616 children ages 0 to 18 years were uninsured. CHI-Napa County was launched "to secure affordable health insurance for lower income children and to connect them with the healthcare services they need."[12] In 2010, CHI-Napa County was case managing over 8500 low-income children in PFI products (Mark Diel, MPH, personal communication; 2011 Jan 18).[a]

The PFI programs available to Napa County children are Medi-Cal, Healthy Families, Healthy Kids, and the KP Child Health Program. Funding for the Healthy Kids program in Napa County was discontinued in 2008 and the 1300 children who had Healthy Kids coverage were subsequently enrolled in the KP Child Health Plan.

Although CHI-Napa County has been very effective in enrolling children and helping them retain health insurance, CHI-Napa County does not have the capability of assessing outcomes, such as preventive care visits or immunization rates of its case managed clients.

… tens of thousands of children and adults in the US continue to develop vaccine-preventable diseases."

Immunizations and Child Health

Deaths from infectious diseases in the US rose 58% from 1980 to 1992 and remain a significant cause of illness and disability.[1] Vaccines can prevent many of these diseases and childhood vaccination has helped to nearly eliminate diseases such as polio, measles, and rubella. Healthy People 2020 noted: "Consideration of indirect savings—prevention of work loss by parents to care for ill children and prevention of death and therefore lost earnings from disability—shows that vaccines routinely recommended for children are highly cost saving."[1] Burns reported that: "Rates of pertussis, measles, and other previously common childhood illnesses have plummeted thanks to the wide administration of effective vaccines to the pediatric population. However, tens of thousands of children and adults in the US continue to develop vaccine-preventable diseases."[12] Guerra et al reported that in 2005, "… only 17% of 24- to 35-month-old children were vaccinated with 6 recommended vaccines on time, and 37% experienced a delay of >6 months for at least 1 vaccine."[13]

Healthy People 2020

On December 2, 2010, Healthy People 2020 launched its 10-year health agenda for the US. Goal (IID-8) of Healthy People 2020 is to "Increase the proportion of children aged 19 to 35 months who receive the recommended doses of DTaP, polio, MMR, Hib, hepatitis B, varicella and PCV vaccines."[1] Healthy People 2020 reports that for each birth cohort immunized at the recommended level, the US would save 33,000 lives, prevent 14 million cases of disease, and reduce health costs by almost $10 billion. Despite this recommendation, approximately 42,000 adults and 300 children die each year in the US from vaccine-preventable illness.[1]

The Centers for Disease Control and Prevention (CDC) has been monitoring immunization coverage in the US since 1994 through the National Immunization Survey, which is conducted by the National Center for Immunization and Respiratory Diseases and the National Center for Health Statistics. The most recent immunization level for children receiving the full set of immunizations was 69% as reported by the National Immunization Survey on the 2009 survey. This was higher than the rate of 68% on the 2008 survey.[1] Targets, goals, and 2009 baselines for individual vaccines are listed in Table 1.

Goals of this Study

The primary outcome of this study is to compare the recommended immunization rates for low-income children insured through PFI with immunization rates for children with PHI in the same medical office. Secondary outcomes will compare children with PFI with those with PHI for linkage to a personal primary care physician (PCP), presence of preventive well-child visits, and prescription of fluoride as recommended for children in Napa County.

Methods

Study Design

This study is a cross-sectional survey of the immunization status and selected markers of health care access for children ages 2 years to 3 years receiving health care at the KP medical offices in Napa, California. All study procedures were approved by the Touro University, California Investigational Review Board.

Study Setting

All children in this study are covered by the Kaiser Foundation Health Plan, Inc (Health Plan) and are assigned to receive their medical care at the KP medi-

Table 1. Baseline immunization status 2009 and targets for Healthy People 2020.[1]

Immunization	Number of doses	No. (%)	Target (%)	US baseline	CA baseline
DTaP	4	370 (90.5)	90	83.9	83.4
Polio	3	380 (92.9)	90	92.8	92.4
MMR	1	383 (93.6)	90	90.0	90.1
Hib	3	383 (93.6)	90	83.6	85.5
Hepatitis B	3	378 (92.4)	90	92.4	89.9
Varicella	1	382 (92.4)	90	89.6	89.9
PCV	4	360 (88.0)	90	80.4	79.9
Fully immunized	19	345(84.4)	80	69.0	70.8

[1] Center for Disease Control and Prevention. Statistics and surveillance: 2009 table data [table on the Internet]. US Department of Health and Human Services: Centers for Disease Control and Prevention; late updated 2010 Nov 16 [cited 2011 Nov 23]. Available from: www.cdc.gov/vaccines/stats-surv/nis/data/tables_2009.htm, click on Coverage with Individual Vaccines and Vaccination Series: by State and Local area (includes birth dose of HepB and 2+ doses Hep A) Excel file.

DTaP = diptheria, tetanus, and pertussis; Hib = Haemophilus influenzae type B; MMR = measles, mumps, and rubella; PCV = pneumococcal conjugate vaccine.

cal offices at 3285 Claremont Way, Napa, CA, 94558. Pediatricians and family medicine physicians of The Permanente Medical Group provided medical care.

Study Sampling Procedure

A list of children younger than age 4 years with active Health Plan insurance who reside in zip codes within Napa County was obtained from the Medical Office Controller in January 2011. The list comprised 2356 names.

Inclusion Criteria. Children ages 24 through 48 months who reside in zip codes 94558 and 94559 with active Health Plan insurance for at least 6 months before December 31, 2010 were eligible to participate in this study. There were 312 children born between January 1, 2007 and December 31, 2007 and 269 children born between January 1, 2008 and December 31, 2008 who met the inclusion criteria. These 581 children were the eligible study population. Table 2 describes sampling details.

Exclusions. Children who reside outside of the city of Napa were excluded. Children in the northern and southern areas of Napa County often receive their health care at facilities other than the Napa medical office building. There were 2118 children with Health Plan insurance less than age 48 months who resided in zip codes 94558 and 94559.

Children with health insurance for <6 months were excluded. Six months of active health insurance should be sufficient to allow catch up immunizations for children new to Health Plan. Healthcare Effectiveness Data and Information Set (HEDIS) requires 12 months of active health insurance with no more than a 45-day gap in coverage for its audits of immunization status. The author considered the 12-month requirement to be too long a time period given the need for children at this age to be up to date on their immunizations as soon as possible. There were 1613 children younger than age 48 months in zip codes 94558 and 94559 who had active Health Plan insurance before July 1, 2010.

Children younger than age 24 months were excluded and children older than age 48 months were excluded. All primary immunizations in this study are due by age 18 months. The 24- to 48-months age groups are consistent with other studies assessing immunization status in children.[14]

One three-year-old child with De George syndrome was excluded from the study because immunization with live virus vaccine is contraindicated because of this child's immune deficiency.

Study Procedure

Data extraction was done by the author in the author's office in the KP medical office building in Napa.

Table 2. Population sample description

Sampling Step	Sample
Children under age 48 months	2356
Children in zip codes 94558 and 94559	2118
Kaiser Foundation Health Plan in effect 7/1/2010	1613
Born between 1/1/2007 and 12/31/2008	581
No medical contraindications to immunization	580

The electronic medical record (EMR) was reviewed and the following data was extracted: presence of personal PCP, documentation of office visits and well-child visits, the primary language used in the home, evidence of fluoride prescription in the pharmacy record, type of active health insurance, and the immunization history as documented in the immunization section of the EMR. If there were no immunizations noted, the problem list was opened to see if a reason for lack of immunizations was noted. Details of office visits, laboratory studies or personal communications between the patient, parents, or physician were not reviewed.

Each child in the study was given a unique identification number. This unique number was used to identify the study participant in the active data file. The active study file did not contain any personally identifiable information.

Health care visits and immunizations given through December 31, 2010 were included in the study. An immunization was recorded as given if that specific immunization and date of administration was documented in the EMR.

Identification of Type of Health Insurance

Several children had more than one type of health insurance during the study period. The most common variations were children switching between Medicaid, Healthy Families, or employer-supplied Health Plan insurance. The most recent active health insurance (ie, the type of insurance in effect for December 2010) was used in assigning the insurance type. Commercial insurance was listed as PHI. Medicaid, Healthy Families and the KP Child Health Plan were considered PFI.

Sample Size Calculations: Selection of Participants from the Eligible Study Population

Publicly funded group. All children between ages 24 and 48 months with PFI were included in the study. There were 55 children in Cohort A (children age 2 years) and 54 children in Cohort B (children age 3 years) who had PFI. The EMRs of 100% (109 children) of this PFI study group population were reviewed.

Private health insurance group. The PHI comparison

Table 3. Study participants by insurance type			
Insurance Type	Children age 2 years	Children age 3 years	Total
Private insurance	150	150	300
Kaiser Permanente Child Health Plan	26	22	48
Medi-Cal	25	18	43
Healthy Families	4	14	18

group was selected from the remaining 471 eligible children. With an estimated immunization rate of 85%, a sample of 300 PHI children was considered adequate to assure with 99% confidence that the sample would not differ by more than 3.2% from the true population proportion. One hundred fifty children age 2 years and 150 children age 3 years were selected by sorting the birthdays of the children by birth date so that the first 150 children with PHI in both Cohort A and Cohort B were selected. The study participants by insurance type are listed in Table 3.

Outcomes and Statistical Analysis

Primary Outcome Measure. Children ages 24 through 48 months who had 4 diphtheria, pertussis and tetanus (DTaP), 3 polio, 1 measles mumps and rubella (MMR), 3 Haemophilus influenzae type b (Hib), 3 hepatitis B, 1 varicella, and 4 pneumococcal conjugate vaccine (PCV) immunizations (listed on the National Immunization Survey as 4:3:1:3:3:1:4) were counted as fully immunized. A child lacking even one immunization was considered not fully immunized. This is consistent with the goals of Healthy People 2020 and the state of California requirements for entering primary school.

The HEDIS immunization goals were changed in 2009 to include hepatitis A, rotavirus, and influenza vaccines. Because these changes to immunization recommendations occurred during the study period, the three additional vaccines were not included.

Secondary Outcome Measures. Linkage of a child to a personal PCP was recorded. Documentation of medical office visits and well-child preventive care visits was noted. There is no fluoride in the water in Napa County and fluoride prescription is recommended for all children in Napa County. Documentation of having a fluoride prescription filled in the KP pharmacy was noted.

Design and Statistical Analysis. The primary outcome variables (fully immunized or not fully immunized) were tested against the exposure variables (PFI compared with PHI). The secondary outcome of presence or absence of a fluoride prescription was also compared by insurance status. Results were stratified by age. These outcomes were also compared by language. Chi-square analysis was used to assess statistical significance for the dichotomous primary

Table 4. Overview of National Immunization Survey study participants					
Cohort	Cohort of children age 2 years January 1, 2008 to December 31, 2008		Cohort of children age 3 years January 1, 2007 to December 31, 2007		Total
Insurance type	PFI	PHI	PFI	PHI	
Number	55	150	54	150	409
Spanish speaking	13	26	31	25	95

PFI = publicly funded health insurance; PHI = private health insurance.

Table 5. Immunization rates for publicly funded health insurance and private health insurance groups					
Immunization	Publicly funded health insurance No. (%)	Private health insurance No. (%)	Odds Ratio	Confidence Interval	p value
4 DTaP[a]	92 (84.4)	278 (92.7)	0.428	0.218, 0.842	0.012
3 IPV[a]	94 (86.2)	286 (95.3)	0.307	0.143, 0.659	0.002
1 MMR	99 (90.8)	284 (94.7)	0.558	0.245, 1.270	0.159
3 Hib[a]	94 (86.2)	289 (96.3)	0.239	0.106, 0.537	< 0.001
3 Hepatits B[a]	95 (87.2)	283 (94.3)	0.408	0.194, 0.858	0.015
1 VAR	99 (90.8)	283 (94.3)	0.595	0.264, 1.342	0.207
4 PCV[a]	49 (45.0)	271 (90.3)	0.087	0.051, 0.150	< 0.001
Fully Immunized	85 (78.0)	261 (87.0)	0.529	0.301, 0.931	0.025

[a] Statistically significant difference in immunization rates between PHI and PFI groups

DTaP = diptheria, tetanus, and pertussis; Hib = Haemophilus influenzae type B; IPV = inactivated polio vaccine; MMR = measles, mumps, and rubella; PCV = pneumococcal conjugate vaccine; PFI = publicly funded health insurance; PHI = private health insurance; VAR = varicella.

outcome of immunization status and the secondary outcome of fluoride prescription. When the number of patients in the 2x2 table was 6 or less, the Fisher Exact Probability Test was used to calculate p values. P values <0.05 were considered significant. Odds ratios (OR) with 95% confidence intervals (CI) were used to compare immunization status and fluoride prescription status between the study groups.

Results

A total of 409 children, who were age 2 and 3 years as of December 31, 2010 and who were assigned to the KP clinic in Napa were included in this study. Three hundred children had PHI and 109 children had PFI. An overview of the study participants is seen in Table 4.

There were 55 children age 2 years and 54 age 3 years in the PFI group. There were 150 children age 2 years and 150 age 3 years in the PHI group. Ninety-five (23.2%) of the participants identified their primary language as Spanish.

Overall, the participants in this study achieved high levels of immunization. The immunizations rates exceeded the Healthy People 2020 goals for each immunization in this study, except for PCV, for which they achieved an 88.0% immunization rate. Overall immunization rates by vaccine are listed in Table 1.

There were, however, significant differences in immunization rates between the PHI and PFI groups. The prevalence of being fully immunized with all 19 required vaccines was significantly lower for the PFI group at 78.0% compared with 87.0% for the PHI group (OR 0.529, CI 0.301 - 0.931, p = 0.025). The immunization rate for pneumococcal vaccine showed the largest difference between the 2 groups and was only 45% for the PFI group compared to 90.3% for the PHI group (OR 0.087, CI 0.051 - 0.150, p < 0.001). Only with vaccines requiring one injection (MMR and varicella) were rates of immunization not significantly different between the PFI and PHI groups. Table 5 demonstrates the immunization rates between the PFI and PHI groups by vaccine.

Table 6. Children from Cohorts A and B lacking immunization

Cohort	All Children	PHI	PFI
A: Children age 2 years	n = 205 (%)	n = 150 (%)	n = 55 (%)
Fully immunized	173 (84.4)	132 (88,0)	41 (74.5)
- lack 1	9 (4.4)	7 (4.7)	2 (3.6)
- lack 2 or more	23 (11.3)	11 (7.3)	12 (21.8)
Refused immunization	2 (1.0)	1 (0.7)	1 (1.8)
B: Children age 3 years	n = 204	n = 150	n = 54
Fully immunized	172 (84.3)	128 (85.3)	44 (81.5)
- lack 1	11 (5.4)	8 (5.3)	3 (5.6)
- lack 2 or more	21 (10.3)	14 (9.3)	7 (13.0)
Refused immunization	5 (2.5)	4 (2.7)	1 (1.9)

PFI = publicly funded health insurance; PHI = private health insurance.

There were also differences in immunization rates between Cohort A and Cohort B. Table 6 shows the number and extent of children lacking immunizations by age and insurance type. The parents of 7 children (2 children age 2 years and 5 children age 3 years) in this study (1.7%) refused to have their children immunized. The parents of years refused immunizations. Of those 7 refusals, 5 were in the PHI group and 2 were in the PFI group. The reasons for refusal of immunization were not documented in the medical records.

The difference in rates of full immunization status between the PFI and PHI groups as a whole was primarily because of the lower immunization rates for PFI children in Cohort A (OR 0.399, CI 0.182 - 0.872, p = 0.019). Table 7 shows the compliance rates for the individual immunizations by insurance type for Cohort A. Table 8 shows the compliance rates for the individual immunizations by insurance type for Cohort B. By age 3 years, the rate of full immunization status for PFI children was still lower than for PHI children, but the

Table 7. Immunizations for Cohort A (age 2 years)

	All n = 204 (%)	PHI n = 150 (%)	PFI n = 54 (%)	Odds ratio	Confidence interval (low)	Confidence interval (high)	p value
DTaP	180 (87.8)	137 (91.3)	43 (78.2)	0.371	0.155	0.888	0.022
Polio[a]	189 (92.2)	144 (96.0)	45 (81.8)	0.208	0.07	0.617	0.004
MMR[a]	192 (93.7)	144 (96.0)	48 (87.3)	0.286	0.092	0.892	0.031
Hib[a]	192 (93.7)	147 (98.0)	45 (81.8)	0.102	0.027	0.393	<.001
Hepatitis B[a]	190 (92.7)	144 (96.0)	46 (83.6)	0.24	0.079	0.727	0.012
Varicella[a]	190 (92.7)	142 (94.7)	48 (87.3)	0.451	0.149	1.365	0.131
PCV	180 (87.8)	136 (90.7)	44 (80.0)	0.453	0.188	1.092	0.072

[a] Fisher Exact Probability Test used for these p values. Other p values by χ^2 analysis

DTaP = diptheria tetanus and pertussis; Hib = Haemophilus influenzae type B; MMR = measles mumps and rubella; PCV = pneumococcal conjugate vaccine; PFI = publicly funded health insurance; PHI = private health insurance.

Table 8. Immunizations for Cohort B (age 3 years)							
	All n = 205 (%)	PHI n = 150 (%)	PFI n = 55 (%)	Odds ratio	Confidence interval (low)	Confidence interval (high)	p value
DTaP[a]	190 (93.1)	141 (94.0)	49 (90.7)	0.521	0.177	1.54	0.183
Polio[a]	191 (93.6)	142 (94.7)	49 (90.7)	0.46	0.152	1.392	0.139
MMR[a]	191 (93.6)	140 (93.3)	51 (94.4)	0.911	0.274	3.033	0.546
Hib[a]	191 (93.6)	142 (94.7)	49 (90.7)	0.46	0.152	1.392	0.138
Hepatitis B[a]	188 (92.2)	139 (92.7)	49 (90.7)	0.646	0.227	1.841	0.287
Varicella	192 (94.1)	141 (94.0)	51 (94.4)	0.814	0.24	2.758	0.479
PCV	180 (88.2)	135 (90.0)	45 (83.3)	0.5	0.21	1.192	0.112

[a] Fisher Exact Probability Test used for these p values. Other p values by χ^2 analysis
DTaP = diptheria tetanus and pertussis; Hib = Haemophilus influenzae type B; MMR = measles mumps and rubella; PCV = pneumococcal conjugate vaccine; PFI = publicly funded health insurance; PHI = private health insurance.

difference was not statistically significant (OR 0.756, CI 0.332 - 0.172, p = 0.502). Immunization status by cohort is summarized in Table 9.

Spanish-speaking children had similar rates of full immunization between the PFI and PHI groups. As a group, Spanish-speaking children had a slightly higher, although not significant, rate of full immunization compared with English-speaking children (OR 1.55, CI 0.774 - 3.11, p = 0.213) as seen in Table 10.

Table 11 shows the primary and secondary outcomes by age and type of insurance. The secondary outcomes were used as surrogates to assess health care access and quality of care for the children in this study.

Every child in this study was linked to a personal PCP. Nearly 100% had a medical office visit documented in the EMR. There was a very high rate of well-child preventive care visits at 98.3% overall: 99.7% of patients with PHI and 94.5% for children with PFI had a well-child visit documented in the EMR.

Fluoride was prescribed to 84.8% of the children in both cohorts. The rate was significantly lower for children in the PFI group at 78.0% compared with 87.3% for children in the PHI group (OR 0.514, CI 0.292 - 0.905, p = 0.019). The low number for the PFI group was almost entirely because of the 65.5% level for Cohort A. The Cohort A PFI group was significantly less likely to have fluoride prescribed than the Cohort B PFI group (OR 0.193, CI 0.066 - 0.566, p = 0.001). Provision of fluoride was nearly identical between the Spanish-speaking and English-speaking patients in this study. Table 12 shows fluoride prescriptions by insurance type and by language.

Table 9. Fully immunized status by cohort and insurance type					
Fully immunized	PFI No. (%)	PHI No. (%)	Odds ratio	Confidence interval	p value
Cohort A	41 (74.5)	132 (88.0)	0.399	0.182, 0.872	0.019
Cohort B	44 (81.5)	128 (85.3)	0.756	0.332, 1.72	0.502
Spanish speaking	38 (86.4)	46 (90.2)	0.688	0.195, 2.43	0.559

PFI = publicly funded health insurance; PHI = private health insurance.

Discussion

Primary Outcome

The major finding of this study is that children ages 2 and 3 years in the KP medical offices in Napa, CA achieved very high rates of immunization and exceeded the Healthy People 2020 goals for each immunization except PCV, which missed the target by 2.0%. The rate of full immunization with all 19 recommended doses of vaccine was 84.4%, exceeding the Healthy People 2020 target of 80% and markedly exceeding the 2009 National Immunization Survey baseline of 69%. Although there were significant differences in vaccination rate between children with PFI and children with PHI, these differences were almost entirely because of low vaccination rates in Cohort A with PFI. By age 3, the differences in immunization rates between children with PFI and children with PHI were not significant and both groups achieved nearly the same rates for each vaccine and for full immunization status.

Secondary Outcomes

All of the children in this study had a personal PCP. Ninety-nine percent of children in this study had an office visit and over 98% had a preventive well-child visit. There was also a significant difference in rates of fluoride prescriptions between the PFI and PHI groups, however this difference was again because of low rates in the Cohort A PFI group. Fluoride prescription rates between the PFI and PHI children were equivalent in Cohort B.

The Medical Home

The remarkable levels of success in achieving high immunization rates and very high rates of health access for the population in this study are a reflection of systems of care designed to assist all patients, regardless of insurance type or language, in meeting their health care goals. The systems and the people working in these systems have lately been labeled the "medical home." In 2002, the American Academy of Pediatrics defined the medical home as:

> "… the medical care of infants, children, and adolescents ideally should be accessible, continuous, comprehensive, and family centered, coordinated, compassionate, and culturally effective. It should be delivered or directed by well-trained physicians who provide primary care and help to manage and facilitate essentially all aspects of pediatric care. The physician should be known to the child and family and should be able to develop a partnership of mutual responsibility and trust with them"[15]

A medical home is supported by an EMR that reminds physicians and staff at every patient contact of immunization status and health care needs regardless of the type of patient contact. It requires culturally sensitive care with sufficient language support in the office. A medical home must have excellent access for well-patient and acute care so that the patients' needs are handled quickly. It requires outreach to children who are behind on immunization. It requires that each child have a personal PCP or nurse practitioner so that a trusting relationship can develop between patient and clinician.

Table 10. Full immunization by language

Language	Total population No. (%)	Fully immunized No. (%)	Odds ratio	Confidence interval	p value
Spanish	95 (23.2)	84 (88.4)	1.55	0.774 – 3.11	0.213
English	314 (768)	261 (83.1)			

Confronting the Barriers to Immunization

There are many barriers to effective immunization practices. There are many studies that have shown disparities in immunization rates for low-income children with PFI.[3,7,16] However, barriers even exist in affluent communities. Barbara Yahn, et al, showed that 47% of families in an affluent community reported barriers to childhood immunization including inconvenience, fears of adverse vaccine reactions, having a sick child and not knowing when the next series was due.[17] Many studies have shown lower immunization rates for African-American and Hispanic children.[3,6] Despite these barriers, there are effective strategies to ensure adequate childhood immunization that are in place in the KP Napa office that may explain the high rate of immunization in this practice.

Access. Having health insurance and access to health care is one of the most important factors in getting children immunized. In their telephone outreach, CHI-Napa County reported that 96.8% of clients have a medical home other than the emergency room and 99.1% reported no barriers to health access. This study showed that 100% of children were linked to a personal PCP and that 99% of the children had had a medical

Table 11. Primary and secondary outcomes by cohort and insurance type

	Cohort A		Cohort B		
	PFI No. (%)	PHI No. (%)	PFI No. (%)	PHI No. (%)	Total No. (%)
Primary outcome					
Fully immunized	41 (74.5)	132 (88.0)	44 (81.5)	128 (85.3)	345 (84.4)
Secondary outcomes					
Primary care physician	55 (100)	150 (100)	150 (100)	54 (100)	409 (100)
Office visit	53 (98.1)	150 (100)	150 (100)	53 (98.1)	405 (99.0)
Well-child visit	52 (96.3)	149 (99.3)	52 (96.3)	149 (99.3)	402 (98.3)
Fluoride prescription	36 (65.5)	130 (86.7)	49 (90.7)	132 (88.0)	347 (84.8)

PFI = publicly funded health insurance; PHI = private health insurance.

Table 12. Fluoride prescriptions by insurance type and language

	No. (%)	Odds ratio	Confidence interval	p value
PFI	85 (78.0)	0.514	0.292 – 0.905	0.019
PHI	262 (87.3)			
Spanish	84 (87.4)	1.31	0.666 – 2.577	0.435
English	264 (88.0)			

PFI = publicly funded health insurance; PHI = private health insurance.

office visit. The overall high immunization rates in this study are a reflection of the excellent access to care for the children in this study.

Although not markedly different, the rates of well-child preventive care visits were lower for the PFI group (OR 0.140, CI 0.027 – 0.731, p = 0.016). KP staff actively work to improve the rate of well-child visits by telephone outreach. The PFI group receives additional support to improve their access to care: children who are case managed by CHI-Napa County receive outreach contact twice a year reminding families to seek preventive care and inquiring about barriers to health care access. The number of PFI children with a well-child visit was consistent with the CHI-Napa County telephone surveys, although it is not clear why some PFI children did not come in for well-child care. More studies are needed to understand the barriers to access for the children with PFI who did not obtain well-child preventive care visits.

Language is often cited as a barrier to receiving immunizations. There were no significant health outcome differences for Spanish-speaking children in this study.

Insurance Type. More than 18% of children age 24 to 48 months in this practice receive PFI. Forty-eight children in the PFI group would currently be uninsured if the KP Child Health Program had not been offered to them when the Napa Healthy Kids program lost its funding in 2008. This study showed that care outcomes were equivalent by age 3 years regardless of type of insurance.

Language. Language is often cited as a barrier to receiving immunizations.[7] There were no significant health outcome differences for Spanish-speaking children in this study. Immunization rates were slightly lower in the PFI group of Spanish speakers, but not significantly so. Spanish speakers actually had higher, although not significantly higher, rates of full immunization in the combined Cohorts A and B (OR 1.55; CI 0.774 - 3.11; p = 0.213). This is likely a reflection of slightly higher PHI coverage in the Spanish-speaking group. Prescription of fluoride was not significantly different between Spanish-speaking and English-speaking patients.

Cultural competency and language skills are necessary to meet the needs of Spanish-speaking patients. The KP Napa practice offers bilingual physicians and staff to meet this need. All patient education materials are available in Spanish and English. Additionally, the CHI-Napa County provides bilingual case managers in their enrollment and outreach programs. These programs reduce the barriers of language in a county that was 38% Hispanic on the recent 2010 census.

Family fears. Parents may have many concerns about vaccine safety. In 2000, Gellin et al noted that 25% of parents believe receiving so many vaccines may weaken immune systems and 19% of parents do not believe vaccines have been adequately tested before licensing for use.[18] KP Napa offers vaccine information statements in most languages to help educate patients on the need for comprehensive vaccination. Patient information about vaccine need and vaccine safety is readily available in KP Napa offices and on the physicians' Web sites. Additionally, physicians and staff must be knowledgeable and comfortable with the discussion of vaccine safety to allay patient and family fears.

Physician concerns. There are many missed opportunities when a child who is eligible to receive a vaccine does not receive it. The most common reasons are that a child has a mild illness and that the visit is for acute and not preventive care.[19] KP Napa physicians are not immune to these concerns and it takes constant attention to immunization needs to achieve high rates. Although some health care systems offer monetary awards to improve immunization rates,[20] KP Napa physicians do not receive financial rewards for care. They do receive nonblinded quarterly reports on their quality indicators so that members of the department can see how they and the department compare with the quality goals.

Complex immunization schedules. Immunization practice has changed markedly from the 3:3:1 (DPT, polio, MMR) schedules in place since 1971. It is even more complicated by combination vaccines that vary in their components. For example, Pediarix and Pentcel both have DTaP and polio, but one has Hib and the other has hepatitis B. When children transfer into a practice, they may have had one or several combination vaccines and yet be lacking on individual vaccines. The EMR at KP Napa offices is able to indicate at each visit which vaccines are deficient and which are up to date. This is particularly important for vaccines such as PCV, which is new in the last decade and requires 4 injections by age 18 months to be effective.

Cost. Cost can be a major factor in vaccine administration. Surveys of pediatricians and family physicians have found 49% of physicians delayed purchase of vaccines because of cost and 38% felt reimbursement for the time and counseling for vaccine administration was not sufficient.[21] Nearly 11% of these physicians considered not offering immunizations in their practice. Referring patients to county public health departments for immunizations will only lower the chances of a child being fully immunized. The KP Napa practice supplies immunizations at no cost to children. There are no financial disincentives to impair fully immunizing the children in this practice.

Limitations in This Study

Assessment of bias. Restricting the study to children in zip codes 94558 and 04559 (city of Napa) removed 238 children (10.1%) from the study. The demographics of this population are not known. Since these children reside outside the city of Napa, they often receive care in other medical centers and were excluded for that reason. Requiring 6 months of active health insurance removed an additional 505 children (21.4%). The choice of how long a patient should have active health insurance is arbitrary, but 6 months of active coverage was felt sufficient by the author. Restricting the study population to children ages 24 to 48 months is also arbitrary but consistent with other studies, as noted previously. Ages 2 and 3 years are appropriate for assessing voluntary primary immunization rates, before the mandatory immunization documentation is required at ages 4 to 6 years when children enter preschool and kindergarten.

Selecting PHI children by birth date resulted in a slightly older cohort because no children born in November or December were included in the study group. Choosing older children may select for higher rates of immunization in the PHI groups, but this was not demonstrated in this study. The number of children with full immunization in each chronological quintile of cohort A with PHI group was 23, 27, 29, 28, and 25 (Average = 26.4, standard deviation [SD] 2.41). The number of children with full immunization in each chronological quintile of Cohort B with PHI group was 25, 25, 27, 23, and 27 (Average = 25.6, SD 1.95). It does not appear the selection process biased Cohort B with PHI towards higher levels of full immunization in the older quintiles of either cohort. Since all primary immunizations should be completed by age 18 months, this selection process was not felt to bias the PHI group.

The administrative record. This study was done without direct patient contact. Patients were considered low-income if they had PFI. However, demographics and family incomes are not known. Insurance types in the PFI group indicate family income less than 250% FPL, but the group is not homogenous. The last active insurance type was known and was documented as the insurance type, but previous insurance status (uninsured, PFI subtypes, or private insurance) is not known. The record of immunizations given before care at KP Napa could be incomplete. Both the PHI and PFI groups may have under-reported immunization records. Barriers to immunization are not known. Although the study was restricted to Napa city zip codes, Napa is not homogenous in income or other demographics. Although CHI-Napa County asks about barriers to access in their outreach efforts, this information is not currently retrievable from their data systems. Further studies are needed to answer these concerns.

Conclusion

The children in this study achieved high rates of immunization that exceeded the Healthy People 2020 target and markedly exceeded the National Immunization Survey 2009 benchmark for full immunization status for the 19 recommended vaccines in this study. Cohort A with PFI was deficient in immunizations and fluoride prescription compared with Cohort A with PHI, but this difference was eliminated by age 3 years. There were no differences in care based on language.

The successful immunization practices and achievement of the secondary outcomes in this study are a reflection of the integrated care model in this practice. The EMR and support systems facilitate comprehensive, coordinated, and accessible care for patients and allow physicians and support staff to practice culturally sensitive and compassionate care—the definition of a medical home. ❖

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Disclosure Statement

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

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References

1. Immunization and infectious diseases [objectives list on the Internet]. Washington DC: US Department of Health and Human Services: HealthyPeople.gov; updated 2011 Nov 21 [cited 2011 Nov 23]. Available from: www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicid=23, click on IID-8 [View Details].
2. Center for Disease Control and Prevention. Statistics and surveillance: 2009 table data [table on the Internet]. US Department of Health and Human Services: Centers for Disease Control and Prevention; last updated 2010 Nov 16 [cited 2011 Nov 23]. Available from: www.cdc.gov/vaccines/stats-surv/nis/data/tables_2009.htm, click on Coverage with Individual Vaccines and Vaccination Series: by State and Local area (includes birth dose of HepB and 2+ doses Hep A) Excel file.

3. Kirschke DL, Craig AS, Schaffner W, Daugherty JR, Narramore J, Griffen MR. Childhood immunization rates before and after implementation of Medicaid managed care. Arch Pediatr Adolesc Med 2004 Mar;158(3):230-5.
4. Dey AN, Schiller JS, Tai DA. Vital health statistics: Summary health statistics for US children: National Health Interview Survey, 2002 [monograph on the Internet]. Atlanta, GA: Centers for Disease Control and Prevention: National Center for Health Statistics: 2004 Mar;10(221).
5. Olson LM, Tang SF, Newacheck PW. Children in the United States with discontinuous health insurance coverage. N Engl J Med 2005 Jul 28;353(4):382-91.
6. Hoffman C, Wang M. Health insurance coverage in America: 2002 data update. Menlo Park, CA: The Kaiser Family Foundation: Kaiser Commission on Medicaid and the Uninsured; 2003 [cited 2011 Nov 16]. Available from: www.kff.org/uninsured/upload/Health-Insurance-Coverage-in-America-2002-Data-Update.pdf.
7. Grant R. Transportation as a barrier to child access: the scope of the problem [slide show on the Internet]. New York: The Children's Health Fund and Battlecreek, MI: WK Kellogg Foundation; 2007 [cited 2011 Nov 23]. Available from: http://apha.confex.com/apha/135am/techprogram/paper_162057.htm, click on Slides (pdf) or Handout.
8. Diringer J, Wunsch B. The future of children's coverage in California. Los Angeles, CA: The California Endowment; 2008 Sep 8.
9. Smith PJ, Stevenson J, Chu SY. Associations between childhood vaccination coverage, insurance type, and breaks in health insurance coverage. Pediatrics 2006 Jun;117(6):1972-8.
10. Lave JR, Keane CR, Lin CJ, Ricci EM, Amersbach G, LaVallee CP. Impact of a children's health insurance program on newly enrolled children. JAMA 1998 Jun 10;279(22):1820-5.
11. Federico SG, Steiner JF, Beaty B, Crane L, Kempe A. Disruption in insurance coverage: patterns and relationship to health care access, unmet need, and utilization before enrollment in the States Children's Health Insurance Program. Pediatrics 2007 Oct:120(4):e1009-16.
12. Mission Statement. The Campaign for Children: Children's Health Initiative Napa County Case Statement 2010-2011 [monograph on the Internet]. Napa, CA: Children's Health Initiative Napa County; 2010-2011 [cited 2011 Nov 23]. Available from: www.napachi.org/?action=about, click on Case Statement.
12. Burns IT, Zimmerman RK. Immunization barriers and solutions. J Fam Pract 2005 Jan;54(1 Suppl):S58-62.
13. Guerra FA, Blatter MM, Greenberg DP, Pichichero M, Noriega FR; Pentacel Study Group. Safety and immunogenicity of a pentavalent vaccine compared with separate administration of licensed equivalent vaccines in US infants and toddlers and persistence of antibodies before a preschool booster dose: a randomized, clinical trial. Pediatrics 2009 Jan;123(1):301-12.
14. McCormick LK, Bartholomew LK, Lewis MJ, Brown MW, Hanson IC. Parental perceptions of barriers to childhood immunization: results of focus groups conducted in an urban population. Health Education Research 1997 Sep;12(3):355-62.
15. Smith PJ, Santoli JM, Chu SY, Ochoa DQ, Rodewald LE. The association between having a medical home and vaccination coverage among children eligible for the vaccines for children program. Pediatrics 2005 Jul;116(1):130-9.
16. Rosenthal J, Rodewald L, McCauley M, et al. Immunization coverage levels among 19- to 35-month-old children in 4 diverse, medically underserved areas of the United States. Pediatrics 2004 Apr;113(4):e296-302.
17. Yahn BP, Xia Z, Edmonson L, Jacobson RM, Jacobsen SJ. Barriers to immunization in a relatively affluent community. J Am Board Fam Pract 2000 Sep-Oct;13(5):325-32.
18. Gellin BG, Maibach EW, Marcuse EK. Do parents understand immunizations? A national telephone survey. Pediatrics 2000 Nov;106(5):1097-102.
19. Szilagyi PG, Rodewald LE. Missed opportunities for immunizations: a review of the evidence. J Public Health Manag Pract 1996 Winter;2(1):18-25.
20. O'Connor AC, Layton CM, Osbeck TJ, Hoyle TM, Rasulnia B. Health plan use of immunization information systems for quality measurement. Am J Manag Care 2010 Mar;16(3):217-24.
21. Freed GL, Cowan AE, Clark SJ. Primary care physician perspectives on reimbursement for childhood immunizations. Pediatrics 2009 Dec;124 Suppl 5:S466-71.

To Do the Possible

Our goal is not to completely eradicate the infection—that would be very difficult —but to produce a vaccine that will prevent not infection but disease. I think this is more possible.

— Luc Montagnier, b 1932, French virologist, 2008 Nobel Laureate in Physiology or Medicine for his discovery of the human immunodeficiency virus

A Single-Blinded, Direct Observational Study of PGY-1 Interns and PGY-2 Residents in Evaluating their History-Taking and Physical-Examination Skills

Sandeep Sharma MD, DrPH(c)

Abstract

Background: Internal Medicine residents and interns are often the first contact for newly admitted patients in a teaching hospital. The proper evaluation, diagnosis, and treatment may depend on this initial encounter.

Objectives: To evaluate the history-taking and physical-examination skills of interns/residents on new admissions to the medical floors; to compare data from the patient encounter to the chart for evidence of accuracy; to measure the time spent on the initial encounter.

Methods: An independent medical observer used a yes/no checklist with 60 variables in a single-blinded observational study. Frequency tables were generated and results were based on descriptive statistics.

Results: In 7 categories specifically aimed at chart review for accuracy, discrepancies were found between what medical post-graduate year (PGY)-1 interns and PGY-2 residents (interns/residents) recorded in the patient's chart and the observed actions during the patient encounter. There were 25 encounters observed. In 64%, the time spent on history taking was <7 minutes. In 68%, the time spent for the physical examination was <5 minutes. In 72%, patients were not asked about family medical history. None of the observed interns/residents took their own measurements of the patient's blood pressure. No intern/resident asked about recent weight loss, weight gain, level of salt intake, despite patients with history of hypertension; nor did they perform any examinations of the eye fundi and accommodation, thyroid, carotids, or hearing. The majority of patients were asked about chest pain, cough, nausea, vomiting, chief complaint, and the onset of symptoms.

Conclusions: This study documents the poor overall performance in the quality of history-taking and physical-examination skills on newly admitted patients.

Introduction

Proper medical care depends not only on the knowledge base of clinicians, but also on their compulsiveness and their integrity. There have been several published studies that evaluate the skills of interns/residents. Evaluation methods used in previous published studies have included direct observation,[1-4] mini-clinical evaluation exercises (CEX),[5-11] objective structured clinical evaluation (OSCE),[12-14] chart review,[15] standardized patients and checklists,[16-21] a 360-degree evaluation instrument,[22] and use of a standardized patient satisfaction questionnaire.[23] Each of these evaluation tools is imperfect. Some tools use artificial situations whereas others suffer from the Hawthorne effect, in which clinical performance of the physician is greatly enhanced by knowledge that they are being evaluated. Moreover, none of these techniques has been designed to assess what the physician actually asked and examined compared with the actual work product. In review of these published articles, there is no single-blinded, direct observation of history and physicals conducted during the actual encounter with the patient. Because of a concern that the usual evaluation tools seriously overestimate physician performance, I undertook a single-blinded, direct observational study of Internal Medicine post-graduate year (PGY)-1 interns and PGY-2 residents (interns/residents) to evaluate their history-taking and physical-examination skills as well as to correlate the accuracy of the observed data collection with what they actually reported.

Methods

Direct Observation and Chart Review

A health policy doctoral candidate with an Educational Commission for Foreign Medical Graduates (ECFMG) certified medical degree with US clinical experience was recruited to directly observe the initial

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history taking and physical examinations performed by interns/residents of a New York City teaching hospital. It was imperative to this study that an independent (not affiliated with the study institution) observer was used who was not known to the interns/residents. The observer introduced himself to both the intern/resident conducting the patient encounter and to the patient as a medical researcher who wanted to learn about taking a proper history and physical examination. With the oral consent of both the intern/resident and the patient, the observer was present in the room and did not interfere with the history-taking and physical-examination process. Among the papers in the observer's hand was a thorough checklist with 60 variables that consisted of yes/no answers regarding the history and physical examination. During the actual patient encounter, the observer discreetly marked on the checklist to avoid relying on his memory to complete the checklist afterwards. The intern/resident was completely unaware that s/he was being evaluated by the observer during the patient encounter. The intern/resident had no prior knowledge from colleagues or the Residency Program Director about an evaluation. Hence, this direct observational study was single-blinded. The observer also recorded the length of time used in both the history-taking and physical-examination portions of the examination as an indication of completeness. Another important element of the checklist was the chart evidence section. After the intern/resident note was written from the encounter, the observer reviewed the results of several variables in the patient's chart to determine the degree of accuracy of the recorded information compared with what was actually performed during the encounter. The 7 variables used for chart review were: eye movements, PERRLA (pupils equal, round, reactive to light and accommodation), blood pressure, pulses, reflexes, muscle strength, and rectal examination. These 7 variables were chosen in particular because comments such as: EOMI (extra ocular movements intact), PERRLA, guaiac are regularly seen in interns/residents' notes.

During the two-week period of the study, 15 interns/residents were evaluated in 25 patient encounters (1 to 3 patients per intern/resident). Of the 25 patients, 14 were female and 11 were male. The 25 encounters consisted of abdominal pain (5), chest pain (3), respiratory disorder (6), neurological conditions (4), and "other" (7), consisting of hypokalemia, fever, sepsis, extremity pain, penile pain, and cellulitis.

Survey

After the observational part of the study was completed, a questionnaire was distributed to all interns/residents (PGY-1 and PGY-2), which asked them to estimate the average time they spent on history taking and physical examination of a new admission to the medical service. They were also asked to estimate how often (percentage of time) they personally completed 34 separate elements of the medical history and how often (percentage of time) they personally performed 26 elements of a physical examination. These elements were identical to the 60 elements the observer evaluated during the observed history taking and physical examination. The interns/residents were told the survey was anonymous and were encouraged to answer the questions honestly. No identifying information such as name, PGY, or sex was asked on the questionnaire to help ensure anonymity. Of 50 questionnaires distributed 43 were completed. Participation in the survey was voluntary.

Coding

The yes/no answers on the checklist were converted into codes (0 = no/not done, 1 = yes/done, 9 = not applicable). The sex of the patient was also coded (0 = female, 1 = male). In the chart evidence section of the checklist, the following codes were designated (1 = completed during encounter, recorded completed in the chart; 2 = completed during encounter, did not record in chart; 3 = did not complete during encounter, did not record in chart; 4 = did not complete during encounter, but, recorded completed in chart). The codes were entered into a software program called SPSS Version 11 (SPSS Inc, Chicago, IL) and statistical analysis used χ^2. The identities of the interns/residents, the patients, and the hospital were all kept anonymous.

This research was approved by the institutional review board of the hospital where the study took place.

Results

Direct Observation and Chart Review

History—There were 25 patient encounters. In 36%, interns/residents did not introduce themselves to the patient. In 72%, the intern/resident did not explain what s/he was there to do.

Table 1. Time comparison of history taking and physical examination in 25 cases

Encounter time	Minimum (minutes)	Maximum (minutes)	Average (minutes)
History taking	2	15	7.30
Physical examination	3	20	5.29

The average length of time, minimum and maximum for both the history-taking and physical-examination portions are seen in Table 1. In 64%, the amount of time spent during history taking was ≤7 minutes. In 32%, the time spent for history taking was ≤5 minutes, and in one case, 2 minutes. However, in 16%, the time spent for history taking was 12 to 15 minutes. Table 2 shows the frequency of occurrence by percentage, for the 36 variables that were asked by the intern/resident during history taking. All patients (100%) were asked about their current medications, however, in 96% of the cases, the patients were not asked if they were taking those medications regularly, as prescribed. Patients were asked about their chief complaint (96%) or when their symptoms started (96%). A majority was asked about symptoms such as chest pain (88%), cough (80%), nausea or vomiting (80%), whereas questions about other symptoms were asked in only a minority of the encounters (ie, urinary problems [36%], visual problems [24%], and joint pain [20%]).

There were 5 variables (level of education, salt intake, weight loss/gain, sexually transmitted infections, or erectile problems) that were not addressed in any of the 25 encounters. Other important historic questions that were asked in <50% of the encounters included: allergies (44%), prior surgeries (32%), family history (28%), dietary history (12%), and occupation history (4%).

Physical Examination—For the physical examination in the 25 encounters, 68% took ≤5 minutes, 84% took ≤6 minutes. In 8%, the physical examination took 3 minutes. On the other hand, in one case, one examiner took 20 minutes and performed a thorough physical examination.

Table 3 shows the number and percentage of cases correctly performed during the physical portion of the examination. No patients were unnecessarily exposed and all patients had cardiac, abdominal, and pulmonary examinations to some extent. In 84% of cases, breath sounds were examined over the gown, and in 76%, cardiac auscultations were performed over the gown. No intern/resident independently took the patient's blood pressure. In 92% of the encounters, pulse was not measured. No intern/resident examined the patient's fundi, felt the carotids, checked the thyroid, or performed a pelvic examination. In a minority of cases, the examiner tested eye movements (4%), tested reflexes (12%), and observed the patient walk (8%). A rectal exam was asked for or performed in only 1 patient (4%) despite 5 patients (20%) presenting with abdominal pain. No pelvic exams were requested despite 2 women patients presenting with abdominal pain. Of the 24 physical exam variables evaluated, 12 were performed <10% of the time and 7 of those variables were never performed during the 25 witnessed examinations.

Chart Review—Figure 1 demonstrates discrepancies in patient chart documentation by the intern/resident between what s/he tested on physical examination and what s/he documented in the written history and physical for each of 7 evaluated variables. A significant number of training physicians misrepresented that they performed tests, when in fact they had not (eye movements 60%, pupils and accommodation 80%;

Table 2. Rankings of variables used in history taking by frequency of occurrence

Variable	Frequency of occurrence (%)
Asked about current medications	100
Asked what the chief complaint was	96
Asked when symptoms started	96
Asked about chest pain	88
Asked about cough	80
Asked about nausea/vomiting	80
Asked about primary care physician	80
Asked about smoking history	76
Asked about alcohol use	72
Asked about illegal drug use	72
Asked about constipation/diarrhea	68
Introduced themselves to the patient	64
Asked about shortness of breath	60
Asked about previous hospitalizations	52
Asked about allergies	44
Asked about urinary problems	36
Asked about previous surgeries	32
For women patients younger than age 60 years, asked about Papanicolaou tests	29
Asked about family medical history	28
Explained to patient that s/he was to conduct a history taking and physical examination	28
Asked about any vision problems	24
Asked about joint pain	20
For women patients younger than age 55 years, asked about last menstrual period	17
Asked about patient's diet	12
Asked about memory problems	12
For women patients younger than age 70 years, asked about mammogram screening	11
Asked about hearing problems	8
Asked about depression	4
Asked about occupational history	4
Asked about weight gain/loss	0
Asked about level of education	0
Asked about salt intake	0
For men patients, asked about erection problems	0
Asked about sexually transmitted infections	0

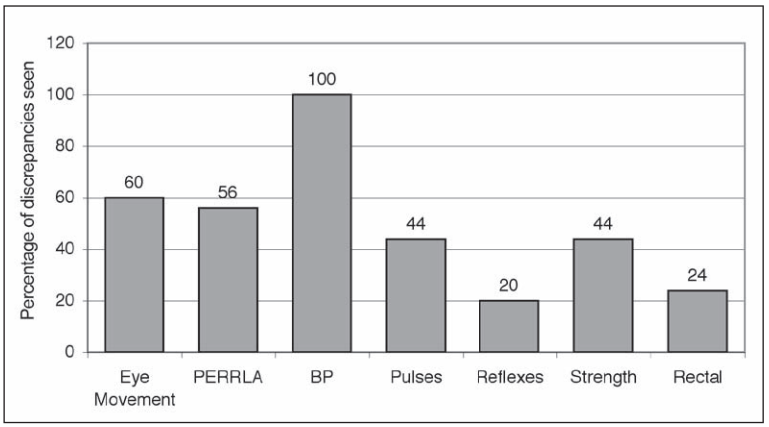


Figure 1. The percentage of discrepancies in intern/resident notes for seven variables, not supported by the observed physical examination.

BP = blood pressure; PERRLA = pupils equal, round, reactive to light, and accommodation

Table 3. Rankings of variables used in physical examination by frequency of occurrence

Variable	Frequency of occurrence (%)
No inappropriate exposure of patients during physical examination	100
Performed abdominal examination	100
Auscultated breath sounds *over* gown	84
Listened to bowel sounds	80
Auscultated heart sounds *over* gown	76
Checked extremity pulses	40
Checked pedal edema	32
Examined pupils with light	24
Auscultated heart sounds under gown	24
Tested muscle strength	20
Auscultated breath sounds under gown	16
Looked in patient's throat	16
For women patients younger than age 70 years, breast exam done or offered	13
Tested reflexes	12
Tested gait	8
Measured pulse with watch	8
Tested eye movements	4
Touch to pinprick or cotton swab	4
Asked about or did rectal examination	4
Measured blood pressure	0
Examined fundus	0
Tested accommodation	0
Tested hearing	0
Felt carotids	0
Examined thyroid	0
Performed pelvic examination	0

blood pressure 100%, pulses 44%, reflexes 20%, muscle strength 44%, and rectal examination 24%). In no cases did a physician examine a variable and fail to document it. Table 4 shows frequency tables on accuracy of documentation in patients' charts.

Intern/Resident Survey

History—On the survey, interns/residents were asked about the 36 historic variables. In all variables except one (current medications), the estimate of tasks completed by the interns/residents was greater, and sometimes significantly greater than the observed frequency. Questions about 8 variables (hearing, depression, occupational history, weight gain/loss, level of education, salt intake, erectile problems, and sexually transmitted infections) were asked <10% of the time although it was estimated each was asked more often, ranging from erectile problems (46%) to occupational history (74 %).

These results contrast with the estimated length of time interns/residents reported on the survey that they spend. The mean amount of time they estimated spending on history taking was 28 minutes (minimum 8 minutes; maximum 90 minutes) vs actual time 7 minutes ($p < 0.001$); whereas the mean time they estimated performing a physical examination was 15 minutes (minimum 5 minutes; maximum 45 minutes) vs actual time of 5 minutes ($p < 0.001$).

Physical Exam—On the survey completed by the interns/residents, in 22 out of 24 physical examination variables, estimated compliance was statistically higher than actual compliance. Six elements of the physical examination were never observed although they were reported to have been performed, from testing fundi examination (9%) to testing pupillary accommodation (69%).

Discussion

The results obtained during this study demonstrated widespread deficiencies in both completeness of history taking and physical examination, and in the integrity of the written report. The study conducted at this institution was extremely important to elucidate intern/resident practices and the single-blinded nature allowed a level of objectivity in assessing medical care for newly admitted patients.

Although it is expected that interns/residents will read notes written in the Emergency Department before commencing the patient encounter on the medical floor, they are taught to complete a thorough history and physical examination. It is unacceptable that in 36% of patient encounters, the interns/residents did not intro-

duce themselves to the patient, but instead immediately began questioning upon entering the room. Patients are reassured if interns/residents explain what they are there to do. These improvements in communication and bedside manner add expected patient benefit.

As shown in Table 1, the amount of time spent on each portion of the examination appears greatly inadequate. Of note, on the survey, interns/residents estimated that they spend an average of 28 minutes for history taking and 15 minutes for physical examination.

The extent of the inadequacies of the interns/residents in performing basic skills in obtaining histories and physical exams is remarkable. Many of the interns/residents omitted a number of questions, which contributed to less time being spent on history taking of the newly admitted patient. Even though there were some patients with chest pain and shortness of breath, no intern/resident asked about weight gain or salt use. Less than half of the interns/residents inquired into such basic areas as allergies, prior surgeries, or family history of medical problems. About 25% of patients were not asked about basic health issues such as smoking, alcohol use, or illicit drug use. Although nearly all interns/residents asked the patient's chief complaint, when the symptoms started, and what the current medications were, these questions were rarely followed up with detailed questions to fully develop the nature of the patient's present illness. In one case in which the patient complained of penile pain, the intern/resident did not ask any questions concerning sexual activity, sexually transmitted infections, erectile problems, or urinary symptoms.

The deficiencies seen on the physical examinations were even more pronounced. Although every patient had, to some extent, an examination of the abdomen, chest, and heart, those examinations were performed over the gown approximately 80% of the time. No other element of the physical examination (with the exception of listening to bowel sounds) was performed more than 40% of the time. Only 1 of the 6 women patients <55 years of age was asked about last menstrual period. Only 1 of the 14 women patients was asked about most recent mammogram. Of the 4 neurologic cases, minimental status exams were not performed. Twelve of the 26 elements evaluated occurred <10% of the time and no intern/resident measured a patient's blood pressure, examined the carotids or thyroid, or performed a pelvic exam. In fairness, one would only expect a rectal or pelvic exam to be requested under appropriate medical conditions, ie abdominal pain.

These results were in stark contrast to the data obtained in the survey. Although there was direct observation of 30% of the interns/residents, the returned surveys sampled 86% of the interns/residents. Although direct correlation is not possible, agreement was reached between the Department Chairman, the Program Director, and the Medical Researcher that, because of their extensive experience training and managing interns/residents in this program, associations could be suggested and potential explanations offered.

Of the 5 questions in the history that were not asked, the survey reported that the questions are usually asked 46% to 72% of the time. In the physical examination,

Table 4. Accuracy of documentation of patient charts

Validity	Frequency	Percentage	Valid Percentage	Cumulative Percentage
Eye movements				
1.00	1	4.0	4.0	4.0
3.00	9	36.0	36.0	40.0
4.00	15	60.0	60.0	100.0
Total	25	100.00	100.00	
PERRLA				
1.00	6	24.0	24.0	24.0
3.00	5	20.0	20.0	44.0
4.00	14	56.0	56.0	100.0
Total	25	100.0	100.0	
Blood pressure				
4.00	25	100.0	100.0	100.0
Pulses				
1.00	9	36.0	36.0	36.0
3.00	5	20.0	20.0	56.0
4.00	11	44.0	44.0	100.0
Total	25	100.0	100.0	
Reflexes				
1.00	3	12.0	12.0	12.0
3.00	17	68.0	68.0	80.0
4.00	5	20.0	20.0	100.0
Total	25	100.0	100.0	
Muscle strength				
1.00	5	20.0	20.0	20.0
3.00	9	36.0	36.0	56.0
4.00	11	44.0	44.0	100.0
Total	25	100.0	100.0	
Rectal examination				
1.00	1	4.0	4.0	4.0
3.00	18	72.0	72.0	76.0
4.00	6	24.0	24.0	100.0
Total	25	100.0	100.0	

1.00 = procedure observed being done and result documented in patient's chart; 3.00 = procedure not observed being done and result not documented in patient's chart; 4.00 = procedure not observed being done but result documented in patient's chart; PERRLA = pupils equal, round, reactive to light, and accommodation

7 items were never examined yet the survey reported that they routinely test these items an average of 43% of the time. No intern/resident personally took a blood pressure, and only 8% actually measured the pulse; yet the survey reported that they personally took the patient's blood pressure 49% of the time and measured the pulse 59% of the time. Interns/residents listened to the lungs under the gown only 16% of the time, although they estimated doing so 89% of the time.

Unfortunately the study also confirmed faculty concerns that there are multiple discrepancies in the charts. For the 7 variables in Figure 1, the percentage of discrepancies in documented examinations ranges from 20% to 100%. It may be common practice to record a blood pressure even if you didn't personally measure it, however, the practice could be considered a subtle form of intellectual deception. This misrepresentation can be minimized by documenting the source of the result or finding in the intern/resident note. The interns/residents also miss the opportunity to see if important vital signs change during the hospital course.

… questions were rarely followed up with detailed questions to fully develop the nature of the patient's present illness.

Completeness of history taking and physical examination practiced during patient encounters is encouraged so that interns/residents may make their own proper assessment and treatment plan. As well, a more thorough history taking and physical examination would make the intern/resident aware of other significant health issues warranting attention.

What are possible explanations for the performance demonstrated in this study? It is difficult to explain these large differences on perception alone. Other operative factors for the inflated estimates in the survey could include: fear of discovery, subject to more control and/or scrutiny, fear of affecting the program's reputation, a sense of shame about actual performance, and fear of offending the Program Director. To what extent any of these factors (or any other factors) is operative is impossible to determine. In terms of medical knowledge, the interns/residents at the institution have been tested in several ways. The average in training score is several points above the national average (58 percentile vs 55 percentile). The pass rate on the boards is consistently near 100%.

At orientation, the medical leadership emphasizes the importance of compulsiveness; and more importantly, they emphasize the necessity for integrity in every aspect of medical practice. It has been stated multiple times to interns/residents that medical mistakes, although regrettable, will be tolerated, but there is no tolerance for dishonesty. Each week the Department Director conducts chief-of-service rounds in which the major emphasis is on proper history-taking and physical-examination techniques. All interns/residents are observed performing CEX examinations with largely satisfactory results. Frequent departmental chart review and morbidity/mortality reviews have not revealed anything to suggest the problems seen in this study.

Even though in their surveys, many interns/residents wrote that they do things when they feel they are appropriate and perform focused histories and examinations, they have been trained to perform a complete history taking and physical examination. The ability to persuade new interns/residents of the validity of this argument is somewhat diluted by the historic insistence to demand a complete multifaceted history and physical examination that includes some elements that rarely affect patient care. Furthermore, this argument was less persuasive when it was observed that, in patients with congestive heart failure, the intern/resident still didn't ask about salt intake or weight gain, or in patients with abdominal pain, no rectal examination or inquiry concerning last menstrual period was entertained, or in the patient with penile pain, no sexual history was taken. It is unclear what the most effective approach would be to change these behaviors.

Limitations

Single-blinded studies of interns/residents are difficult to conduct because direct observation of too many encounters over an extended period of time could alert them to a study and be communicated to colleagues, perhaps even jeopardizing future single-blinded studies. It was also important to minimize the Hawthorne effect by using an observer unknown to the interns/residents, and to prevent the examiners from noticing the evaluator's notetaking during the patient encounter. Given this, before this study began, it was determined that 25 patient encounters using 15 different interns/residents would be sufficient to reach valid and reliable conclusions about the attention given to newly admitted patients on the medical floors. The study took place in August of the academic year.

Conclusion

This single-blinded, direct observational study delineated systematic deficiencies in the thoroughness of history taking and physical examinations conducted by interns/residents. The chart review portion provided an accuracy comparison of the observed physical examination to the intern/resident's documentation. The study also demonstrated what real patients, newly admitted to the medical units, faced when encountering interns/residents under everyday, nontesting circumstances. The

Hawthorne effect may play a key role in the performances of interns/residents in previously published studies not blinded to the examiner. More studies with a single-blinded approach are needed to get a true picture. ❖

Disclosure Statement

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

References

1. Holmboe ES. Faculty and the observation of trainees' clinical skills: problems and opportunities. Acad Med 2004 Jan;79(1):16-22.
2. Holmboe ES, Hawkins RE, Huot SJ. Effects of training in direct observation of medical residents' clinical competence: a randomized trial. Ann Intern Med 2004 Jun 1;140(11):874-81.
3. Li JT. Assessment of basic physical examination skills of internal medicine residents. Acad Med 1994 Apr;69(4):296-9.
4. Jouriles NJ, Emerman CL, Cydulka RK. Direct observation for assessing emergency medicine core competencies: interpersonal skills. Acad Emerg Med 2002 Nov;9(11):1338-41.
5. Norcini JJ, Blank LL, Arnold GK, Kimball HR. The mini-CEX (clinical evaluation exercise): a preliminary investigation. Ann Intern Med 1995 Nov 15;123(10):795-9.
6. Norcini JJ, Blank LL, Duffy FD, Fortna GS. The mini-CEX: A method for assessing clinical skills. Ann Intern Med 2003 Mar 18;138(6):476-81.
7. Hatala R, Ainslie M, Kassen BO, Mackie I, Roberts JM. Assessing the mini-Clinical Evaluation Exercise in comparison to a national specialty examination. Med Educ 2006 Oct;40(10):950-6.
8. Malhotra S, Hatala, R, Courneya CA. Internal medicine residents' perceptions of the Mini-Clinical Evaluation Exercise. Med Teach 2008;30(4):414-9.
9. Blank LL, Grosso LJ, Benson JA Jr. A survey of clinical skills evaluation practices in internal medicine residency programs. J Med Educ 1984 May;59(5):401-6.
10. Nair BR, Alexander HG, McGrath BP, et al. The mini clinical evaluation exercise (mini-CEX) for assessing clinical performance of international medical graduates. Med J Aust 2008 Aug 4;189(3):159-61.
11. Durning SJ, Cation LJ, Markert RJ, Pangaro LN. Assessing the reliability and validity of the mini-clinical evaluation exercise for internal medicine residency training. Acad Med 2002 Sept.;77(9):900-4.
12. Sloan DA, Donnelly MB, Johnson SB, Schwartz RW, Strodel WE. Assessing surgical residents' and medical students' interpersonal skills. J Surg Res 1994 Nov;57(5):613-8.
13. McIlroy JH, Hodges B, McNaughton N, Regehr G. The effect of candidates' perceptions of the evaluation method on reliability of checklist and global rating scores in an objective structured clinical examination. Acad Med 2002 Jul;77(7):725-8.
14. Wass V, Jolly B. Does observation add to the validity of the long case? Med Educ 2001 Aug;35(8):729-34.
15. Ognibene AJ, Jarjoura DG, Illera VA, Blend DA, Cugino AE, Whittier FC. Using chart reviews to assess residents' performances of components of physical examinations: a pilot study. Acad Med 1994 Jul;69(7):583-7.
16. Cohen DS, Colliver JA, Marcy MS, Fried ED, Swartz MH. Psychometric properties of a standardized-patient checklist and rating-scale form used to assess interpersonal and communication skills. Acad Med 1996 Jan;71(1 Suppl):S87-9.
17. Han JJ, Kreiter CD, Park H, Ferguson KJ. An experimental comparison of rater performance on an SP-based clinical skills exam. Teach Learn Med 2006 Fall;18(4):304-9.
18. Day RP, Hewson MG, Kindy P Jr., Van Kirk J. Evaluation of resident performance in an outpatient internal medicine clinic using standardized patients. J Gen Intern Med 1993 Apr;8(4):193-8.
19. Boulet JR, McKinley DW, Norcini JJ, Whelan GP. Assessing the comparability of standardized patient and physician evaluations of clinical skills. Adv Health Sci Edu Theory Pract 2002;7(2):85-97.
20. Hassett JM, Zinnerstrom K, Nawotniak RH, Schimpfhauser F, Dayton MT. Utilization of standardized patients to evaluate clinical and interpersonal skills of surgical residents. Surgery 2006 Oct;140(4):633-8.
21. MacRae HM, Vu NV, Graham B, Word-Sims M, Colliver JA, Robbs RS. Comparing checklists and databases with physicians' ratings as measures of students' history and physical-examination skills. Acad Med 1995 Apr;70(4):313-7.
22. Joshi R, Ling FW, Jaeger J. Assessment of a 360-degree instrument to evaluate residents' competency in interpersonal and communication skills. Acad Med 2004 May;79(5):458-63.
23. Jagadeesan R, Kaylen DN, Lee P, Stinnett S, Challa P. Use of a standardized patient satisfaction questionnaire to assess the quality of care provided by ophthalmology residents. Ophthalmology 2008 Apr;115(4):738-43.

Most Valuable Experience

One of the most valuable experiences the student may have from a pedagogical point of view is to be required to perform a complete physical examination on a patient under the eye of a senior instructor.

— Martini's Principles and Practice of Physical Diagnosis*, 1935, Yale Kneeland, Jr and Robert F Loeb, editors*

CME credits available for this article — see page 95.

ORIGINAL RESEARCH & CONTRIBUTIONS

Early Detection of Colon Cancer—The Kaiser Permanente Northwest 30-Year History: How Do We Measure Success? Is It the Test, the Number of Tests, the Stage, or the Percentage of Screen-Detected Patients?

David Moiel, MD
John Thompson, MD

Abstract

Introduction: Colorectal cancer (CRC) is the fourth most common malignancy in the Kaiser Permanente Northwest (KPNW) Region. The goals of CRC screening are early diagnosis of cancer in the preclinical state, down-staging of tumors, and increasing survival. This historical review summarizes the screening strategies since 1980 and their impact on early diagnosis, stage, and survival. During this period, the KPNW Tumor Registry documented the stage and survival, and screen-detection status of patients. We have observed that the percentage of screen-detected case measure has provided critical information that has contributed to the present success. CRC screening efforts by the end of 2010 had provided early diagnosis for one-third of patients.

Methods: KPNW membership has undergone more than 540,000 fecal blood tests, an estimated 130,000 flexible sigmoidoscopies (FS), and more than 100,000 colonoscopies. Since 1980 members older than age 50 years have increased from 48,627 to 137,617. This report represents a review of 5458 patients. Since 1980, 5 distinct periods of CRC screening have been compared. In 1980, the CRC screening practice was primarily office-based fecal occult blood testing (FOBT) and proctosigmoidoscopy. Data from the initial home-based FOBT testing initiative (1985), transitioning to an FS program (1995), adoption of colonoscopy (2005), and subsequent reintroduction of FOBT testing (2006) allows examination of results by period. After ever-increasing promotion of endoscopy, the goal of screening shifted from "screen detection to prevention by polypectomy."

Results: By reexamining the outcomes of the CRC strategies from 1980-2005, the nature of the colonoscopy label of "gold standard" was questioned leading to a return to FOBT testing. Since then, the percentage of screen-detected patients exceeded expectations with a 6-fold increase (5% to 33%) allowing KPNW to reach its highest level of early detection.

Discussion: By examining the KPNW experience, we have come to better understand the significance of effectiveness measures: number of tests, stage of disease, percentage of screen-detected cancers and their relationship to survival. We examined the measures used to assess success and conclude that the current metrics —the number of examinations and disease stage—do not accurately reflect the effectiveness of screening efforts. Early detection of CRC saves lives when a program tests the most at-risk people. Using a good test (FOBT/fecal immunochemical test) that is able to reach more people, rather than the "perfect test" that reaches fewer people, transforms an ineffective program into a successful one. A critical element was the transition of the individual testing to population screening.

Introduction

Screening: The Public Face

In June 1985, President Ronald Reagan was diagnosed with colon cancer.[1] This announcement stimulated public interest in early detection. The National Cancer Institute provided research support for early detection hoping "to reduce CRC deaths by 50% by the year 2000."[2] The Kaiser Permanente (KP) Northwest (KPNW) Center for Health Research,[3] the KP Northern California (KPNC) Division of Research[4] and the Group Health Organization Center for Health Promotion all received grants to examine their colorectal cancer (CRC) activities.

Again, in 1998, national attention refocused on colon cancer screening, when Katie Couric, a national TV commentator, was faced with her husband's illness and death from CRC. Her efforts led to the creation

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of the National Colon Cancer Research Alliance. She was then invited to provide Congressional testimony to the Senate Select Committee on Aging in 2000 about cancer screening.[5] She also provided television coverage of her own colonoscopy, which boosted CRC awareness and galvanized support for colonoscopy as the primary screening tool.

Medicare reimbursement for colonoscopy, national consensus guidelines supporting colonoscopy, and specialty society endorsement of endoscopic screening all accelerated the shift from fecal occult blood testing (FOBT) and flexible sigmoidoscopy (FS) to colonoscopy as a primary tool. Medicare funding for colonoscopy in 2001 was seen as an entitlement, and colonoscopy rapidly became the new "gold standard." *I want my colonoscopy* was heard loud and clear from patients.

Screening: the Clinician's Dilemma Nationally

In 1963, V Gilbertson, MD, at the Minnesota Cancer Detection Center, began reporting a reduction in the overall incidence of rectosigmoid cancers in the 25-year follow-up of 21,150 patients after removal of all polyps during 113,800 proctosigmoidoscopic exams.[6,7] The Minnesota prospective randomized-controlled study of FOBT, from 1975-1978, randomized 46,551 patients into 3 FOBT screening arms: annual, biennial, and routine care. After 13 years, they reported a 33% and 6% (respectively) reduction in CRC deaths between the two screening groups as compared to the unscreened group. Of note, there was no overall difference in the death rate in the 3 groups during the report of the first 13 years of the study.[8]

In 1983, Hardcastle reported a United Kingdom prospective study of FOBT screening of 20,525 patients randomized to screening and control groups.[9] The study findings supported the benefits of FOBT screening with earlier stages of disease at discovery and a presumed survival benefit. In 1996, he reported additional results of 152,000 patients with a survival benefit of 16%.[10] Ongoing trials in Sweden, Denmark, France, and the US during the next 13 years provided more information about FOBT screening.[11,12] The initial optimistic improvements in survival in the Minnesota study were not replicated in subsequent studies. Using statistical simulation programs, the large differences seen in screening benefits in different studies were reassessed, resulting in a reduction of the expected benefits.[13,14]

As complexity, costs, and time limited the possibility of future randomized studies, investigators focused on case-control studies. The series of studies undertaken at that time were designed to rapidly learn which initiatives would meet the National Cancer Institute goal of improving survival by 2000. In 1988, Selby examined the KPNC Multiphasic Evaluation program and the use of proctosigmoidoscopy within the population, demonstrating a reduction in CRC mortality.[4] In the following year, the same group reported favorable results from FOBT testing.[15] Studies continued over the next decade reflecting on the appropriate screening intervals for FS, colonoscopy, and FOBT testing.[16] A Veterans Administration CRC screening project reported the feasibility of screening colonoscopy and their results.[17,18] The National Polyp Study reported data that supported the effectiveness of polypectomy in the prevention of CRC.[19]

In 2009, the US Preventive Services Task Force (USPSTF) reexamined previous recommendations of FOBT screening for all individuals older than age 50 years (2002, 2008), and later limited screening beyond age 76 years.[20,21] In 2009, a large series from the United Kingdom demonstrated the efficacy and benefits of FS screening.[22] In the spring of 2010, the National Institutes of Health State-of-the-Science Conference on Colorectal Screening endorsed FOBT/fecal immunochemical test (FIT) testing as the primary outreach for early detection, noting efficacy for endoscopy modalities.[23]

For over a half-century of research, physicians and researchers had learned that CRC screening is effective in providing an early diagnosis, leading to a more favorable stage at presentation, and reducing CRC mortality. They had tested various population-based strategies that changed to accommodate presumed "best practices." They embraced the belief that removal of all advanced neoplasms was a successful primary prevention strategy. They smeared, scoped, and hoped they were on the right path.

… convinced by medical experts that colonoscopy was the "gold standard" and confused by conflicting guidelines … redirection to FOBT/FIT testing was a profound dilemma for the clinician.

Kaiser Permanente Northwest Program: 1980-2010

From 1980 to early 1985, preventive care services were primarily delivered through the KPNW Health Appraisal Program, an Allied Health Practitioner-based clinic for routine physical examination. CRC screening was done using Hemoccult II kits (Beckman-Coulter; Brea, CA) with a 3-day dietary restriction. Though there were variations with instructions for diet, indications, collection, and laboratory processing, the most significant reason for the limited effectiveness was that most positive-FOBT patients did not receive a radiographic or endoscopic clearance of the colon. The lack of a standardized workup was reflected in the 1980 screen-detection rate of 5%.

By 1983, it was clear the CRC screening was ineffective, so a new

comprehensive plan was proposed (David Clarke, MD; personal communication; 1984 Nov 7)[a].[24] The support of CRC testing required a standardized set of processes, an algorithm for the workup of a positive FOBT test, a Tumor Registry-based computerized tracking system, a 60-cm FS program, and outcome monitoring.

On May 15, 1985, the redesign was launched, followed a few weeks later by the announcement of President Reagan's diagnosis. After the launch, all positive-FOBT patients were evaluated by a protocol with a clinical resolution in almost all cases. As Tumor Registry staff had been trained to monitor cancer care, it was natural to monitor the workup of the positive-FOBT patients to ensure quality. To date, KPNW has tracked 13,631 patients with a positive FOBT, derived from 541,522 patient tests. Since 2009, the FIT test has been replacing the FOBT test and has >5% positivity rate. The FOBT-positive workup algorithm initially recommended clearing the colon by FS and barium enema, and was later modified in 2005 to employ colonoscopy.

From 1985 to 1995, there was skepticism about the efficacy of FOBT screening.[25] The KPNW guideline changed to FS screening in 1995, with an active de-emphasis of FOBT testing. In 2001 (Craig Fleming, MD; personal communication; 2001)[b], the FS strategy was re-reviewed concluding FS as the best overall option,[26] even though there was clear evidence that FOBT was effective.[27] Using simulation modeling, it was predicted that the cost savings from FS screening would accrue after 35 years, only after the program was in place for 30 years.[28]

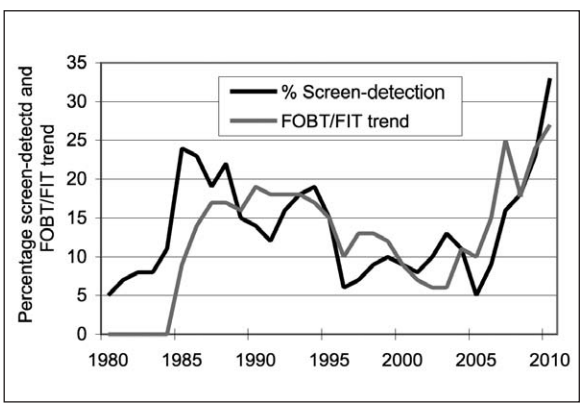


Figure 1. Percentage of screen detection relative to FOBT/FIT trend, 1980 to 2010.

FIT = fecal immunochemical test; FOBT = fecal occult blood testing

Until 2005, colonoscopy was primarily reserved for symptomatic patients, though afterwards there was pressure to expand its screening indications. Colonoscopy screening was heavily promoted by the national media, specialty groups, and reimbursed by Medicare. The results of colonoscopy trials broadened the colonoscopy discussion by including secondary "prevention by polypectomy" with the removal of all polyps.[29] Cost-effectiveness of this strategy was questioned at this time.[30] The KPNW Region and the nation were unprepared for the rapid increase in demand for colonoscopy. Since 2005, even with extraordinary efforts to provide timely screening services, KPNW has been unable to meet the demand. Recommending any other screening strategy was felt to be a failure of current best practices, but we noted screen-detection performance was deteriorating.

KPNW leaders took the opportunity during the fall immunization campaign in 2006 to restart the FOBT testing program. The decade-long success of FOBT testing (1985-1995) produced an 18% (12-24%) screen-detection rate, compared with the FS period (1996-2005) at 9% (5-13%). By 2005, the screen-detection rate declined to 5%, which led to readoption of FOBT testing. On the basis of the flu campaign and internal performance data, FOBT testing was the primary screening recommendation in 2007. Subsequently, FIT replaced FOBT in 2009.[31] The overall results of screen-detection are reflected in Figure 1.

Patients and clinicians were slow to change to a new strategy, convinced by medical experts that colonoscopy was the "gold standard" and confused by conflicting guidelines. This redirection to FOBT/FIT testing was a profound dilemma for the clinician. One physician's description, overheard in the lunchroom, was, "It felt like downshifting to reverse." They needed to trust the redirection, but were faced with the problem of explaining an old strategy that was so actively discouraged just a few years earlier.

Key Elements of Kaiser Permanente Northwest Screening Approach

"The greatest risk factor for a condition that has an effective screening test is the failure to be screened" (Tom Vogt, MD; personal communication; 1991).[c]

Following publication of large prospective-randomized studies, Northwest Permanente physicians increased cancer screening in their routine patient health appraisal during their office visits. Although well intentioned, much of the overall population at risk for CRC were never screened employing this strategy.

Over the years, there have been four key elements that have affected KPNW's present success:

1. Measuring the success of the screening efforts by the percentage of population reached, and the number of screen-detected cases found.

   Since 1990, research has focused on the accuracy of the "best test," rather than patient acceptance, resource availability, cost, and outcomes.
2. Shifting from episodic office-based screening to a population-based strategy.

Historically, prevention was linked to an episodic office-based testing model. In the search for quality and value in health care delivery, purchasers, insurers, policy makers, patients, and quality organizations have included cancer screening as a key indicator. In 2003, Healthcare Effectiveness Data and Information Set (HEDIS) adopted the percentage of the eligible population screened for CRC as a core quality measure.

3. The development and availability of innovative systems to reduce barriers, enhance tracking and follow-up, and measure outcomes.

   These included the FOBT registry (1985) and disease management and follow-up systems using the computerized Tumor Registry databases.

4. Use of the Panel Support Tool (2006) to provide a platform for staff to eliminate care gaps in cancer screening.

   KPNW inreach (office contacts) and outreach (non-office) efforts have contributed to continued improvement in CRC HEDIS measures during the last 6 years. KPNW is approaching HEDIS targets of >72% for commercial members, and >80% for Medicare members being screened by either laboratory or endoscopy testing.

KPNW has supported successive strategic improvements in early detection of CRC over time (Table 1).

Table 1. Testing and screening strategies

Years	Testing strategy
1980-1984	Routine office-based care
1985-1995	FOBT testing
1996-2005	FS testing
2005-2008	Colonoscopy testing
Years	**Population-screening strategy**
2006-2010	Panel Support Tool inreach
2006-2010	CRC outreach with phone and mail
2006-2010	FOBT/FIT inreach and outreach

CRC = colorectal cancer; FIT = fecal immunochemical test; FOBT = fecal occult blood testing; FS = Flexible sigmoidoscopy

Since 1980, CRC screening goals have remained focused on early detection and prevention. As information from each time period was reviewed, shifts to the strategy noted above evolved. For example, in 2005, when the percentage of screen-detected cases fell to a 5% level again, a figure identical to the rate in 1980, the process was reexamined. Even after introducing more effective inreach and outreach patient contacts, increasing the number of endoscopies, and noting early stage shift, KPNW failed to find more screen-detected patients. The program realized that employing the most accurate screening method did not make a difference in screen-detection rate overall, if the availability of endoscopic resources and patient unwillingness to comply with the strategy did not support the program. Additionally, removal of adenomatous polyps as a method to prevent CRC could not demonstrate a beneficial effect on the entire population unless a much higher percentage of the membership could be reached by this strategy. Thus in 2006, a pivotal year, the CRC screening guideline was changed back to FOBT testing. An aggressive outreach campaign commenced, first with FOBT (2006) and subsequently with FIT (2009), by introducing interactive voice recognition phone outreach (2008), CRC mailings, birthday letters, and annual FIT testing reminders. Also beginning in 2006, the electronic medical record—HealthConnect—began providing clinicians with a gap analysis for each patient at every clinical contact using the Panel Support Tool. Enhancing the prevention mission with this combination of inreach and outreach activities increased the number of FOBT and FIT tests submitted.

Methods

The KPNW Region provides health and medical care to almost 500,000 members from SW Washington, the Portland metropolitan area and Salem, OR. Since 1980, members older than age 50 years have increased from 48,627 to 137,617. Unique characteristics made outcome assessments possible: a membership that is a valid statistical sample of the larger Pacific Northwest, an accredited Tumor Registry, a unique individual health record number for hospital and outpatient care, a unified electronic medical record, and supporting electronic databases.

Since 1960, the Tumor Registry has collected and tracked data on all new cancers originating in the KPNW membership. In 1976, the Tumor Registry began performing computerized tracking of abnormal test results that might represent malignancy. This system expanded in 1985 to include the positive-FOBT patients. From 1980 to 2010, 5999 patients were accessioned into the Tumor Registry database. This report represents a review of 5458 patients, including synchronous tumor (coded to the highest stage), and excluding all patients with metachronous tumors, unknown stage, and unknown screen-detection status. During this study period, there has been no organized outreach for the high-risk

populations: patients with a history of polyps or intestinal cancer.

The Tumor Registry abstracts the age, sex, site, stage (See Sidebar: Surveillance and Epidemiology End Results [SEER]),[32] treatment, recurrence, clinical status, survival, cause of death, and screen-detection status. The Tumor Registry has maintained a follow-up rate of over 95%.

In 1988, the Center for Health Research, Portland, OR, was awarded a National Cancer Institute grant to study CRC cases from 1980 to 1988, examining the reliability of intermediate variables as surrogate measures for survival.[4] For this study, screen-detected CRC was defined as the diagnosis of an In-Situ or invasive cancer of the colon and rectum (excluding: anal, squamous cell, cloacogenic, carcinoid, lymphoma, melanoma, or appendiceal cancers) with no symptoms of bleeding, anemia (hemogram parameters were corrected for age and sex), new constipation or diarrhea, abdominal pain, abdominal mass, perforation, or significant nonintentional weight loss. All other patients were considered symptomatic or non-screen-detected. This definition of screen detection has remained unchanged for the duration of the review. The intestinal sites were defined as right colon (cecum to splenic flexure), left colon (descending, and sigmoid), and rectal (rectosigmoid and rectum). This site distribution permitted reliable assessments of the impact of flexible sigmoidoscopy on the early detection efforts. Since 1984, the CRC outcomes have been reviewed annually.

In 1989, a Tumor Registry data field of screen-detection was added to the abstraction process to facilitate the review of program performance. Whether a cancer patient diagnosis was made by screen detection, or by symptom, a searchable data field was created, updated, and crosschecked by the Tumor Registry staff. When paper charts were replaced in 1994 with HealthConnect, the review of laboratory tests, pathology, imaging reports, and operation and procedure notes became easier for all reviewers.

To further understand the characteristics of the screen-detected population, a companion database was created so that additional information about screening tests (laboratory, imaging, or endoscopy), personal characteristics (history of polyps or colon cancer, family history), nonscreened symptoms (anemia, bleeding, obstruction, perforation, mass, unexplained weight loss), and delays in care, would supplement the data from the Tumor Registry.

Surveillance and Epidemiology End Results (SEER) staging classification

- **In Situ (IS):** cancer limited to epithelium
- **Localized (LOC):** cancer invading lamina propria
- **Regional Direct (REGD):** cancer extending into peritoneum and adjacent tissue (ie, mesentery, adjacent organs)
- **Regional Lymph Node and Both (REGLB):** cancer involving regional nodes, or regional nodes and adjacent tissue (ie, mesentery, adjacent organs)
- **Distant (DIST):** cancer to distant nodes and organs.

Table 2. Screen-detection percentages by period

Year	Screening strategy	Percentage
1980	Office-based care	5
1985	FOBT testing	24
1990	FOBT testing	14
1995	FS testing	15
2000	FS testing	9
2005	FS testing	5
2010	FOBT/FIT program	33

FIT = fecal immunochemical test; FOBT = fecal occult blood testing; FS = flexible sigmoidoscopy

Results

This study sought to determine the best measure of success in detecting CRC.

Screening periods

From 1980–2010, 5458 colorectal cancer patients represented KPNW members who may have been screened by 1 of 4 strategies: office-FOBT, home-FOBT/FIT, FS, or colonoscopy. It was not until 2006, that CRC screening transitioned from office-based testing to the present population-based focus, with active inreach and outreach strategies. Table 2 shows the initiatives that reflected best practice for the normal-risk population during 5-year intervals, with the percentage of screen-detected cases.

Screening tests

Variations in the percentage of cancers that were screen-detected are related to the frequency of FOBT/FIT testing. Screening peaks in 1985-1986 at 24% and 2009-2010 at 28% coincided with the increases in FOBT/FIT testing. The lowest screen-detection percentage periods were in 1980 and 2005 at 5%. The 1980 period represented office-based ambulatory care, whereas 2005 was a transitional period from FS to colonoscopy screening. When the nadir of screening reached 5% in 2005, the test that was predominately leading the screening effort was FS, even though more than 7000 colonoscopies were done that year.

In 2006, active outreach was introduced contributing to the remarkable increase, almost tripling the volume of FOBT/FIT tests from 13,362 (2005) to 37,916 (2010). Colonoscopies increased from 7123 (2005) to 18,255 (2010), predominately accommodating the colonoscopy workup of positive-fecal testing, rather than screening.

Risk

Average-risk patients, who have no history of colonic polyps, cancer, or high-risk family history, represent the majority of the study patients. There were 531 average-risk screen-detected patients: 436 by FOBT/FIT, 68 by FS, and 29 by colonoscopy. Figure 2 demonstrates the influence of each test on screen detection in the average-risk population.

From 1995 to 2005, the impact of FS examinations identifying screen-detected cancers was small, finding only 68 average-risk patients. Similarly, from 1995 to 2010, the colonoscopy screening only marginally influenced the overall screen-detection percentages with only 29 average-risk patients diagnosed out of almost 100,000 colonoscopies. Most colonoscopy testing is done for positive-FOBT/FIT tests and high-risk patients (history of polyps, CRC, and positive family history of CRC). As the number of referrals for colonoscopy screening increased, there were difficulties in providing screening access for average-risk patients.

Stage

From 1980 to 2010, the screening-success calculation was converted to improved stage of disease based on the effectiveness of the screening percentage as noted in Figure 3. The main improvements in In-Situ and Localized staging are at the expense of the Regional-Direct stage. There is minimal change in the Regional-Nodal and Distant (DIST) disease categories. By comparing the stages between the least effective (5%), present state (33%), and best outcome (100%) scenarios, increasing the percentage of screen-detection provides the best survival. This provides a more realistic picture of the differences found between routine care, and an aggressive screening program. Table 3 illustrates 5-year survival rates for these stages in the KPNW population.

Table 3. Five-year survival rates for disease stages in the Kaiser Permanente Northwest population

Disease stage	Rate (%)
In Situ	98
Localized	93
Regional direct	84
Regional nodal	71
Distant	7

Variations in 5-year survival are based on age, location, and screen-detection status. The difference in survival between the screen-detected and symptomatic Regional Lymph Node and Both (REGLB) patient is 79% and 63% respectively (Figure 4). We note that even if all patients are screen-detected, some will die of disease. It is estimated that the silent phase for most CRC ranges up to 10 years. We have a 6- to 24-month lead time in patients who refuse an initial workup and subsequently become symptomatic.

Distribution

We have examined the percentage of screen detection during two time frames: 1980 to 1984 and 2007 to 2010, to see if there are significant differences when considering the location of the cancer in the colon. There has been an improvement in the stage of cancers when considering the location of cancer from the right and left colon, and the rectum. The impact of screening technique may influence the distribution of cancers as FS and colonoscopy have different ranges, though the influence of colonoscopy has been smaller than we may have expected.

We note that there is some shift to lower stages for right and left colon, and rectal tumors, but have

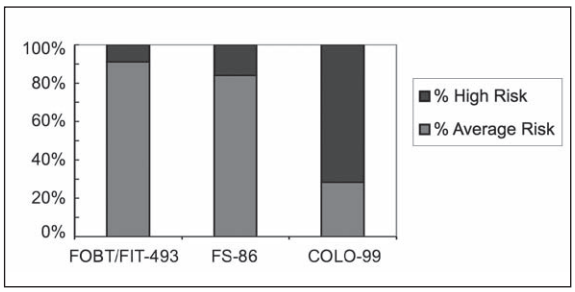


Figure 2. Screen-detected colorectal cancer and risk status.

COLO = colonoscopy; FIT = fecal immunochemical test; FOBT = fecal occult blood test; FS = flexible sigmoidoscopy

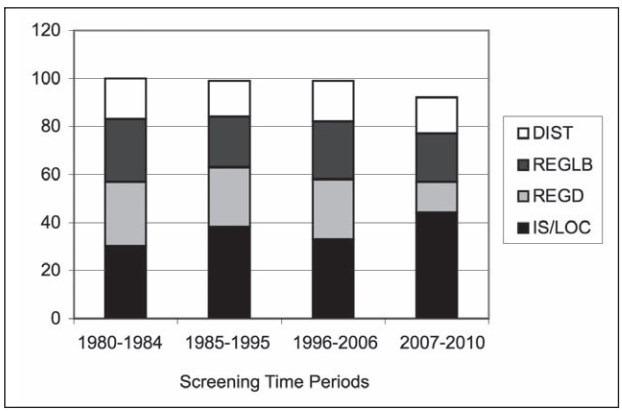


Figure 3. Colorectal cancer SEER stage trends, 1980 to 2010.

DIST = Distant; IS = In Situ; LOC = Localized; REGD = Regional Direct; REGLB = Regional Lymph Node and Both; SEER = Surveillance and Epidemiology End Results

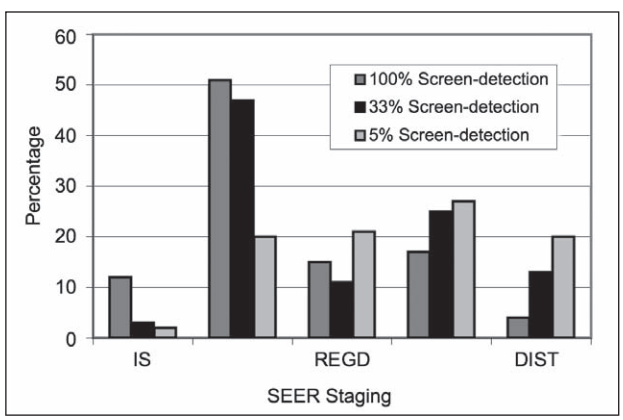


Figure 4. Relationship of colorectal cancer stage distribution and screen-detection effectiveness.

DIST = Distant; IS = In Situ; REGD = Regional Direct; SEER = Surveillance and Epidemiology End Results

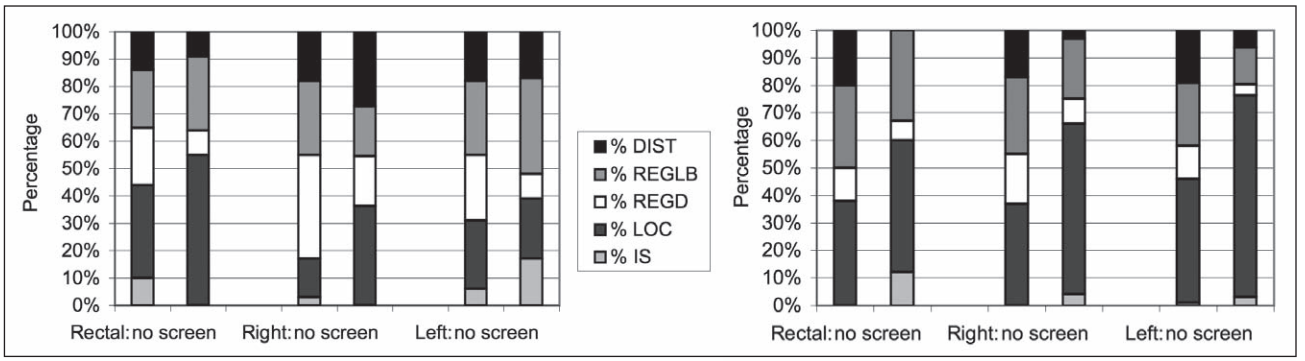


Figure 5a (left). Relationship of colorectal cancer screen-detection status, 1980 to 1984 (5% to 13%), to site and stage.
Figure 5b (right). Relationship of colorectal cancer screen-detection status, 2007-2010 (16% to 33%), to site and stage.

DIST = Distant; IS = In Situ; LOC = Localized; REGD = Regional Direct; REGLB = Regional Lymph Node and Both

to acknowledge the percentage of REGLB and DIST totals are about the same in Figure 5a. It should be kept in mind that the percentage of early detection is low, 5% to 13%. When the percentage of screen detection increased to 16% to 33% in Figure 5b, we have noted a more dramatic stage shift in almost all categories in all 3 locations, though there is minimal change in the percentage of REGLB. It is unclear what other influences are affecting stage distribution in the non-screened patients between the 2 time periods, because of their similarity.

Survival

Screening success from 1980 to 2010 has been linked to stage of disease. Early stage disease (In Situ, and Localized) is trended over time with improvements coming from the reduction of the Regional stage. There is negligible change in the percentage of cases with a DIST stage over the study period. However, the recent changes noted in Figure 4 suggest that increasing the number of screenings may generate a beneficial change in DIST stages as well.

Changes in early stage disease (In Situ and Localized) appear to mirror the percentage of screen-detection activities. The increasing slope of early stage disease from 1994 to 2005 is not consistent with the reduction of screen-detection percentage as noted as a gradual decline from 1994 to 2005. Table 4 presents the distribution of stage and screening status, comparing outcomes of most- and least-effective screening prospects.

Table 4. Distribution for Screening at 5% and 100% Levels

Percentage	In Situ	Localized	Regional Direct	Regional Nodal	Distant
Screening at 100%	12	51	15	17	4
Screening at 5%	2	20	21	27	20

Table 5. Survival at 5-Years of 100 Patients by Stage and Screening Levels

Percentage	In Situ	Localized	Regional Direct	Regional Nodal	Distant	5-year alive
Screening at 100%	12	48	13	13	0	86
Screening at 5%	2	18	17	7	1	55

The KPNW five-year survival outcomes were derived directly from our population. Table 5 demonstrates the survival differences of an effective screening program compared with an unsuccessful testing program.

Incidence

The national SEER database has demonstrated a reduction in the incidence of CRC, but the KPNW incidence of colon and rectal cancer has not changed since 1991 for either men or women. The prospect that approximately 250,000 endoscopies (FS and colonoscopies) since 1991 have not influenced the incidence is disappointing. On further examination, there is a reduction in CRC in the left colon with a shift of lesions to the right colon.[33] If this could be attributed to a polypectomy effect, then we would expect to see a reduction in cancers in the rectum, which did not occur.

Screen detection and stage as metrics

The goal of early detection is to discover the cancer in its earliest stage. It is common practice to assess the success of early detection activities by identifying the percentage of

early stage disease: In Situ and Localized. The relationship between the percentage of screen-detected CRC and early stage disease is demonstrated by the gradual increase in In-Situ and Localized stage from 1995 to 2005, when the screen-detection was gradually declining to 5% (Figure 6).

Discussion

We have reviewed the last 30 years of KPNW experience in CRC screening, examining the present success by considering the key elements of the program. We have reviewed the influence of tests, population-based screening, systems of care, and inreach and outreach elements in the KPNW program. Achieving the best screening results in the last 2 years was a culmination of organizational initiatives.

When the KPNW Colon Cancer Task Force in 1984 proposed an improvement process for FOBT testing, we did not expect to continue to readjust the CRC strategy. We performed careful reviews of effectiveness over the years, and changed the strategies on the basis of presumed best practices. The early successes of FOBT testing from 1985 to 1995 were lost for over a decade, as the guidelines shifted to the "best test" and "prevention by polypectomy." As we noted, a continuous decline in screening performance, the outcome data was contributory to a fortunate dramatic reversal of strategy.

In reviewing the overall effects of screening, we have attempted to examine the effective opportunities and benefits by comparing the lowest and highest periods of screening. If KPNW expects any greater benefits from future screening, we need to redouble efforts to the patients not tested, focusing on the demographics of the patients with advanced stages. This may not be as easy as increasing the number of tests performed. Additionally, we have evidence that screening also improves survival because of within-stage shifting.[3,4]

In summary, early detection of colon cancer saves lives when a program tests the most at-risk people. Using a good test (FOBT/FIT) that is able to reach more people, rather than the "perfect test" that reaches fewer people, transforms an ineffective program into a successful one when the strategy moves from individual testing to population-based screening. Rather than simply measure the number of tests, we identified the rate of screen-detected cases over time. Without high numbers of screening in the at-risk population, the stage shift from DIST and Regional Nodal disease will not occur and will prevent the best population outcomes from occurring. The organizational commitment to move from a testing strategy to a screening program was a key decision in its success. By organizing a screening program to test the largest number of average-risk individuals with an acceptable and deliverable test, the screening program has saved lives. We started a journey to change the care for patients with CRC in 1985, tried multiple strategies, and have managed to use our experience to establish a successful program. ❖

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Disclosure statement

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

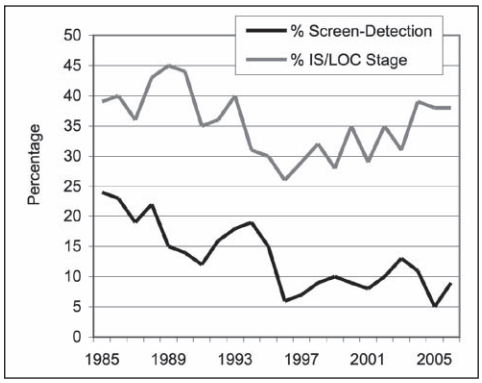


Figure 6. Relationship percentage of screen-detection and percentage of In-Situ and Localized stage.
IS = In Situ; LOC = Localized

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References

1. Brown ML, Potosky AL. The presidential effect: the public health response to media coverage about Ronald Reagan's colon cancer episode. Public Opin Q 1990 Fall;54(3):317-29.
2. Greenwald P, Sondik EJ. Cancer control objectives for the nation, 1985-2000. Bethesda, MD: National Cancer Institute; 1986. DHHS publication no. 86-2880, National Cancer Institute Monograph No. 2.
3. Mullooly J. Evaluation of a colorectal cancer screening program in an HMO. Presentation at the 1990 Annual Meeting of the American Public Health Association; 1990 Oct 4; New York.
4. Selby JV, Friedman GD, Quesenberry CP Jr, Weiss NS. A case-control study of screening sigmoidoscopy and mortality from colorectal cancer. N Engl J Med 1992 Mar 5;325(10):653-7.
5. Sizing M. Katie Couric: a personal tragedy sparks a public campaign to prevent colon cancer. LE Magazine [serial on the Internet] 2005 Mar [cited 2011 Nov 28];[about 3 p]. Available from: www.lef.org/magazine/mag2005/mar2005_cover_couric_01.htm?source=search&key=Colon%20Cancer.

The early successes of FOBT testing from 1985 to 1995 were lost for over a decade, as the guidelines shifted to the "best test" and "prevention by polypectomy."

6. Gilbertsen VA. Proctosigmoidoscopy and polypectomy in reducing the incidence of rectal cancer. Cancer 1974 Sep;34(3):suppl:936-9.
7. Gilbertsen VA, McHugh R, Schuman L, Williams SE. The earlier detection of colorectal cancer: a preliminary report of the results of the Occult Blood Study. Cancer 1980 Jun 1;45(11):2899-901.
8. Mandel JS, Bond JH, Church TR, et al. Reducing mortality from colorectal cancer by screening for fecal occult blood. Minnesota Colon Cancer Control Study. N Engl J Med 1993 May 13;328(19):1365-71. Erratum in: N Engl J Med 1993 Aug 26;329(9):672.
9. Hardcastle JD, Farrands PA, Balfour TW, Chamerlain J, Amar SS, Sheldon MG. Controlled trial of faecal occult blood testing in the detection of colorectal cancer. Lancet 1983 Jul 2;2(8340):1-4.
10. Kronborg O, Fenger C, Olsen J, Jørgensen OD, Søndergaard O. Randomised study of screening for colorectal cancer with faecal-occult-blood test. Lancet 1996 Nov 30;348(9040):1467-71.
11. Kewenter J, Brevinge H, Engaråas B, Haglind E, Ahrén C. Results of screening, rescreening, and follow-up in a prospective randomized study for detection of colorectal cancer by fecal occult blood testing. Results for 68,308 subjects. Scand J Gastroenterol 1994 May;29(5):468-73.
12. Kronborg O, Fenger C, Olsen, J Bech K, Søndergaard O. Repeated screening for colorectal cancer fecal occult blood test. A prospective randomized study at Funen, Denmark. Scand J Gastroenterol 1989 Jun;24(5):599-606.
13. Towler B, Irwig L, Glasziou P, Kewenter J, Weller D, Silagy C. A systematic review of the effects of screening for colorectal cancer using the faecal occult blood test, hemoccult. BMJ 1998 Aug 29;317(7158):559-65.
14. Lannsdorf-Vogelaar I, Wilschut J, van Ballegooijen M. Stage-specific survival of screen-detected versus clinically diagnosed colorectal cancer—evidence from the FOBT screening trials. Presentation at the Methods and Applications for Population-Based Survival; 2010 Sep 20;Frascati, Italy. Powerpoint presentation available from: www.irpps.cnr.it/it/system/files/S_Lansdorp.pdf.
15. Selby JV, Friedman GD, Quesenberry CP Jr, Weiss NS. Effect of fecal blood testing on mortality from colorectal cancer. A case-controlled study. Ann Intern Med 1993 Jan 1;118(1):1-6.
16. Winawer SJ, Fletcher RH, Miller L, et al. Colorectal cancer screening: clinical guidelines and rationale. Gastroenterology 1997 Feb;112(2):594-642. Erratum in: Gastroenterology 1997 Mar;112(3):1060; Gastroenterology 1998 Mar;114(3):625.
17. Lieberman DA, Smith FW. Screening for colon malignancy with colonoscopy. Am J Gastroenterol 1991;86(8):946-51.
18. Lieberman DA, Weiss DG, Bond JH, Ahnen DJ, Garewal H, Chejfec G. Use of colonoscopy to screen asymptomatic adults for colorectal cancer. Veterans Affairs Cooperative Study Group 380. N Engl J Med 2000;343(3):162-8. Erratum in: N Engl J Med 2000 Oct 19;343(16):1204.
19. Winawer SJ, Zauber AG, Ho MN, et al. Prevention of colorectal cancer by colonoscopic polypectomy. The National Polyp Study Workgroup. N Engl J Med 1993 Dec 30;329(27):1977-81.
20. Zauber AG, Lansdorp-Vogelaar I, Knudsen AB, Wilschut J, van Ballegooijen M, Kuntz KM. Evaluating test strategies for colorectal cancer screening: a decision analysis for the US Preventive Services Task Force. Ann Intern Med 2008 Nov 4;149(9):659-69.
21. US Preventive Services Task Force. Screening for colorectal cancer: recommendations and rationale. Ann Intern Med 2002 Jul 16;137(2):129-31.
22. Atkin WS, Edwards R, Kralj-Hans I, et al; UK Flexible Sigmoidoscopy Trial Investigators. Once-only flexible sigmoidoscopy screening in prevention of colorectal cancer: a multicentre randomized controlled trial. Lancet 2010 May;375(9726):1624-33.
23. NIH State-of-the-Science Conference Statement on enhancing use and quality of colorectal cancer screening. Bethesda, MD: National Institutes of Health 2010 Feb 2-4;27(1).
24. Winchester DA, Shull JH, Scanlon EF. A mass screening program for colorectal cancer using chemical testing for occult blood in the stool. Cancer 1980 Jun 15;45(12):2955-8.
25. Bandeau ML, Eddy DM. The workup of the asymptomatic patient with a positive fecal occult blood test. Med Decis Making 1987 Jan-Mar;7(1):32-46.
26. Frazier AL, Colditz GA, Fuchs CS, Kuntz KM. Cost-effectiveness of screening for colorectal cancer in the general population. JAMA 2000 Oct 18;284(15):1954-61.
27. Mandel JS, Church TR, Bond JH, et al. The effect of fecal occult-blood screening on the incidence of colorectal cancer. N Engl J Med 2000 Nov 30;343(22):1603-7.
28. Loeve F, Brown ML, Voer R, van Ballegooijen M, van Oortmarssen GJ, Habbema JD. Endoscopic colorectal cancer screening: a cost-saving analysis. J Natl Cancer Inst 2000 Apr 5;92(7):557-63.
29. Sonnenbreg A, Delcò F, Inadomi JM. Cost-effectiveness of colonoscopy in screening for colorectal cancer. Ann Intern Med 2000 Oct 17;133(8):573-84.
30. Ladabaum U, Song K. Projected national impact of colorectal cancer screening on clinical and economic outcomes and health services demand. Gastoenterology 2005 Oct;129(4):1151-62.
31. Allison JE, Sakoda LC, Levin TR, et al. Screening for Colorectal Neoplasms with new Fecal Occult Blood Tests: Update on Performance Characteristics. J Natl Cancer Inst 2007 Oct 3;99(19):1462-70.
32. Young JL, Roffers SD, Ries LAG, Fritz AG, Hurlbut AA (eds). SEER summary staging manual—2000: codes and coding instructions. Bethesda, MD: National Cancer Institute NIH Pub No. 01-4969; 2001. p 86-96.
33. Gupta AK, Melton LJ 3rd, Peterson GM, et al. Changing trends in the incidence, stage, survival, and screen-detection of colorectal cancer: a population-based study. Clin Gastroenterol Hepatol 2005 Feb;3(2):150-8.
34. Kafadar K, Prorok PC. Effect of length biased sampling of unobserved sojourn times on the survival distribution when disease is screen detected. Stat Med 2009 Jul 20;28(16):2116-46.



"Angles and Edges"
photograph

J Richard Gaskill, MD

"This is a high-angle view of the southwest corner of the East Building, National Gallery of Art, Washington, DC. I liked the elegant simplicity of the image created by sunlight, shadow, and sky."

Dr Gaskill is a retired otolaryngologist from the Kaiser Permanente Santa Clara Medical Center.

Centering Parenting: Pilot Implementation of a Group Model for Teaching Family Medicine Residents Well-Child Care

Pooja Mittal, DO

Introduction

Well-child care is a core service of primary care with the overall goal of promoting the physical health, cognitive growth, and emotional well-being of children. Leaders in child health care recommend that to achieve this goal, primary care physicians use a parent-centered approach, with a focus on the parent–child relationship in the context of family, culture, and community.[1] To meet this goal in the family medicine residency program at the University of California, San Francisco Department of Family and Community Medicine, we are testing the use of Centering Parenting,[2] a parent-centered group-care model for providing well-child care to address the needs of our socioeconomically disadvantaged patient population. Here we describe the use of this model and report on its evaluation.

Patients begin their experience in prenatal groups, then transition into parenting groups. This approach emphasizes the parent- and group-centered concepts developed in prenatal groups, specifically the integration of health assessment, education, and support. To integrate these concepts, Centering Parenting focuses on continuing positive support by valuing and building on successes within groups started during pregnancy. Relationships that develop in prenatal groups support peer-to-peer learning and trust, and they transition well into Centering Parenting, where parents continue to build on their collective knowledge about caring for their babies. The groups have an average size of four mother-baby pairs.

Methods

Since the pilot began in 2010, 3 parenting groups have been established, and they meet over the course of a year on an expanded schedule (including visits when members' babies are 2 weeks, 4 weeks, 6 weeks, 8 weeks, 3 months, 4 months, 6 months, 8 months, 10 months, and 12 months old for a total of 10 visits). Each group visit lasts for 2 hours, with an additional 1 hour required for premeeting planning and postmeeting reflection. Three residents in postgraduate year 2 or 3, chosen for specific groups on the basis of language concordance and schedule, are participating in the pilot program, one connected with each group. The residents attend a daylong, on-site training program led by instructors certified in the Centering Parenting model of facilitating group visits. Within our clinical setting, the coordinator is a faculty member trained in the facilitation techniques.

The faculty member and residents meet before the group does and plan the opening, content, and structure of the group. Various openings are used, including games and stress-reduction exercises. The content is based on relevancy to the group at that time. For example, the Edinburgh Postpartum Depression Scale is employed in the early infancy period, especially to discuss stress, support, and self-care for mothers. Early on, infant massage is taught as a means for bonding with and calming babies. As the babies get older, more time is devoted to doing developmental activities. The physicians do all of the examinations and individual portions with patients and assist in mothers' self-measurements (pressure and weight) and obtain measurements of the babies. After a brief check-in, parents pose questions to their group for discussion. All questions that come up in the private physician-parent encounter are discussed by the groups, and parents use their collective insight to educate one another. Any necessary individual care, such as placement of intrauterine devices or vaccination, is done after the groups meet. Also after the groups meet, the residents and faculty members participate in debriefing for self-reflection and continued teaching.

The physicians participating in the groups were surveyed regarding their experience of the program when the groups had completed their ten sessions. The items were presented as dichotomous yes/no choices.

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Results

The results of the physician survey appear in Table 1. The physicians reported significant improvement in most areas of their skills and knowledge. As one of our residents said,

> *It has been one of my favorite experiences of residency. It is such a privilege to get to learn from our patients about the range of normal, and even more exciting, to see how empowered they feel teaching each other. I wish we all had the chance to have this experience as residents, and I really think it is the wave of the future in terms of how to best provide family-centered maternal and child health care in a primary care setting.*

This sentiment was mirrored by the patients' reports of their experiences: In focus-group discussions, they universally said that the biggest group advantage was developing closer relationships with physicians and having the support of their peers. However, physicians' satisfaction levels and their perception of staff satisfaction levels were mixed, suggesting that the change in practice represented by the Centering Parenting program was perceived as challenging for both physicians and staff.

Discussion

In contrast to standard care, the Centering Parenting model allows residents to experience comparative development as well as interactions among a group of parents and children. We believe that the biggest advantage that this group exercise offers residents is the ability to see many babies at the same time longitudinally. They can see development in motion: the one-month-old baby compared with the three-month-old baby in the group; signs that the parents notice to determine readiness for solids; discussions about home safety for a child who has started crawling. These discussions and the availability of all of the babies at the same time, on an ongoing basis, provide education in child development that is clearer and longer-lasting than afforded by traditional well-child care. Also, because most residents do not have their own children, the group setting performs the important function of helping them to learn about child development in a much more organic way than the traditional care setting allows. Additionally, the expanded schedule of the group model allows for more time to learn and discuss development, both with parents and with residents.

… the biggest group advantage was developing closer relationships with physicians …

The extra time with patients provided by the group model forges a stronger bond between physician and parent. Patients are supported in their own context: their peers from the community. Group discussions engage patients, who share their culture and parenting practices with the rest of the group.

We believe that this model of teaching and providing well-child care is effective in promoting the overall health of children and their families. Beyond its early success, integrating this program into our residency program as a whole remains a challenge. We are currently planning the expansion of the pilot program for residents in postgraduate year 2 and 3. ❖

Table 1. Evaluative results of physician surveys

Component assessed	No. of positive responses (%)
Improvement in ability to:	
Provide culturally competent care	4 (80)
Assess development in the first year of life	4 (80)
Provide anticipatory guidance	5 (100)
Address issues with parents that are common in well-child care	4 (80)
Be more efficient	3 (60)
Bond with patients more effectively	4 (80)
Improvement in quality regarding:	
Patient satisfaction	4 (80)
Staff satisfaction	2 (40)
Compliance with guidelines for care	1 (20)
Patient education	4 (80)
Provider satisfaction	2 (40)
No improvement in any area	0 (0)

Disclosure Statement

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

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References

1. Schor EL. Rethinking well-child care. Pediatrics 2004 Jul;114(1):210–6.
2. Centering Healthcare Institute [homepage on the Internet]. Boston, MA: Centering Healthcare Institute, Inc; © 2009–11 [cited 2011 Sep 22]. Available from: www.centeringhealthcare.org.

CME credits available for this article — see page 95.

ORIGINAL RESEARCH & CONTRIBUTIONS

Implementation Study

Regional Expansion of Minimally Invasive Surgery for Hysterectomy: Implementation and Methodology in a Large Multispecialty Group

Esteban Andryjowicz, MD
Teresa Wray, MD

Abstract

Introduction: Approximately 600,000 hysterectomies are performed in the US each year, making hysterectomy the second most common major operation performed in women. Several methods can be used to perform this procedure. In 2009, a Cochrane Review concluded "that vaginal hysterectomy should be performed in preference to abdominal hysterectomy, where possible. Where vaginal hysterectomy is not possible, a laparoscopic approach may avoid the need for an abdominal hysterectomy. Risks and benefits of different approaches may however be influenced by the surgeon's experience. More research is needed, particularly to examine the long-term effects of the different types of surgery."

This article reviews the steps that a large multispecialty group used to teach non-open hysterectomy methods to improve the quality of care for their patients and to decrease the number of inpatient procedures and therefore costs. The percentages of each type of hysterectomy performed yearly between 2005 and 2010 were calculated, as well as the length of stay (LOS) for each method.

Methods: A structured educational intervention with both didactic and hands-on exercises was created and rolled out to 12 medical centers. All patients undergoing hysterectomy for benign conditions through the Southern California Permanente Medical Group (a large multispecialty group that provides medical care to Kaiser Permanente patients in Southern California) between 2005 and 2010 were included. This amounted to 26,055 hysterectomies for benign conditions being performed by more than 350 obstetrician/gynecologists (Ob/Gyns).

Results: More than 300 Ob/Gyns took the course across 12 medical centers. On the basis of hospital discharge data, the total number of hysterectomies, types of hysterectomies, and LOS for each type were identified for each year. Between 2005 and 2010, the rate of non-open hysterectomies has increased 120% (from 38% to 78%) and the average LOS has decreased 31%.

Introduction

Hysterectomy is the second most common surgical procedure undergone by women in the US, with approximately 600,000 hysterectomies being performed each year.[1] The procedure can be an open one, such as total abdominal hysterectomy or subtotal abdominal hysterectomy, which leaves the cervix behind, or a non-open one, such as vaginal hysterectomy (VH), laparoscopic supracervical hysterectomy (LSH), total laparoscopic hysterectomy (TLH), or laparoscopy-assisted vaginal hysterectomy (LAVH). Minilaparotomy hysterectomy has some advantages over open hysterectomy,[2] but although this procedure is done within the Southern California Permanente Medical Group (SCPMG), it could not be identified within our coding system and thus is not further discussed here.

The organization Advancing Minimally Invasive Gynecology Worldwide (AAGL) has recently stated that *"most hysterectomies for benign disease should be performed either vaginally or laparoscopically and that continued efforts should be taken to facilitate these approaches. Surgeons without the requisite training and skills required for the safe performance of VH or LH should enlist the aid of colleagues who do or should refer patients requiring hysterectomy to such individuals for their surgical care."*[3]

SCPMG is a multispecialty medical group with 6000 physicians providing medical care for Kaiser Permanente (KP) patients in Southern California. Between 2005 and 2010, SCPMG physicians performed 26,055 hysterectomies.

The average rate of non-open hysterectomy across the US last noted in 2003, was

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approximately 35%,[1] consistent with SCPMG data, before 2005. More recent national data are not available yet. Some more recent articles show rates between 43.2% to 64.2% (Cedars Sinai Hospital,[4] The Permanente Medical Group in Northern California [Rebecca U Margulies, MD, personal communication, 2011 May],[a] and Brigham and Women's Hospital[5]).

A Cochrane review found:

> *… that vaginal hysterectomy meant quicker return to normal activities, fewer infections and episodes of raised temperature after surgery, and a shorter stay in hospital compared to abdominal hysterectomy.*
>
> *Laparoscopic hysterectomy meant quicker return to normal activities, less blood loss and a smaller drop in blood count, a shorter stay in hospital, and fewer wound infections and episodes of raised temperature after surgery compared to abdominal hysterectomy, but laparoscopic hysterectomies have a greater risk of damaging the bladder or ureter (the tube leading to the bladder from the kidney) and are longer operations.*
>
> *No benefits were found for laparoscopic versus vaginal hysterectomy. Laparoscopic hysterectomies are longer operations associated with a higher rate of substantial bleeding.*[6]

Individual physicians within SCPMG had been performing various types of non-open hysterectomy (including traditionally taught VH) since 1991, but there had not been a concerted effort to train physicians in the entire Region. An effort began in 2005 to increase the proportion of non-open hysterectomies within SCPMG. This article reviews the process involved, the change in non-open hysterectomy rates, changes in the length of stay (LOS), and changes in total costs. Several steps occurred simultaneously to generate interest in this project, including a presentation on the merits of non-open hysterectomy to the Regional Chiefs of Obstetrics/Gynecology (Ob/Gyn), data from a study on LSH conducted at one of the centers,[7] the appointment of a new Regional Chief of Ob/Gyn, and a receptive Regional Medical Director in charge of quality and clinical analysis. This led to the idea that if a training program were created and expert mentorship became available, SCPMG could become a national leader in non-open hysterectomy and thus improve the quality of medical care for their patients.

Table 1. Coding used for data collection for benign hysterectomy, 2005–2010

Closed hysterectomies
Laparoscopic supracervical hysterectomy (68.31)
Laparoscopic total abdominal hysterectomy (68.41)
Laparoscopic-assisted vaginal hysterectomy (68.51)
Other vaginal hysterectomy (68.59)
Open hysterectomies
Total abdominal hysterectomy + other subtotal abdominal hysterectomy (68.39, 68.4, 68.49)
Discharges in which the principal diagnosis was malignant neoplasm (codes 140.xx–208.xx from the *International Classification of Diseases*, 9th Revision) were excluded
Radical hysterectomies (68.61, 68.69, 68.71, 68.79) were excluded
Pelvic exenterations (68.8) were excluded

Methodology

The 12 SCPMG Chiefs of Ob/Gyn wanted to increase the percentage of non-open hysterectomies performed so that SCPMG would eventually be the national leader for the procedure. The Regional Chief of Ob/Gyn was given the mandate to create a teaching program to help reach this goal.

Preparation

Discharge data for benign hysterectomy were used to identify three key components at each medical center: total hysterectomies, type of hysterectomies performed, and LOS for each type of hysterectomy (Table 1). No approval from an institutional review board was indicated, because our study was a retrospective chart review and patients could not be identified, either directly or through identifiers linked to them.

It was believed that the program had to create expertise at each medical center with all types of non-open hysterectomy so that every Ob/Gyn would be able to tailor the type of surgery to the individual patient. The program would also emphasize how to set up an operating room for minimally invasive surgery (MIS); how to function as a team; and how to minimize, recognize, and manage complications. It was believed that there had to be development of intraregional proctoring, with two champions at each medical center. It was hoped that there would be a reduction and standardization of the LOS for non-open hysterectomies at the same time.

Eight "content experts" were selected to create and then implement a regional teaching program. They were known within the Region for their technical expertise, teaching ability, and commitment to excellent patient care and to SCPMG. At the first group meeting, each instructor declared his or her favorite hysterectomy method on the basis of interpretation of the literature and experience. A consensus on preoperative preparation and postoperative care was

reached through four face-to-face meetings. The group could not agree on a "best" method of non-open hysterectomy, so it was decided to teach each of four types during the courses.

Intervention

A content expert presented each major type of non-open hysterectomy, reviewing aspects that the other methods had in common and going into more depth for methodologies that were unique.

The average LOS for non-open hysterectomy decreased to 24 hours (a 34% decrease) …

A basic science lecture on energy sources was included, along with a section on avoiding, identifying, and managing intraoperative complications. The group visited each of the 12 medical centers to encourage optimal local participation. The course was 9 hours long, half of it being didactic, with inclusion of videos, and the other half being hands-on learning and practicing of advanced laparoscopic skills. The videos were created and organized to teach important techniques for each type of non-open hysterectomy. The hands-on session used modified FLS (Fundamentals of Laparoscopic Surgery) Trainer Boxes[8] (Tables A and B; online only[b]). These had been proven to improve laparoscopic skills.[9]

For more options for style of learning, all lectures were posted at KP DocuShare, a Web-based Intranet holding area of information for SCPMG clinicians, and could be reviewed before or after the courses (http://dms.kp.org/docushare/dsweb/View/Collection-209036 [password protected]). A pre-course worksheet and agenda (Tables A and B; online only[b]) was sent to all participants at least one week before the event at each medical center.

All exercise and surgical videos were uploaded to YouTube.com so that individuals could view them before or after the course: www.youtube.com/results?search_query=MISP2009 (Table A; online only[b]).

Evaluation

Regional education staff helped prepare a questionnaire to be filled out by course participants before receiving continuing medical education credit of 8.5 hours.

Table 2. Types of non-open hysterectomy 2008–2009

	2008 (%)	2009 (%)
Laparoscopic supracervical hysterectomy	698 (27)	739 (23)
Total laparoscopic hysterectomy	444 (17)	786 (25)
Laparoscopic-assisted vaginal hysterectomy	641 (25)	780 (25)
Vaginal hysterectomy	806 (31)	877 (28)
Total	2589	3182

Funding

SCPMG provided funding for the FLS Trainer Boxes, portable video monitors, laparoscopic needle-drivers and knot-pushers, and scissors ($100,000 total). One of the authors (EA) modified each of the FLS Trainer Boxes (www.youtube.com/watch?v=YX5bhdOgPqo). The individual medical centers covered instructors' salary during presentations, along with the time and costs of modifying the FLS Trainer Boxes. Individual participants used their education half-days from two consecutive weeks, so that they could maintain patient access. Several companies (with contracts approved by the KP National Product Council) provided some of the equipment for the sessions (Table C; online only[b]). There were no conflicts of interest identified in the provision of supplies by these companies. When the course was completed, 30 FLS Trainer Boxes and equipment were distributed proportionately across the 12 medical centers for continued local learning and practice.

Results

Approximately 300 Ob/Gyns attended the educational intervention (85% of SCPMG's total number of Ob/Gyns).

Hysterectomies Performed

Although the total number of hysterectomies increased in 2008 and 2009, it then decreased to the 2005–2007 level (Figure 1A). The percentage of non-open hysterectomies increased regionally by 120% between 2004 and 2010 (from 38% to 78%; Figure 1B).

The average LOS for non-open hysterectomy decreased to 24 hours (a 34% decrease), whereas the average LOS for open hysterectomy has remained essentially unchanged at 72 hours (Figure 1C).

Interestingly, data for 2008 and 2009 show that the rate for LSH decreased by 4%, the rate for TLH increased by 8%, the rate for LAVH did not change, and the rate for VH decreased by 4% (Table 2).

Cost

The savings realized from this intervention and program are detailed in Table 3 and Table 4. Hospital LOS decreased by 2 days, saving an estimated $5000 per patient (SCPMG budgeting office, personal communication, 2010 Nov). With the doubling of the rate of non-open hysterectomies, the total annual savings is calculated to be $9.3 million.

Discussion

Quality Improvement

The intent to significantly increase the percentage of non-open hysterectomies across the Region has been accomplished. Because the Cochrane Review[6] and AAGL[3] suggest that this is the best method of hysterectomy, this translates to improved care for our patients.

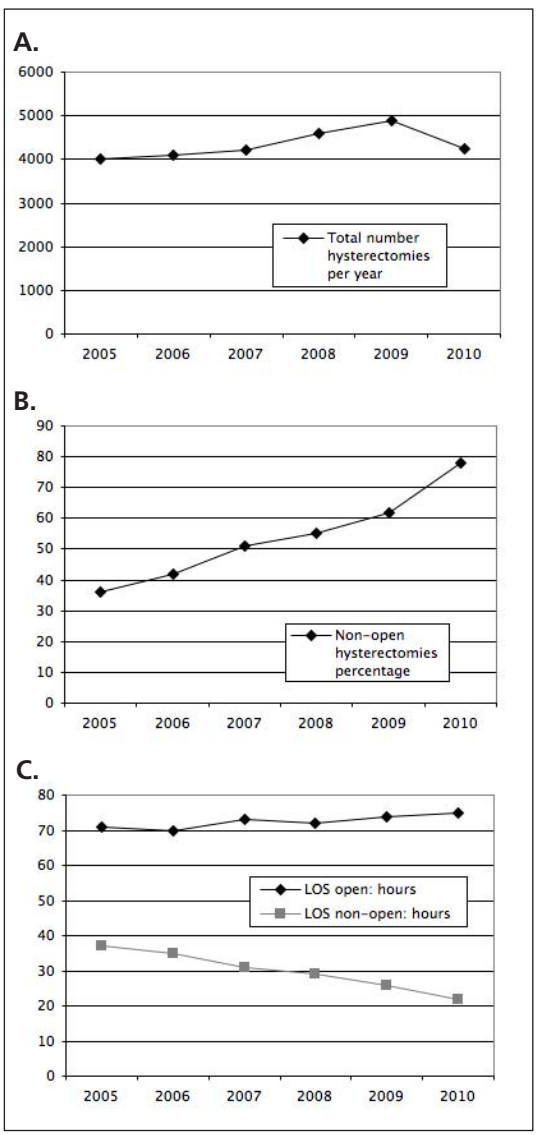


Figure 1. Combined hysterectomy data for SCPMG for 2005 through 2010: A) total number of hysterectomies per year; B) percentage of hysterectomies that were non-open; C) hospital length of stay (LOS) for open versus non-open hysterectomies.

SCPMG = Southern California Permanente Medical Group.

Service

A decrease in variance and total LOS compared with open hysterectomy translates to an annual extra 3732 hospital-bed days available for our patients. There is less chance of postponement of non-open hysterectomy on high-activity days because these are almost always outpatient procedures.

Morale

Morale among staff is not quantifiable. The Regional Chiefs believe, however, that as the MIS program progressed, the communication and camaraderie between medical centers and among the Ob/Gyns improved.

Cost

In light of health care reform legislation, there is increased national interest both in the continuing increases in the cost of health care and in controlling costs while improving quality. The financial impact of the MIS program has been significant, with the average hospital LOS decreasing by 2 days. With more than double the number of non-open hysterectomies performed now compared with before the MIS program, the total yearly savings has reached $9.3 million. It is estimated that for each 1% increase in the rate of non-open hysterectomies, a savings of $215,000 and 89 hospital days can be anticipated.

Limitations

Because our study is a retrospective review of discharge data, it is only as accurate as the discharge coding. A recent study from Northern California KP (Rebecca U Margulies, MD, personal communication, 2011 May),[a] in which for one year, each chart for a patient undergoing benign hysterectomy was reviewed, did not show a significant number of miscoded cases.

During the five-year time period, there would have been other confounding variables that have not been addressed here, including the number of new-hire physicians, number of retiring physicians, impact of other courses attended by the physicians, and changes in patients' requests for type of hysterectomy. These likely would be occurring in other groups across the country, yet similar changes in non-open hysterectomies have not been reported, to our knowledge.

KP is a large multispecialty group with the integration of three components (Medical Groups, hospitals, and insurance), so our program may not be reproducible outside of this type of system.

Table 3. Savings realized non-open vs open hysterectomy per patient from LOS

Parameter	Value
Non-open average LOS	25.6 hours
Open average LOS	72.1 hours
Average difference in LOS	2 days
Average cost per day of hospitalization	$2500+
Total savings realized per patient	$5000

LOS = length of stay.

Table 4. Total SCPMG yearly savings with 78% non-open hysterectomy rate vs national 35% rate

Parameter	Value
US national hysterectomy rate	35% non-open
SCPMG hysterectomy rate (2010)	78% non-open
SCPMG benign hysterectomies performed annually (average)	4340
SCPMG annual additional non-open hysterectomies compared with national average (78%-35%) × 4340	1866
Average hospital days saved per non-open hysterectomy	2 days
Total hospital days saved annually	3732 days
Savings from LOS per each non-open hysterectomy	$5000
Total savings annually	$9.3 million

LOS = length of stay; SCPMG = Southern California Permanente Medical Group.

Next Steps

A study is being set up within SCPMG to determine which types of non-open hysterectomy provide the best outcome for patients at the best value.

Conclusions

A large increase in rate of performance of the optimal type of hysterectomy has been achieved in a large group in a five-year period. The use of a structured course with available expert mentoring was a key component. Appropriate regional and local medical-center support was essential to this success. The same success should be achievable in other motivated groups. ❖

[a] East Bay Urogynecology Division Director; Assistant Chief for GYN Perioperative Services; Chair, Interdisciplinary Practice Committee; Department of Obstetrics & Gynecology, Oakland Medical Center, CA.

[b] Tables available from: www.thepermanentejournal.org/issues/2011/fall/4172-vaginal-hysterectomy.html#tables.

Disclosure Statement

The author(s) are partners in SCPMG with no other conflicts of interest to disclose.

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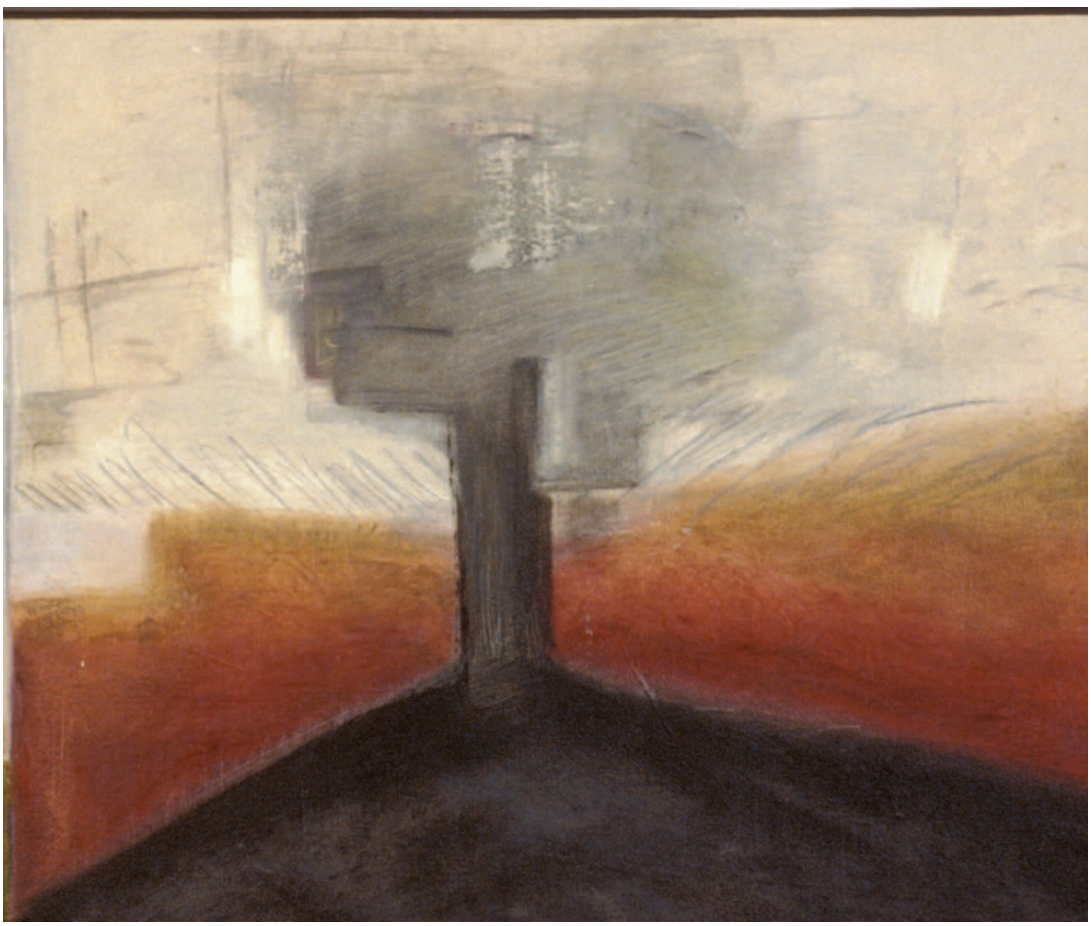
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References

1. Wu JM, Wechter ME, Geller EJ, Nguyen TV, Visco AG. Hysterectomy rates in the United States, 2003. Obstet Gynecol 2007 Nov;110(5):1091–5.
2. Royo P, Alcázar JL, García-Manero M, Olartecoechea B, López-García G. The value of minilaparotomy for total hysterectomy for benign uterine disease: a comparative study with conventional Pfannenstiel and laparoscopic approaches. Int Arch Med 2009 Apr 22;2(1):11.
3. AAGL Advancing Minimally Invasive Gynecology Worldwide. AAGL position statement: route of hysterectomy to treat benign uterine disease. J Minim Invasive Gynecol 2011 Jan–Feb;18(1):1–3.
4. Measuring the quality of care at the Cedars–Sinai Center for Minimally Invasive Gynecologic Surgery [monograph on the Internet]. Los Angeles, CA: Cedars–Sinai Medical Center; © 2011 [cited 2011 Sep 26]. Available from: www.cedars-sinai.edu/Patients/Quality-Measures/Clinical-Areas/Measuring-the-Quality-of-Care-at-the-Cedars-Sinai-Center-for-Minimally-Invasive-Gynecologic-Surgery.aspx.
5. Jonsdottir GM, Jorgensen S, Cohen SL, et al. Increasing minimally invasive hysterectomy: effect on cost and complications. Obstet Gynecol 2011 May;117(5):1142–9.
6. Nieboer TE, Johnson N, Lethaby A, et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev [serial on the Internet] 2009 Jul 8 [cited 2011 Sep 26];(3):CD003677 [about 186 p]. Available from: http://onlinelibrary.wiley.com/o/cochrane/clsysrev/articles/CD003677/frame.html.
7. Hoffman CP, Kennedy J, Borschel L, Burchette R, Kidd A. Laparoscopic hysterectomy: the Kaiser Permanente San Diego experience. J Minim Invasive Gynecol 2005 Jan–Feb;12(1):16–24.
8. Fundamentals of Laparoscopic Surgery [homepage on the Internet]. Los Angeles, CA: Society of American Gastrointestinal and Endoscopic Surgeons; © 2003–2010 [cited 2011 Sep 26]. Available from: www.flsprogram.org.
9. Fundamentals of Laparoscopic Surgery [homepage on the Internet]. Los Angeles, CA: Society of American Gastrointestinal and Endoscopic Surgeons; © 2003–2010 [cited 2011 Sep 26]. FLS supporting literature. Available from: www.flsprogram.org/index/fls-supporting-literature/.



"A Bare Tree in Winter"
Oil on canvas

Mary T Shannon, MSW, MS

"This piece was inspired by a client who wrote about the harsh winters while growing up on a farm in the Midwest. Because I specialize in using art and narrative in my private practice, I am inspired almost daily by the creations of my clients.

"As an artist, author, psychotherapist, and specialist in narrative medicine, I am able to bring all of these elements together to provide patients and clinicians with a unique blendof therapeutic healing."

Visit Ms Shannon's Web site: www.marytshannon.com for more examples of her art, a list of publications, books, writing prompts, and upcoming "Writing for Your Life" groups.

REVIEW ARTICLE

Quality Measurement and Improvement in General Surgery

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Abstract

Increasing emphasis is being placed on health care quality measurement and improvement in the US. Within general surgery, several sophisticated quality-measurement and outcomes systems have been developed. These include the National Surgical Quality Improvement Program, the use of selective referral and centers of excellence, the Surgical Care Improvement Project, and the World Health Organization Surgical Safety Checklist. This article reviews each of these quality-improvement initiatives, highlights their relative contributions, and discusses future directions of quality improvement within general surgery.

Measuring and improving the quality of health care is an increasingly important goal in American medicine. Patients and their families request information on outcomes, payers require health care systems to address variations in quality of care, and credentialing agencies demand evidence that hospitals meet performance standards. Within general surgery, the American Board of Surgery has implemented new standards for maintenance of certification, requiring surgeons to monitor their own performance.[1] The Joint Commission also tracks key indicators of surgical safety and monitors surgeon-specific performance as part of its credentialing process.[2] Payers in both the public and private sectors are rapidly implementing centers of excellence and pay-for-performance programs, further driving the need to systematically track and improve the quality of surgical care.[3]

The importance of measuring and improving surgical quality is well established, but it is unclear how best to accomplish these objectives. Time-consuming review of medical records, the tardiness of retrospective quality measures, and the accuracy and fairness of public report cards are frequently cited shortcomings of current methods.[4] However, surgeons and national surgical organizations, such as the American College of Surgeons (ACS), are developing more precise and timely methods of measuring surgical quality, with the goal of ultimately improving outcomes. This article discusses current initiatives in quality measurement and improvement within general surgery and highlights future directions within the field of surgical outcomes.

The National Surgical Quality Improvement Program

The ACS National Surgical Quality Improvement Program (NSQIP) is the most widely recognized quality-measurement system for noncardiac surgery in the US.[2] It was originally developed in the Department of Veterans Affairs health system in response to a 1986 congressional mandate for the system to compare its risk-adjusted surgical outcomes with those in the private sector.[5] NSQIP's overarching purpose is to improve the quality of surgical care not by identifying bad surgeons but rather by focusing on the processes and structure of care at the levels of surgical subspecialty and surgical service. Outcomes of interest include 30-day postoperative mortality and morbidity, chosen primarily because of their importance and relative ease of data collection. From 1991 through 2001, the Department of Veterans Affairs saw a 27% decline in postoperative mortality and a 45% decrease in postoperative morbidity, along with decreased length of stay and improved patient satisfaction scores.[6]

After validation in three academic medical centers, NSQIP was launched in the private sector in 1999, and in 2004, the system partnered with the ACS with the goal of nationwide involvement. Data abstraction is conducted by trained clinical nurse abstractors according to well-tested procedures and rigorously defined variables. A comprehensive set of clinical and laboratory risk factors are assessed for every patient, and submitted data are externally audited to ensure their completeness and accuracy.[6] Well-validated risk-adjustment models incorporate data from a random mix of procedures.

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Participating hospitals receive robust, risk-adjusted surgical outcomes, expressed relative to other hospitals as "observed to expected" (O/E) ratios. (An O/E ratio <1 indicates that the hospital is performing better than expected, given the comorbidities of its patient population and surgical case complexity; an O/E ratio >1 indicates that the hospital is performing poorer than expected. For example, an O/E mortality ratio <1 means that fewer deaths occurred than anticipated in comparison with peer hospital performance.) These biannual comprehensive reports are blinded, allowing participating centers to compare their risk profiles and outcomes with those of peer medical centers and national averages.[6] Multiple studies have demonstrated that institutions can enhance outcomes by directing performance-improvement initiatives in areas where they seem to be outliers.[7–9]

Currently, more than 300 hospitals participate in the ACS NSQIP, and in 2002, the Institute of Medicine named the NSQIP "the best in the nation" for measuring and reporting surgical quality and outcomes.

To ensure continued success of this program, future efforts include focusing on specific, more complex procedures and limiting the number of clinical data collected, thereby decreasing the data-collection burden without sacrificing the accuracy of the outcomes models.[1] Currently, a large number of variables are required to accurately adjust for differences in risk factors when evaluating outcomes among many procedures. However, as seen in cardiac surgery, using fewer than ten main variables affects risk adjustment when restricting analysis to the single procedure of coronary artery bypass grafting, and initial studies in general surgery confirm that limited models using as few as five variables generate adequate risk adjustment for procedure-specific outcomes.[10] Additional future steps include incorporating information about processes of care, which describe the care that patients actually receive. For example, processes of care related to surgical procedures include appropriate preoperative imaging and the perioperative use of beta-blockers. Process-of-care measures provide member hospitals with more reliable performance measures and more actionable outcomes data.[1]

Selective Referral and Centers of Excellence

Better patient outcomes have been reported when complex surgical procedures are performed at high-volume hospitals and academic medical centers. This phenomenon was first noted in 1979, when Luft et al reported that the mortality rate for certain surgeries was inversely proportional to the number of procedures performed.[11] Since then, numerous studies have continued to describe this relationship, including several reviews suggesting that a large number of deaths may be attributed to elective, high-risk surgery performed in low-volume centers.[12–14]

The strength of this evidence has prompted health care researchers, advocacy groups, and other organizations to call for regionalization, the process of concentrating high-risk procedures at high-volume centers. For instance, the Leapfrog Group for Patient Safety, a national consortium of private and public purchasers of health insurance, has encouraged patients undergoing any one of six surgical procedures (coronary artery bypass grafting, abdominal aortic aneurysm repair, aortic valve replacement, weight-loss surgery, esophagectomy, and pancreatectomy) to choose a hospital "that has a high success rate for [stated procedure] and also has lots of experience with the procedure." Several consumer-oriented Web sites, including one provided by the Leapfrog Group, provide patients with procedure-specific outcomes for local hospitals, listing rates of postoperative complications and compliance with selected perioperative processes of care.[15]

Although it has been more than 30 years since that report by Luft et al, with ample demonstration of the benefit of volume-based referral for complex procedures, referral patterns of patients have not completely evolved. Patients with operable pancreatic cancer are still treated in low-volume centers, with varying results, and a 2002 report of a study investigating mortality after esophagectomy noted a 23% mortality rate at low-volume centers, nearly 3 times as high as that seen in high-volume centers.[12] More recently, another study noted that of the 874 hospitals performing esophagectomies, more than 90% performed fewer than 3 esophagectomies annually.[13] In a final example involving patients undergoing coronary artery bypass grafting, one study showed that more than 300 deaths could be averted in the US annually if the mortality rate at very-low-volume hospitals was equal to that seen in very-high-volume centers.[14]

Improved outcomes are not necessarily limited to having a surgical procedure performed in a high-volume center. Perhaps unsurprisingly, there is also evidence noting that the outcomes of surgical procedures depend on individual surgeon volume. One notable 2003 study concluded that for 8 complex procedures,

… volume of surgery in individual specialties and specific procedures should not be used as a surrogate for quality of care.[17]

patients treated by high-volume surgeons had decreased mortality rates when compared with those undergoing surgery performed by low-volume surgeons. Moreover, the authors noted that individual surgeon volume was responsible for a large proportion of the effect of being treated in a high-volume hospital.[16] "Practice" does confer better outcomes.

Despite these important findings, volume alone is not a guarantee of quality. In reflecting on 15 years of surgical outcomes as studied through the NSQIP, Itani concluded that volume of surgery in individual specialties and specific procedures should not be used as a surrogate for quality of care.[17] The findings of earlier studies support this, cautioning that high-volume hospitals could still deliver poor care if the quality of systems are inadequate.[18] More investigation is needed into this controversial topic.[17]

The Surgical Care Improvement Project

The Surgical Care Improvement Project (SCIP) is a national partnership of organizations seeking to reduce complications of surgical care. Developed by the Centers for Medicare & Medicaid Services to decrease surgical morbidity, SCIP uses evidence-based medicine to establish surgical practice guidelines.[19] Collaborating with other national organizations such as the American Hospital Association, the Centers for Disease Control, and the Joint Commission, the SCIP has developed quality measures pertaining to perioperative processes of care associated with a high incidence and cost of complications. To date, the Centers for Medicare & Medicaid Services has required only data collection and reporting for institutions to receive their full market basket (a structured payment based on an index-weighted mix of goods and services as evaluated over a period of time); however, beginning in 2011, payments were to depend on performance metrics. Data for these measures are publicly reported.

Targeted areas of clinical improvement include appropriate use of antibiotics to reduce surgical-site infection; perioperative use of beta-blockers to reduce the risk of cardiac events; proper prophylaxis for deep vein thrombosis; optimal temperature and blood glucose control, particularly in patients undergoing cardiac surgery; and processes of care that aim to reduce postoperative pneumonia.[19]

SCIP measures employ a multidisciplinary approach to reduce the incidence of surgical complications. To illustrate, in an effort to eliminate surgical-site infections, practice guidelines target prophylactic antibiotic administration within one hour before surgical incision, the appropriate antibiotic choice in light of the surgery, use of clippers (not razors) for hair removal, immediate normothermia after surgery, and postoperative normoglycemia for patients undergoing cardiac surgery. Rather than focusing on antibiotics alone, SCIP targets several key aspects of perioperative care to reduce the risk of surgical-site infections.

SCIP measures are continually being reassessed and revised on the basis of the most up-to-date medical guidelines and evidence-based medicine. Although SCIP measures are evidence-based, some studies fail to demonstrate a link between adherence to SCIP measures and improvement in surgical outcomes such as surgical-site infections.[20] There has not been convincing evidence that improvements in compliance are associated with better outcomes.

The World Health Organization Surgical Safety Checklist

Avedis Donabedian was a pioneer in the field of health care quality. One of his lasting contributions is the basic framework that he developed with which to think about health care quality. Known as Donabedian's triad, it emphasizes the key elements of structure, process, and outcome when evaluating the quality of health care.[21] The three initiatives already described in this article each fit into one of these categories. Selective referrals and centers of excellence aim to change the structure of health care delivery by establishing regional centers of expertise for complex surgeries. The SCIP measures promote adherence to specific perioperative processes of delivering care, thereby falling under the domain of a process initiative. The ACS NSQIP focuses on health care outcome, specifically the morbidity and mortality for surgical procedures. Although each of these initiatives is a valuable contribution to improving surgical quality of care, what we describe next is a novel approach that does not fit neatly into any of Donabedian's categories.

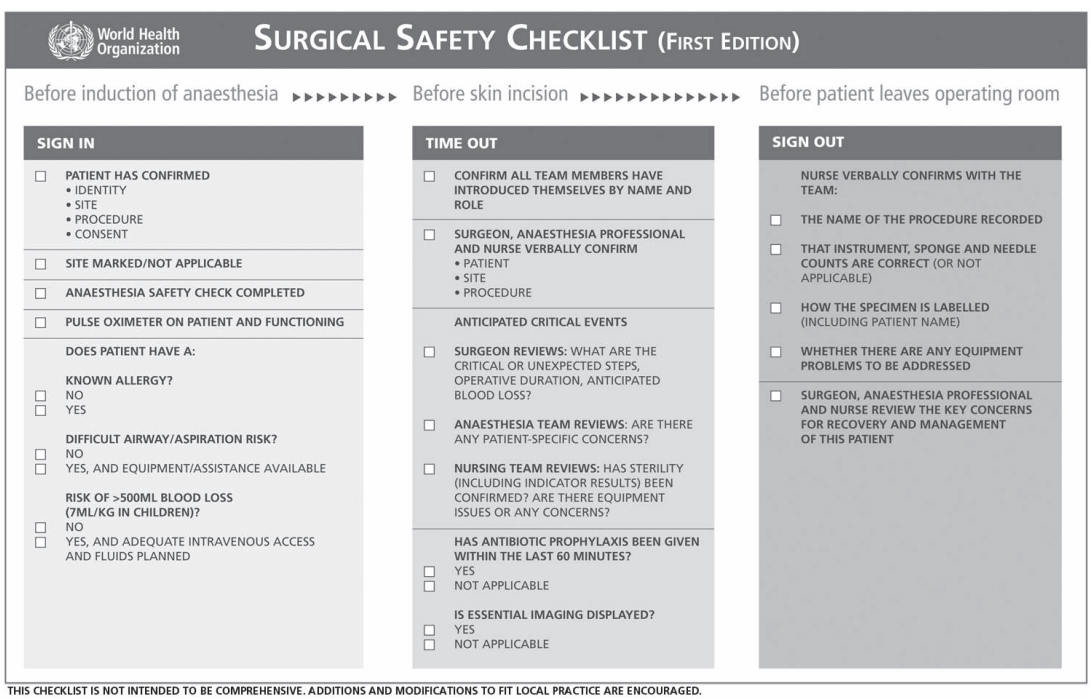
In 2008, in an effort to improve surgical safety and reduce surgical errors, the World Health Organization (WHO) released a safety checklist identifying multiple recommended practices to ensure the safety of surgical patients. This was subsequently formatted into a 19-item checklist focusing on perioperative events that occurred before three crucial steps of surgery: before induction of anesthesia, before skin incision, and before the patient leaves the operating room (OR).[22]

Before the induction of anesthesia, confirmation of patient identity and planned procedure, site marking, and identification of any known allergies or risk of excessive

blood loss are among the checklist items that must be covered. Before skin incision, reconfirmation of the patient's name and procedure, announcement of any anticipated critical events, and introduction of all members of the OR staff must occur. Finally, before the patient leaves the OR, the circulating nurse must verbally confirm the name of the procedure, announce completion of correct instrument and sponge counts, and ensure appropriate specimen labeling. The complete Surgical Safety Checklist is shown in Figure 1.

Introduction of the Surgical Safety Checklist was associated with significant improvements in surgical outcomes. Most notably, a reduction in postoperative complications and deaths of >30% was seen in a landmark trial conducted in 8 socioeconomically diverse hospitals from around the world (Toronto, Canada; New Delhi, India, Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, WA, US). A decrease in postoperative surgical-site infections, unplanned returns to the OR, deaths, and overall complications occurred at all sites, independent of surgical case mix and whether the center was located in a high-income or low-income area.[22] Although evidence supporting decreased surgical complications and deaths was strong, it was not clear what precisely led to this improvement. Authors of the initial validation study hypothesized that use of the checklist "involved both changes in systems and changes in the behavior of individual surgical teams"; the mechanism for improvement was multifactorial rather than consisting of simply checking off boxes in the OR. Indeed, at one site, the checking of intraoperative pulse oximetry rates increased by 50%, and at a second site, the rate of implementation of sponge counts increased from 0% to 92.4%. Finally, the overall rate of appropriate use of antibiotics increased from 56% to 83%; this intervention is a well-known means of reducing surgical-site infections and certainly contributed to the decreased rate of postoperative complications.[22]

Although the WHO Surgical Safety Checklist has been demonstrated to improve the quality of surgical care, its impact depends on how effectively it is implemented. In addition, use of the checklist is not universal, and some hospitals prefer to maintain other safeguards for patient safety, including presurgery checks that were in use before the WHO Surgical Safety Checklist was developed.[23] Some remain unconvinced that compliance with these commonsense practices could lead to such drastic reduction in morbidity and mortality, whereas others contend that the surgical Hawthorne effect—that is, outcomes


World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

☐ PATIENT HAS CONFIRMED
- IDENTITY
- SITE
- PROCEDURE
- CONSENT

☐ SITE MARKED/NOT APPLICABLE

☐ ANAESTHESIA SAFETY CHECK COMPLETED

☐ PULSE OXIMETER ON PATIENT AND FUNCTIONING

DOES PATIENT HAVE A:

KNOWN ALLERGY?
☐ NO
☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
☐ NO
☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
☐ NO
☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

☐ CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE

☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM
- PATIENT
- SITE
- PROCEDURE

ANTICIPATED CRITICAL EVENTS

☐ SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?

☐ ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?

☐ NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
☐ YES
☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
☐ YES
☐ NOT APPLICABLE

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

☐ THE NAME OF THE PROCEDURE RECORDED

☐ THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)

☐ HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)

☐ WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED

☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

Figure 1. World Health Organization Surgical Safety Checklist, created by the World Alliance for Patient Safety.
Reproduced with permission from www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Checklist_finalJun08.pdf.

improve when surgeons know they are being evaluated—is responsible for the observed effects.[24]

Recently, a more comprehensive perioperative safety system (formally entitled the Surgical Patient Safety System [SURPASS]) involving nearly 11 checklists and 100 items was developed and implemented in 6 regional hospitals in a study conducted in the Netherlands. Some items were identical to those seen on the WHO surgical checklist, such as confirmation of patient identification and verification of surgical site, but this more comprehensive checklist included other items such as communication of postoperative instructions between caregivers and clarification of discharge instructions to the patient. In the study, the rate of complications declined by one-third, from 15.4% to 10.6%, and mortality declined by nearly one-half, from 1.5% to 0.8%.[25]

… patients with incomplete checklists were more likely to develop a complication …

Authors of the Netherlands trial built on prior experience and designed a study that avoided some of the limitations seen in earlier work. Specifically, because the safety system was implemented in hospitals that already tracked and monitored surgical outcomes, results could not as easily be attributed to the surgical Hawthorne effect.[24] Additionally, a strong correlation was noted between how thoroughly the checklist was completed and the rate of complications; patients with incomplete checklists were more likely to develop a complication than were those with completed checklists. Finally, five similar hospitals serving as study controls went without implementation of a comprehensive checklist; morbidity and mortality rates remained unchanged in that group.[25]

Shortcomings of the SURPASS approach were reported to include the onus of completing 11 checklists and the potential for alert fatigue in caregivers as the novelty of such an extensive intervention wanes over time.[25] Indeed, the true value of such a comprehensive checklist may become apparent only over time.

Future Directions and Conclusions

Although great strides have been made in the measurement and improvement of surgical outcomes, there is still work to do. Outcomes studies completed thus far generally have explored a defined set of perioperative variables and how they relate to postoperative morbidity and mortality and have been less likely to investigate processes of care. This has been largely because of the difficulty inherent in capturing the multifaceted information required to report on processes of care. However, although the ACS NSQIP currently does not collect information on processes of care, future efforts will likely incorporate data on those process measures required by the SCIP guidelines.[1]

There are several benefits to reporting on process-of-care measures. Process-based feedback may be more quickly incorporated into surgical practice, as opposed to analysis of morbidity and mortality rates, which do not necessarily provide a direct interpretation of why some outcomes are better than others. Additionally, incorporation of SCIP measures into the ACS NSQIP will help simplify data-collection efforts because the SCIP guidelines are important components of several pay-for-performance initiatives. Finally, process-of-care analysis will help identify best practices, an important component of surgery improvement efforts currently missing from outcomes measures.

In addition to incorporating information on processes of care, there are increasing calls for standardized measurement of communication and information transfer. Several reports of studies cite communication breakdown as a common cause of surgical errors and adverse events, and it is known that deficits in information transfer adversely affect processes of care.[26] Effective and standardized communication among all members of the OR team, in addition to preoperative and postoperative caregivers, will facilitate surgical safety. The researchers who conducted the SURPASS trial hypothesized that rates for postoperative complications decreased as a result of more effective communication and hand-offs between clinicians.

Finally, direct measurement of surgical skills may play a growing role in future quality measurement and improvement efforts. Traditionally, surgical skills have been assessed in the OR through direct observation by mentors and peers, but there is mounting pressure for more formal measurement.[27] Precisely how to measure these skills has not been clearly established, and reasons for this include lack of objective assessment methodology, lack of proper infrastructure for implementation, and high costs associated with individual performance analysis. Regardless, it is clear that quality measurement and improvement in general surgery is here to stay. ❖

Disclosure Statement

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References

1. Birkmeyer JD, Shahian DM, Dimick JB, et al. Blueprint for a new American College of Surgeons: National Surgical Quality Improve-

ment Program. J Am Coll Surg 2008 Nov;207(5):777–82.
2. The Joint Commission [homepage on the Internet]. Oakbrook Terrace, IL: The Joint Commission; © 2011 [cited 2011 Jun 20]. Available from: www.jointcommission.org/.
3. Birkmeyer NJ, Birkmeyer JD. Strategies for improving surgical quality—should payers reward excellence or effort? N Engl J Med 2006 Feb 23;354(8):864–70.
4. Ilminen GR. Improving healthcare quality measurement. Quality Progress 2003 Dec;36(12):62–6.
5. Khuri SF, Henderson WG, Daley J, et al; Principal Site Investigators of the Patient Safety in Surgery Study. The patient safety in surgery study: background, study design, and patient populations. J Am Coll Surg 2007 Jun;204(6):1089–102.
6. American College of Surgeons National Surgical Quality Improvement Program [homepage on the Internet]. Chicago, IL: American College of Surgeons; © 2011 [cited 2011 Jun 20]. Available from: www.acsnsqip.org.
7. Gibbs J, Clark K, Khuri S, Henderson W, Hur K, Daley J. Validating risk-adjusted surgical outcomes: chart review of process of care. Int J Qual Health Care 2001 Jun;13(3):187–96.
8. Daley J, Forbes MG, Young GJ, et al. Validating risk-adjusted surgical outcomes: site visit assessment of process and structure. National VA Surgical Risk Study. J Am Coll Surg 1997 Oct;185(4):341–51.
9. Raval MV, Hamilton BH, Ingraham AM, Ko CY, Hall BL. The importance of assessing both inpatient and outpatient surgical quality. Ann Surg 2011 Mar;253(3):611–8.
10. Dimick JB, Osborne NH, Hall BL, Ko CY, Birkmeyer JD. Risk adjustment for comparing hospital quality with surgery: how many variables are needed? J Am Coll Surg 2010 Apr;210(4):503–8.
11. Luft HS, Bunker JP, Enthoven AC. Should operations be regionalized? The empirical relation between surgical volume and mortality. N Engl J Med 1979 Dec 20;301(25):1364–9.
12. Lemmens VE, Bosscha K, van der Schelling G, Brenninkmeijer S, Coebergh JW, de Hingh IH. Improving outcome for patients with pancreatic cancer through centralization. Brit J Surg 2011 Oct;98(10):1455–62.
13. Funk L, Gawande AA, Semel ME, et al. Esophagectomy outcomes at low-volume hospitals: the association between system characteristics and mortality. Ann Surg 2011 May;253(5):912–7.
14. Birkmeyer JD, Siewers AE, Finlayson EV, et al. Hospital volume and surgical mortality in the United States. N Engl J Med 2002 Apr 11;346(15):1128–37.
15. The Leapfrog Group [homepage on the Internet]. Hospital comparisons. Washington, DC: The Leapfrog Group; © 2011 [cited 2011 Jun 20]. Available at www.leapfroggroup.org/cp.
16. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. N Engl J Med 2003 Nov 27;349(22):2117–27.
17. Itani KM. Fifteen years of the National Surgical Quality Improvement Program in review. Am J Surg 2009 Nov(5 Suppl);198:S9–S18.
18. Khuri SF, Henderson WG. The case against volume as a measure of quality of surgical care. World J Surg 2005 Oct;29(10):1222–9.
19. Surgical Care Improvement Project [monograph on the Internet]. Oakbrook Terrace, IL: The Joint Commission; 2011 Feb 7 [cited 2011 Jun 20]. Available from: www.jointcommission.org/surgical_care_improvement_project/.
20. Ingraham AM, Cohen ME, Raval MV, Ko CY, Nathens AB. Comparison of hospital performance in emergency versus elective general surgery operations at 198 hospitals. J Am Coll Surg 2011 Jan;212(1):20–8. e1. Erratum in: J Am Coll Surg 2011 Jun;212(6):1100-1.
21. Donabedian A. The quality of care. How can it be assessed? JAMA 1988 Sep 23–30;260(12):1743–8.
22. Haynes AB, Weiser TG, Berry WR, et al; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med 2009 Jan 29;360(5):491–9.
23. Abdel-Galil K. The WHO surgical safety checklist: are we measuring up? Br J Oral Max Surg 2010 Jul;48(5):397–8.
24. Birkmeyer JD. Strategies for improving surgical quality—checklists and beyond. N Engl J Med 2010 Nov 11;363(20):1963–5.
25. de Vries EN, Prins HA, Grolla RM, et al; SURPASS Collaborative Group. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med 2010 Nov 11;363(20):1928–37.
26. Kripalani S, LeFevre F, Phillips CO, Williams MV, Basaviah P, Baker DW. Deficits in communication and information transfer between hospital-based and primary care physicians: implications for patient safety and continuity of care. JAMA 2007 Feb 28;297(8):831–41.
27. Reznick RK, MacRae H. Teaching surgical skills—changes in the wind. N Engl J Med 2006 Dec 21;355(25):2664–9.

Fundamental Requirements

Carry out the two fundamental surgical requirements:
see what you are doing and leave a dry field.

— Charles Horace Mayo, 1865-1939, American physician and one of the founders of the Mayo Clinic

REVIEW ARTICLE

New Technology Review Process: The Laparoscopic Adjustable Gastric Band

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Abstract

The Interregional New Technologies Committee (INTC) is one evaluation route for new medical technologies or technologies with expanded indications within Kaiser Permanente (KP). The primary focus of the INTC is to consider all available published evidence on a particular technology, surgical technique, or implantable device for a specific clinical indication and provide a recommendation on the sufficiency of the evidence for determining net medical benefit to Permanente Medical Group leaders and Kaiser Foundation Health Plan management throughout KP Regions. This iterative process provides an objective, evidence-based assessment to inform decision making by physicians and support the most appropriate care for KP members. This overview illustrates the INTC process and how it supports clinical decision making using implantation of laparoscopic adjustable gastric bands (LAGBs) as an example. In February 2011, the US Food and Drug Administration (FDA) approved lowering the acceptable body mass index for the Lap-Band from 35 to 30 kg/m^2 for patients with at least one comorbid condition. It is difficult to find published studies on medical technologies that have been recently approved by the FDA. The manufacturer often submits clinical data to the FDA, but details are frequently not publicly available at the time of approval. The LAGB example demonstrates the complex issues addressed by the INTC, particularly when there is some evidence of short-term improvement in outcomes with a medical device but little if any confirmation of long-term safety or effectiveness.

The laparoscopic adjustable gastric band (LAGB), a device surgically implanted around the upper stomach to restrict food intake, has been the focus of recent news. Two LAGB devices are currently approved by the US Food and Drug Administration (FDA): the Lap-Band from Allergan (Irvine, CA) and the Realize Solution from Ethicon Endo-Surgery (Cincinnati, OH). In February 2011, the FDA approved lowering the acceptable body mass index (BMI) for the Lap-Band from 35 kg/m^2 to 30 kg/m^2 for patients with at least one comorbid condition.[1] News reports indicate that the new approval greatly increased the number of eligible US patients from 13 million under the prior recommendation to approximately 32 million.[2] Within Kaiser Permanente (KP), the Interregional New Technologies Committee (INTC) is one evaluation route for new medical technologies or technologies with expanded indications. This article provides an overview of the INTC process and how it supports clinical decision making about whether to expand the use of LAGB on the basis of the FDA's recent ruling.

Background on the Interregional New Technologies Committee

The INTC, chaired by a surgeon, represents a broad stakeholder group. Primarily composed of physicians from various specialties from all 8 KP Regions, the INTC also includes subject-matter experts from technology assessment, ethics, benefits, research, and legal departments. Its primary focus is to consider all available published evidence on a particular technology, surgical technique, or implantable device for a specific clinical indication and provide a recommendation on the suf-

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ficiency of the evidence to Permanente Medical Group leaders and Kaiser Foundation Health Plan management throughout KP Regions. The INTC reviews 30 to 40 different technologies each year.

The INTC review encompasses a broader scope than an FDA review. The FDA is interested in safety and short-term efficacy data, whereas the INTC is also looking at effectiveness, longer-term safety, and durability. *Efficacy* refers to how a treatment performs in a specific patient population under optimally controlled conditions, and *effectiveness* refers to how a treatment performs in a broader patient population and under general conditions in a community-based setting. The INTC review focuses on the quality, quantity, and consistency of the evidence and may also include data from alternative technologies or interventions.

The INTC discussion provides an objective starting point for complex topics when it is time to consider potential patient use. The INTC does not determine coverage, make operational decisions, or consider cost. Each Region is responsible for evaluating the impact and implications of INTC recommendations with respect to the Region's benefit structure, regulatory issues, and delivery system, as well as for communicating any changes in that structure to appropriate clinicians in the Region. Table 1 provides an overview of the INTC review process.

Technology Assessment: Internal and External Resources

In addition to the INTC's review of technologies, there are resources within KP that provide information on medical technologies. One example is the Technology Assessment and Guidelines (TAG) Unit based in the Department of Clinical Analysis in the Southern California Permanente Medical Group. Composed of analysts with graduate degrees in epidemiology, biostatistics, and/or public health, the TAG Unit provides technology-assessment assistance to KP physicians throughout the program. In the Northern California Region, The Permanente Medical Group's (TPMG) New Medical Technology provides support to the Northern California and Mid-Atlantic Regions. Both the Southern California and Northern California technology-assessment groups work closely with the INTC. The INTC also often uses credible, external technology assessments to efficiently manage KP resources.

Topic Selection

Topics are routed to the INTC from a variety of sources. These may include published studies, physician requests, FDA approvals, ongoing internal and external technology-assessment topics, Interregional Chiefs' Groups and other interregional groups and meetings, INTC members, and news reports. Member inquiries may also prompt reviews when routed through Member Services or treating physicians. Topics are investigated and compiled for polling committee members, and then they are selected on the basis of the level of interest from multiple Regions. Topics not reviewed by the INTC may be routed to internal or external technology-assessment groups to provide evidence reviews for topic originators.

Topics may be suggested at any time, but if the focus of the review is device-related, the topic is typically brought to the INTC after FDA approval. Figure 1 illustrates a possible timeline for FDA approval and introduction of new medical technology. Little is known about devices when they are initially approved by the

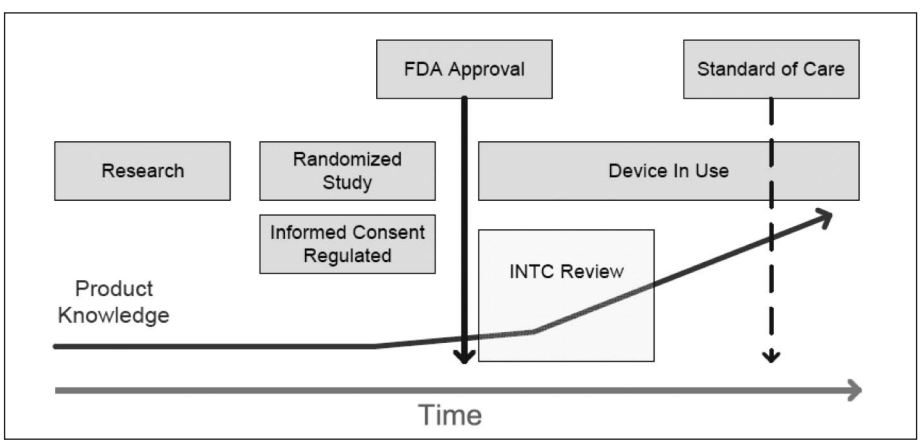


Figure 1. Possible timeline for Food and Drug Administration (FDA) approval and introduction of new medical technology. Initially little is known about the approved device. Although the actual time frame is different for each technology, the review by the Interregional New Technologies Committee (INTC) typically takes place after FDA approval and before the device is widely distributed.

Table 1. Overview of the INTC review process

INTC process	Process details	Details for consideration of LAGB implantation
Identification of topics	Topics come from patient or clinicians request, news reports, published studies, FDA approval, ongoing internal and external technology-assessment topics, Interregional Chiefs' groups or other interregional groups and meetings, and INTC members.	An INTC member requested an update after hearing news of the FDA panel review for the expanded indications for the LAGB. INTC staff confered with the CMI Bariatric Peer Group and with other KP Regions and committee members to confirm interest in the update.
Compilation of technology assessments	INTC staff confer with internal and external groups to locate existing resources and updates.	The TAG Unit provided prior bariatric surgery assessments and agreed to provide an update.
Literature review	An analyst searches the medical literature for published studies. Additional information is gathered, including data submitted to the FDA, adverse-event data posted on the FDA Web site, updated guidelines, and position statements from specialty organizations and government agencies.	A TAG Unit analyst updated existing assessments for bariatric surgery. The Bariatric Peer Group provided input for the PICO model and clinical questions.
Regional clinical input	INTC members and regional representatives request clinical input on the topic by e-mail or phone.	Clinical input was collected from the Interregional Bariatric Peer Group. In general, KP bariatric surgeons prefer gastric bypass over LAGB because it produces greater weight loss and better resolution of comorbidities, and because some patients entering the KP system with the LAGB in place have had complications, requiring its removal.
Determination of presenter	The INTC is composed of physicians from various specialties, and one of them agrees to review and present the topic. At times, a clinical expert will be invited to present, or the analyst will present.	The TAG Unit analyst agreed to present the topic.
Presentation of internal data	Internal data, if available, are requested and prepared for presentation.	A representative of the Southern California Bariatric Registry attended the INTC meeting and presented bariatric surgery data. A member of the Interregional Bariatric Peer Group also attended the INTC meeting and provided additional input.
Distribution of materials	Members download meeting material three weeks in advance of the meeting, review all assessments, and have access to associated literature.	Members arrived at the meeting ready to discuss the evidence and other issues surrounding the topic.
INTC meeting	Before the meeting, the clinical input collected from all Regions is distributed to the members. At the meeting, the evidence is presented, and various issues are discussed.	The current evidence base for the LAGB and other bariatric surgery procedures for patient populations with a lower BMI consisted primarily of retrospective reviews or small case series studies with short-term follow-up. Concerns regarding the LAGB remain, including erosion, reoperation, and LAGB removal. The committee agreed that comparative data and complete follow-up of long-term outcomes are needed to fully assess bariatric procedures.
Determination of recommendation	A draft recommendation is proposed, and the members vote on a recommendation that is based on the sufficiency or insufficiency of the evidence (quality, quantity, consistency).	Approved recommendation: There is insufficient evidence to determine whether the LAGB is a medically appropriate treatment option for adult patients with diabetes with a BMI of ≥30 and ≤35 kg/m^2. The existing evidence is of insufficient quantity and quality.
Circulation of findings	INTC staff provide detailed meeting minutes and recommendations. After the INTC approves the minutes, they are posted on an internal Web site and distributed to all KP Regions by e-mail.	Those who were asked to submit clinical input for the meeting were provided with the collected clinical input, the meeting minutes, and the recommendations.
Regional decision on actions	The regional KP Medical Groups, Kaiser Foundation Health Plans and Hospitals, and the interregional KP groups decide how to apply the findings and/or to implement the recommendation.	Findings and actions are discussed at an Interregional Bariatric Peer Group meeting. In this case, the INTC project manager attended the meeting and provided details.

BMI = body mass index; CMI = Care Management Institute; FDA = Food and Drug Administration; INTC = Interregional New Technologies Committee; KP = Kaiser Permanente; LABG = laparoscopic adjustable gastric band; PICO = Patient, Intervention, Comparison, and Outcome; TAG = Technology Assessment and Guidelines.

FDA, so the topic may be brought back to the INTC when significant published literature becomes available. Technologies expected to have a high rate of distribution may be reviewed before FDA approval, and in some cases, technologies that have become widely distributed may also be reviewed by the INTC.

The Laparoscopic Adjustable Gastric Band

The LAGB is an inflatable silicone ring, typically implanted laparoscopically during a hospital stay of less than one day. Weeks after the initial surgery, the patient returns and the subcutaneous reservoir is accessed and injected with saline to expand the LAGB to limit the amount of food consumed. Current guidelines suggest that patients treated with an LAGB should be seen by a physician three to eight times the first year, one to four times the second year, and one to two times per year thereafter.[3] As with any bariatric surgery, a multidisciplinary approach and good patient compliance improve outcomes.

The FDA initially approved LAGB for patients with a BMI of ≥35 kg/m^2 with multiple comorbidities (such as type 2 diabetes mellitus) and in patients with a BMI of ≥40 kg/m^2 without comorbidities. Recently expanded indications include patients with a BMI of 30 kg/m^2 and at least 1 comorbidity. When the INTC was examining this topic for the recently approved indications, its primary task was to evaluate the evidence for patients with a lower BMI who received the LAGB, and also to compare outcomes for alternative treatments for these patient populations. Although an alternative treatment, such as gastric bypass, may not fall directly within the FDA's purview, it does so in laparoscopic banding because there is an associated device involved. Guidelines for weight thresholds for bariatric surgery are set by the National Institutes of Health, but the FDA's expanded approval for the LAGB goes beyond these and other existing guidelines.[4]

The Review Process

Before an INTC meeting, an analyst prepares an assessment—a report detailing the available medical literature; position statements from specialty organizations, medical societies, and government agencies; and any other relevant information. Committee members and their staff also monitor and interact with external technology-assessment groups, using their resources when available. For the meeting on the LAGB, a TAG Unit analyst provided the assessment summarizing the published evidence on the use of LAGBs in patients who met the recent FDA-approved indications. TAG Unit analysts start with a standardized template to maintain a consistent search and report structure.

The scope of the assessment is guided by clinician and expert input in the area of interest. Clinical questions are formulated, and the PICO model (Patient, Intervention, Comparison, and Outcome) is used to clarify the scope of the report. A different scope can lead to the selection of different studies, so this step is critical for obtaining information that is useful for and relevant to the discussion. For this case, the INTC considered patients with a BMI between 30 and 35 kg/m^2 with type 2 diabetes. Interest in other comorbidities such as hypertension would also define specific patient populations, and each would be investigated separately. The intervention in this example is the use of the LAGB, and the comparison selected was laparoscopic Roux-en-Y gastric bypass (RYGBP). RYGBP is a surgical procedure producing malabsorption and is commonly used in the US and within KP, so it was the most relevant comparator. Lifestyle modification, other surgical treatments, and medical therapies are also alternative treatments and were described in the assessment.

When reviewing a topic, the committee frequently discusses which treatment or therapy would be considered the best comparator, as trials may use a comparator that is outdated or not as effective. In analyzing the use of LAGB, the committee might also have questioned why RYGBP would be selected as a comparator, because typically, those in the new BMI range would not be offered surgery under existing guidelines. Would medical management be a better comparator? The benefits and harms may be examined for each treatment considered.

For the outcome portion of the PICO model, the parameters might be percentage of excess weight loss, of resolution of type 2 diabetes, and of adverse events. When analyzing multiple studies, it is important to understand the measure used. For example, some studies might use elimination of diabetes medication as the outcome measure, and other studies might use an intermediate outcome measure, such as a threshold for laboratory results: a fasting glucose level of <7 mmol/L or a glycated hemoglobin level of <6%. The existence of multiple types of measures and different definitions of diabetes resolution make it difficult to analyze and summarize results, as resolution rates will vary depending on how they are defined and reported.

The analyst determines the search criteria on the basis of the clinical questions and information from the PICO model, performs a search, and selects relevant

… the committee frequently discusses which treatment or therapy would be considered the best comparator, as trials may use a comparator that is outdated or not as effective.

literature. Data are extracted from selected publications. This is a detailed process done by hand; however, the TAG Unit is evaluating software options to aid in the process. The analyst performs a critical appraisal, a process of systematically assessing and interpreting research studies to evaluate validity, results, and relevance. This involves evaluating the risk of bias that may affect studies' validity and conclusions about the intervention effect.

Absent high-quality, low-attrition, and long-term follow-up studies, it is difficult to predict benefits and harms for this new patient population.

Determining Clinical Effectiveness

An essential tool used to review the literature is the evidence hierarchy or pyramid. The INTC is most interested in evidence from studies that have directly compared the intervention of interest to usual care or placebo and report health outcomes. Duration of follow-up is of particular interest because it determines the durability of effectiveness and any identification of potential late adverse events. This level of evidence and adequate duration of follow-up are typically not available for many new technologies. In these situations, lower-level evidence such as case series studies are reviewed.

The search for studies for patients receiving an LAGB who have a BMI between 30 and 35 kg/m^2 and type 2 diabetes revealed a meta-analysis that included a total of 27 patients treated with an LAGB from 3 separate studies and one additional recent retrospective review comparing results for 109 patients treated with the LAGB with results for 109 patients treated with gastric bypass.[5,6] The retrospective study reported that gastric bypass provided superior weight loss and diabetes remission (28% vs 55% at 6 to 12 months). A diabetes remission rate of 28% in the LAGB group appears to be lower than the remission rate reported by other studies of patients with a higher BMI who were treated with the LAGB (48%).[7]

It is difficult to find reports of studies on medical technologies that have been recently approved by the FDA. The manufacturer often submits clinical data to the FDA, but details are frequently not publicly available at the time of approval. In fact, the data may never be published in a peer-reviewed medical journal. Thus the INTC may also consider data for patients falling outside this new BMI group and then discuss whether the outcomes can be extrapolated to other populations.

Because the evidence in the lower-BMI group is limited, the committee can examine data available for originally approved indications for LAGBs. Two meta-analyses have compared the use of LAGBs with RYGBP for patients who meet current National Institutes of Health guidelines for BMI and comorbidities and have found that RYGBP produces weight loss superior to that produced by LAGB (62% vs 48% for the study by Demaria et al and 63% vs 49% for the study by Garb et al).[6,8] Buchwald et al also found RYGBP to be superior to LAGBs for resolution of type 2 diabetes (72% vs 48%).[7] Some studies have suggested RYGBP has immediate effects on insulin secretion in type 2 diabetes, and patients may be discharged after bypass surgery without the need for diabetes medication.[9] The entry of a technology when an existing treatment has superior outcomes creates additional discussion for INTC members. Trade-offs in morbidity of the procedure such as recovery time, patient acceptance, delivery-system advantages, or other factors, may warrant consideration.

Although these meta-analyses indicate that gastric bypass is superior to LAGB as far as effectiveness, the committee also looks closely at the limitations of the studies reviewed in the meta-analysis and the validity of the meta-analysis itself. The meta-analysis by Garb et al[8] reported on >7000 patients; however, >70% of the studies analyzed were retrospective in nature, and patient attrition at 3 years was 83% for LAGBs and 89% for RYGBP. Studies have demonstrated that patient compliance is a critical factor in outcomes[10]; thus, INTC discussions frequently include the issue of patient compliance. Clinical experts provide comments and recommend methods of improving compliance.

The importance of long-term follow-up is highlighted in a recent report by DiGiorgi et al showing that 24% of 42 patients who underwent gastric bypass had a reemergence of diabetes after 3 years.[11] Interestingly, the study also reported that the reemergence of diabetes occurred in patients who had a lower preoperative BMI. Absent high-quality, low-attrition, and long-term follow-up studies, it is difficult to predict benefits and harms for this new patient population.

Determining Safety

Safety is a top concern of the committee. As with any implanted device, adverse events may occur at any time after LAGB placement. Infection and port-related complications can occur, which may require port removal, possibly followed by replacement concurrently or at a later date. Other potential problems include LAGB slippage and pouch dilation, which may require LAGB repositioning, replacement, or deflation, followed by reinflation after a few months. The adjustable gastric band is composed of silicone. It surrounds and constricts the upper portion of the stomach, which may lead to ischemia and erosion. Erosion, a potentially life-threatening event, can occur when the LAGB

harms the tissue and starts to penetrate the stomach wall. Removal of an LAGB and repair of any damage are often technically very challenging.

Long-term follow-up is needed, particularly because an LAGB may remain in the patient for many years. The INTC will examine the data for the expected rate of each type of adverse event over time. In many cases this is difficult because studies report events poorly, have different detection and reporting mechanisms, and are small with wide confidence intervals.

Another resource for information on adverse events is the FDA Manufacturer and User Facility Device Experience database.[12] Data are limited because submission by physicians, other clinicians, and patients is voluntary. Less than 1% of the adverse events in this database are reported by physicians.[13] Nevertheless, the database can provide some information on the types of adverse events occurring in the community setting. A search revealed >8000 adverse-event reports for LAGBs, including 80 deaths, which raised concern among INTC members.

Over the last few years, there has been an increase in advertisements promoting easy weight loss with minimally invasive surgery. Some community medical centers have started to promote LAGBs to individuals in this lower BMI range, and patient requests are increasing. Few, if any, harms are discussed, and patients' expectations of easy weight loss does not prepare them for the change in lifestyle that accompanies LAGB implantation. Despite inadequate long-term safety data for LAGBs, patients may be unaware of the importance of continued follow-up and may neglect to schedule appointments with physicians. This may lead to patients delaying treatment for complications that would have been easier to treat if seen sooner. The INTC review process provides physicians with current safety evidence that they can use to better inform patients.

Committee Discussion

Topics dealt with by the INTC are frequently complex. The INTC must navigate the issues of appropriate medical use, considering the innovation horizon. Many devices are continuously evolving to improve outcomes. New versions of a device may be introduced into the market with little or no clinical data, and studies frequently include multiple versions of a particular device. Although there is an expectation that device changes will lead to improved outcomes, this is not always the case and cannot be assumed. The INTC must also be aware of surgical techniques and other factors that change over time that also may affect outcomes.

Many INTC members have served for several years and keep the discussion consistent and reduce bias. Members also bring to the table perspectives from the various stakeholder groups. For example, those with an ethics background may discuss disease burden, access to care, and conflicts of interest such as manufacturer sponsorship of studies or study authors' financial benefits.

INTC members are responsible for communication with their Region by gathering clinical input and recommending new topics. Members also connect with interregional specialty groups and Chiefs' groups. In the case of LAGBs, the Interregional Bariatric Peer Group, which suggested topics, advised regarding timing and formulated the assessment questions. The KP Department of Research and other internal research groups may also supply data on various topics. For the LAGB topic, a representative of the Southern California Bariatric Registry attended the INTC meeting and presented bariatric surgery data.

During the committee meeting, there was concern about LAGB removal rates, reoperation, and adverse events such as erosion. In summary, the evidence base for implantation of the LAGB and for other bariatric

Interregional New Technologies Committee Recommendation Language

Interregional New Technologies Committee recommendations will take one of the following forms:

1. There is sufficient evidence to determine that the technology is medically appropriate (or is a medically appropriate treatment/diagnostic option) for select patients.
2. There is insufficient evidence to determine whether the technology is medically appropriate for any patient; *or* there is insufficient evidence to determine whether the technology is a medically appropriate treatment/diagnostic option for any patient.
   a. The existing evidence regarding how the technology effectively prevents or diagnoses or treats or manages the health condition is of insufficient quantity and/or quality.
   b. The existing evidence regarding how the technology effectively prevents or diagnoses or treats or manages the health condition is conflicting or inconsistent.
   c. There is no evidence on the use of this technology in the prevention or diagnosis or treatment or management of this health condition.
3. There is sufficient evidence to determine that the technology is generally not medically appropriate (or is not a medically appropriate treatment/diagnostic option) for any patients.

surgery procedures for lower-BMI patient populations consisted primarily of retrospective reviews or small case series studies with only short-term follow-up. The INTC debated longer-term patient issues such as consequences of LAGB removal and weight regain or recurrence of comorbidities. Loss of access to follow-up data, particularly if a member leaves KP, was also a concern. The committee members agreed that comparative data and complete follow-up of long-term outcomes are needed to fully assess bariatric procedures for the lower-BMI patient population.

INTC members reached the following recommendation (See sidebar: Interregional New Technologies Committee Recommendation Language). There is insufficient evidence to determine whether implantation of the LAGB is a medically appropriate treatment option for adult patients with diabetes and a BMI of 30 to 35 kg/m^2. The existing evidence is of insufficient quantity and quality.

Conclusion

The INTC considers many complex issues, as discussed here using LAGB implantation as an example. For many new technologies that are reviewed, the committee determines that there is insufficient evidence; however, the evidence review is invaluable for understanding the present and future implications of technology and health care delivery models. With so many unanswered questions and concerns, it is likely that KP will proceed cautiously with the use of LAGBs in this new patient population. Aggregation of internal patient outcomes may facilitate clinical decisions in the future. After INTC meeting details are distributed to the Regions, staff will continue to monitor future trials and other information and bring the topic back to the INTC as appropriate. This complex, multidisciplinary, and iterative process provides an objective, evidence-based assessment to inform decision making by physicians and support the most appropriate care for KP members. ❖

Disclosure Statement

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

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References

1. US Food and Drug Administration. FDA expands use of banding system for weight loss [press release on the Internet]. Washington, DC: US Department of Health and Human Services 2011 Feb 16 (cited 2011 Oct 17]. Available from: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm245617.htm.
2. Salahi L. FDA panel recommends Lap Band expansion [monograph on the Internet]. New York: ABC News: Nightline 2010 Dec 2 [cited 2011 Oct 17]. Available from: http://abcnews.go.com/Health/WellnessNews/fda-panel-lap-band-expansion/story?id=12308753.
3. Sauerland S, Angrisani L, Belachew M, et al; European Association for Endoscopic Surgery. Obesity surgery: evidence-based guidelines of the European Association for Endoscopic Surgery (EAES). Surg Endosc 2005 Feb;19(2):200–21.
4. National Institutes of Health. Health information: obesity [monograph on the Internet]. Bethesda, MD: National Institutes of Health [updated 2011 Apr 7]. Available from: www.nhlbi.nih.gov/guidelines/obesity/index.htm.
5. Fried M, Ribaric G, Buchwald JN, Svacina S, Dolezalova K, Scopinaro N. Metabolic surgery for the treatment of type 2 diabetes in patients with BMI <35 kg/m2: an integrative review of early studies. Obes Surg 2010 Jun;20(6):776–90.
6. Demaria EJ, Winegar DA, Pate VW, Hutcher NE, Ponce J, Pories WJ. Early postoperative outcomes of metabolic surgery to treat diabetes from sites participating in the ASMBS bariatric surgery center of excellence program as reported in the Bariatric Outcomes Longitudinal Database. Ann Surg 2010 Sep;252(3):559–66; discussion 566–7.
7. Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. JAMA 2004 Oct 13;292(14):1724–37. Erratum in: JAMA 2005 Apr 13;293(14):1728.
8. Garb J, Welch G, Zagarins S, Kuhn J, Romanelli J. Bariatric surgery for the treatment of morbid obesity: a meta-analysis of weight loss outcomes for laparoscopic adjustable gastric banding and laparoscopic gastric bypass. Obes Surg 2009 Oct;19(10):1447–55.
9. Pories WJ. Bariatric surgery: risks and rewards. J Clin Endocrinol Metab 2008 Nov;93(11 Suppl 1):S89–96.
10. Shen R, Dugay G, Rajaram K, Cabrera I, Siegel N, Ren CJ. Impact of patient follow-up on weight loss after bariatric surgery. Obes Surg 2004 Apr;14(4):514–9.
11. DiGiorgi M, Rosen DJ, Choi JJ, et al. Re-emergence of diabetes after gastric bypass in patients with mid- to long-term follow-up. Surg Obes Relat Dis 2010 May-Jun;6(3):249–53.
12. US Food and Drug Administration. MAUDE—Manufacturer and User Facility Device Experience [database on the Internet]. Washington, DC: US Department of Health and Human Services; updated 2011 Sep 30 [cited 2011 Oct 17]. Available from: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.
13. Greenfield LJ. Medical device adverse event reports and the Food and Drug Administration. J Vasc Surg 2004 Aug;40(2):395–6.

CASE STUDY

A Case of an Abdominal Mass: Follicular Lymphoma

Tina L Walker, MD
Gabriel E Lopez, MD

Abstract

Follicular lymphoma (FL) is the second most common subtype of non-Hodgkin lymphoma. The disease usually affects older individuals, with the average age at diagnosis being 63.5 years. Only in 4% of cases is the disease diagnosed in individuals younger than age 40 years. The case presented in this report describes the diagnosis of FL in a 38-year-old woman and highlights the variability of this disease. Tumor grading, disease staging, and the Follicular Lymphoma International Prognostic Index score can be valuable aids in prognosis. Treatment consists of close observation or radiation therapy for early-stage disease, and rituximab with combination chemotherapy regimens for more advanced disease. Cure is rare. Treatment is predominately handled by oncologists, but these patients will likely first present to their primary care physicians. Symptoms can be subtle at times, so it is essential to be able to recognize them to provide the patient with timely treatment.

Introduction

Lymphomas are divided into two general categories, Hodgkin lymphoma and non-Hodgkin lymphoma (NHL). NHL is far more common than Hodgkin lymphoma.[1] Differences between these two major types of lymphoma can be detected by microscopy. Within these two large groups, there are a myriad of subtypes. Of instances of NHL, 22% are follicular lymphoma (FL). Diffuse large B-cell lymphoma is the most common lymphoma in the US, and FL is the second most common.[1] The mean age of persons in Sweden when their FL is diagnosed is 63.5 years, and only 4% are younger than age 40 years at time of diagnosis.[2]

Presentation varies widely among patients with FL. It can include palpable adenopathy detected by the patient or clinician during examination. Adenopathy can be present peripherally throughout the body, including in the cervical, axillary, and inguinal areas. Often adenopathy is intermittent, with waxing and waning symptoms, for unclear reasons. It can also take the form of palpable abdominal masses, which can be asymptomatic or can cause obstructive symptoms in the gastrointestinal or genitourinary tract.[3]

Systemic complaints, or B symptoms, are reported in approximately 20% of patients with FL[4] and consist of fever, unexplained weight loss, and profuse night sweats. Considering the vagueness of symptoms or the lack of symptoms altogether, the variation in patients' presentation is considerable. This can make detecting FL in the primary care setting a challenge. Because the presenting symptoms of fatigue and lymphadenopathy are so nonspecific, the diagnosis of FL is frequently delayed, and disease is usually found in multiple sites once discovered. The following case illustrates a presentation of FL in the primary care setting and the diagnostic testing that revealed its presence.

Case Report

A 38-year-old Hispanic woman presented to our clinic with pain in the center of her lower abdomen. The pain was sharp, constant, and severe and radiated to her back. Symptoms had begun three days earlier and were getting worse. She reported feeling feverish and chills intermittently during the preceding three days. She also described, on questioning, increased urinary frequency during that time. Her medical history included a previous diagnosis of Hashimoto thyroiditis and bilateral conductive hearing loss. She had three pregnancies and has two children. She had a diastasis recti separation in the abdominal wall noted after the birth of her last child. She was taking no medications regularly. She reported never smoking, never taking street drugs, and drinking alcohol sparingly. Her family history provided no additional information.

On examination, the patient was in no distress. Her temperature was 37.3°C (99.1°F); blood pressure, 101/69 mm Hg; pulse, 105 beats per minute, and respirations, 20 breaths per minute. Her height was 1.626 m (5'4"), and

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her weight was 59.603 kg (131 lb 6.4 oz). Her weight was essentially unchanged during the preceding year. There was no palpable adenopathy. Her heart rhythm was regular, and her lungs were clear. A large diastasis recti separation was felt in the center of the abdomen, which was also noted on examination two months before this visit. A large, firm, tender, mobile mass was palpated in the left lower quadrant of her abdomen.

The abdominal mass was initially thought to be an enlarged spleen, and an ultrasound was ordered. The patient's condition was diagnosed as cystitis, and she was given trimethoprim-sulfamethoxazole, 160-800 mg, as oral tablets, which she took twice daily for 10 days.

Laboratory tests were ordered. Urinalysis showed a specific gravity of 1.004. All other components of urinalysis were within normal limits. A urine culture yielded no growth. The patient's hemoglobin level was 12.3 g/dL, and her white blood cell count was 10,600 per mm^3 (10.6×10^9 per liter), with 82.2% neutrophils. Serum electrolyte, blood urea nitrogen, and creatinine levels were within normal limits. Her alanine aminotransferase and aspartate aminotransferase levels were within normal limits, as was the total bilirubin level. Findings on the mononucleosis test for heterophile antibody were negative. An abdominal ultrasound revealed a $8.4 \times 6.8 \times 7.5$ cm heterogeneous solid mass in the anterior lower left. Of note, an ultrasound of the abdomen produced unremarkable findings 7 months earlier when the patient presented with right-sided flank pain. A computed tomography (CT) scan of the abdomen and pelvis was suggested and performed with administration of oral and intravenous contrast.

CT scans showed a large, lobulated mass within the left small-bowel mesentery (Figure 1). Mesenteric vessels in the area were encased. There were several adjacent prominent lymph nodes within the mesentery of the small bowel. The state of other abdominal and pelvic organs were unremarkable, as was that of bony structures. There was no bowel obstruction. The Surgery Department recommended a CT-guided needle biopsy of the mass. This was performed, and the pathology findings were FL, grade 3. Immunohistochemistry showed a B-cell type with positive findings for cluster of differentiation (CD) 10, CD20, B-cell lymphoma 2 (BCL-2), and BCL-6.

The patient was referred to the Oncology Department. Her serum lactate dehydrogenase level was within normal limits at 132 IU/L. Positron-emission tomography (PET) scanning revealed lymphoma, and no disease was seen above the diaphragm, in the spleen, or in the bone marrow (Figure 2). Bone marrow biopsy showed no evidence of involvement by lymphoma. A multigated acquisition scan was performed, and the patient's cardiac ejection fraction was measured at 67%. She underwent six cycles of R-CHOP chemotherapy (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone). A subsequent PET scan obtained 2.5 months after the first scan showed complete response of the lymphoma to therapy, with no evidence of active residual lymphoma (Figure 3). The Oncology Department continues to monitor her closely.



Figure 1. Cross-sectional computed tomography image of the abdomen and pelvis with oral and intravenous contrast showing a mass in the left small-bowel mesentery and several prominent lymph nodes in the adjacent small bowel.

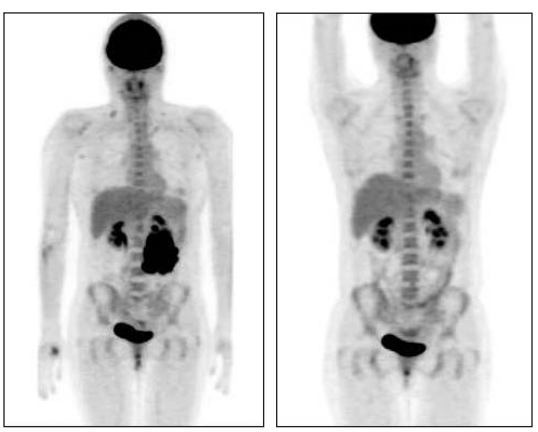


Figure 2. (left) Positron-emission tomography image obtained before treatment showing a large, lobulated lymphoma in the left abdomen.

Figure 3. (right) Positron-emission tomography image obtained after chemotherapy—2.5 months after the pretreatment image in Figure 2 (left)—showing no active residual lymphoma.

Discussion

Although the genetic hallmarks involved in FL have been extensively studied, the pathogenesis is not completely understood. In up to 90% of cases, there are breakpoint regions in chromosome 18 and reshuffled aspects of BCL-2.[5,6] A resulting translocation, t(14;18), leads to an increased expression of BCL-2, an oncogene that hastens apoptosis and leads to increased cell survival time.[7] FL develops from follicle B cells, including both centrocytes (smaller) and centroblasts (larger) types of cells.[8] Obtaining a tissue sample for histologic analysis is paramount in the diagnosis and grading of FL. Excision of an enlarged lymph node or core needle biopsy of a mass aids in the identification of FL. Fine-needle aspiration can miss the diagnosis of lymphoma and, if performed, should always be followed by a tissue biopsy.[9]

Establishing FL grade requires attention to the proportion of centroblasts present. Aggressive FL has more centroblasts, and the higher number of these cells, the higher the grade of the FL, with grade 3 being the highest assignable grade.[10] Blood tests and bone marrow analysis are also routinely done, in addition to immunohistochemistry of the biopsy sample. There is also the Follicular Lymphoma International Prognostic Index (FLIPI), which can be helpful when considering prognosis in FL. The FLIPI score can be calculated by assigning one point to each of these criteria: age >60 years, serum lactate dehydrogenase level above normal, a hemoglobin level of <12.0 g/dL, designation of stage 3 or intravenous FL, and the number of involved nodal areas >4.[11] A higher FLIPI score places the individual at higher risk of dying. A score of 0 to 1 is considered low risk, 2 is intermediate, and 3 to 5 is high risk. The patient described here had a FLIPI score of 2 (one point for the stage and the other for the number of lymph nodes involved). Staging of FL examines the number of involved lymph nodes and describes the anatomic extent of the disease.

The overall course of FL varies widely. Some patients have swift tumor growth and spread, leading to enlargement of lymph nodes and organs, causing discomfort and possibly obstruction. Others opt not to receive treatment and may live free of symptoms for years. Spontaneous regression of FL has also been observed.[12] FLIPI score and tumor grade are useful indicators for prognosis of FL and can aid in determining the course that the disease will take.

Treatment of FL is contingent on the stage of the disease. Radiation to the involved area is the treatment of choice in the early stages.[13] Stage 1 FL involves one lymph node region and potentially an extralymphatic site (stage 1E). Stage 2 has two or more lymphatic regions involved on the same side of the diaphragm and may also involve an extralymphatic site (stage 2E).[14] Radiation therapy is the treatment of choice for FL in stages 2 and 3, with 10-year survival reported to be between 60% and 80%.[15]

Chemotherapy is indicated in more advanced stages of FL. Stage 3 involves lymphatic regions on both sides of the diaphragm. Stage 3 can include involvement of the spleen (stage 3S), adjacent extralymphatic sites (stage 3E), or both (stage 3ES). Stage 4 disease involves one or more extralymphatic site(s) diffusely.[14] Treatment regimens of the more advanced stages of FL often include the monoclonal antibody agent rituximab. The use of this agent, along with combination chemotherapy, has shown to provide better control of the disease and increased survival.[16]

Understanding lymphoma as an entity can be daunting for patients. Testing, diagnosis, staging, grading, prognosis, and disease progression can be overwhelming and complicated.

Several chemotherapeutic agents are combined for the treatment of FL. The R-CVP (rituximab, cyclophosphamide, vincristine, and prednisone) combination can be used, as can this same set of medications with added doxorubicin (R-CHOP). There is no single standard of care when selecting the combinations of medications, and the treated patients comprise a heterogeneous group in which outcomes fluctuate and are complex to quantify.[17]

Patients should be monitored at regular intervals for relapse. A favorable response to treatment is initially widespread across cases of FL, but there is no cure for the disease. Relapse is common, as is the likely progression of FL.[18] It is important for patients with FL to be provided with information regarding their disease. Understanding lymphoma as an entity can be daunting for patients. Testing, diagnosis, staging, grading, prognosis, and disease progression can be overwhelming and complicated. Therefore, it is imperative that both the oncologist and those in primary care monitor for relapse and assist the patient in understanding the disease.

Conclusion

Although much of the diagnosis and treatment of FL will be carried out by oncologists, initially patients with FL will likely find themselves in the office of their primary care physician. The road that unfolds before the patient can include fear-provoking imaging, biopsies, tumor grade and immunohistochemistry assignments, staging, and treatments. Familiarity with the presenta-

tion, etiology, and treatment of FL will help clinicians better serve their patients.

The average age of patients at diagnosis of FL is 63.5 years. The case described here involves a 38-year-old woman. This disparity highlights one aspect of the variable presentation of FL. Inconsistencies also exist from individual to individual in respect to the progression and course of FL.

Treatment options and combinations for FL are many. None are curative. Patients diagnosed with FL require monitoring at regular intervals and support from both their specialists and their primary care physicians. More information for patients, their families, and their clinicians can be found at www.cancer.org, www.cancer.gov, and www.lls.org/. ❖

Disclosure Statement

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

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References

1. Armitage JO, Weisenburger DD. New approach to classifying non-Hodgkin's lymphomas: clinical features of the major histologic subtypes. Non-Hodgkin's Lymphoma Classification Project. J Clin Oncol 1998 Aug;16(8):2780–95.
2. Goldin LR, Björkholm M, Kristinsson SY, Turesson I, Landgren O. Highly increased familial risks for specific lymphoma subtypes. Br J Haematol 2009 Jun;146(1):91–4.
3. Krikorian JG, Portlock CS, Cooney P, Rosenberg SA. Spontaneous regression of non-Hodgkin's lymphoma: a report of nine cases. Cancer 1980 Nov 1;46(9):2093–9.
4. Anderson T, Chabner BA, Young RC, et al. Malignant lymphoma. 1. The histology and staging of 473 patients at the National Cancer Institute. Cancer 1982 Dec 15;50(12):2699–707.
5. Cleary ML, Galili N, Sklar J. Detection of a second t(14;18) breakpoint cluster region in human follicular lymphomas. J Exp Med 1986 Jul 1;164(1):315–20.
6. Cleary ML, Smith SD, Sklar J. Cloning and structural analysis of cDNAs for bcl-2 and a hybrid bcl-2/immunoglobulin transcript resulting from the t(14;18) translocation. Cell 1986 Oct 10;47(1):19–28.
7. Graninger WB, Seto M, Boutain B, Goldman P, Korsmeyer SJ. Expression of Bcl-2 and Bcl-2-Ig fusion transcripts in normal and neoplastic cells. J Clin Invest 1987 Nov;80(5):1512–5.
8. Cossman J, Neckers LM, Hsu S, Longo D, Jaffe ES. Low-grade lymphomas. Expression of developmentally regulated B-cell antigens. Am J Pathol 1984 Apr;115(1):117–24.
9. Hehn ST, Grogan TM, Miller TP. Utility of fine-needle aspiration as a diagnostic technique in lymphoma. J Clin Oncol 2004 Aug 1;22(15):3046–52.
10. Ott G, Katzenberger T, Lohr A, et al. Cytomorphologic, immunohistochemical, and cytogenetic profiles of follicular lymphoma: 2 types of follicular lymphoma grade 3. Blood 2002 May 15;99(10):3806–12.
11. Solal-Céligny P, Roy P, Colombat P, et al. Follicular lymphoma international prognostic index. Blood 2004 Sep 1;104(5):1258–65.
12. Horning SJ, Rosenberg SA. The natural history of initially untreated low-grade non-Hodgkin's lymphomas. N Engl J Med 1984 Dec 6;311(23):1471–5.
13. McLaughlin P, Fuller LM, Velasquez WS, et al. Stage I–II follicular lymphoma. Treatment results for 76 patients. Cancer 1986 Oct 15;58(8):1596–602.
14. Carbone PP, Kaplan HS, Musshoff K, Smithers DW, Tubiana M. Report of the Committee on Hodgkin's Disease Staging Classification. Cancer Res 1971 Nov;31(11):1860–1.
15. Guadagnolo BA, Li S, Neuberg D, et al. Long-term outcome and mortality trends in early-stage, Grade 1–2 follicular lymphoma treated with radiation therapy. Int J Radiat Oncol Biol Phys 2006 Mar 1;64(3):928–34.
16. Salles G, Mounier N, de Guibert S, et al. Rituximab combined with chemotherapy and interferon in follicular lymphoma patients: results of the GELA-GOELAMS FL2000 study. Blood 2008 Dec 15;112(13):4824–31.
17. Friedberg JW, Taylor MD, Cerhan JR, et al. Follicular Lymphoma in the United States: first report of the national LymphoCare Study. J Clin Oncol 2009 Mar 10;27(8):1202–8.
18. Cheson BD, Pfistner B, Juweid ME, et al; International Harmonization Project on Lymphoma. Revised criteria for malignant lymphoma. J Clin Oncol 2007 Feb 10;25(5):579–86.

Leap the Nile

When thou examinest the obstruction in his abdomen
and thou findest that he is not in a condition to leap the Nile …
say thou to him: "It is the Blood that has got itself fixed and does not circulate."

— Ebers Papyrus, *circa 1550 BC, Egyptian medical papyrus*



"Meditation on the Beach"
acrylic on canvas
18x22"

Mohamed Osman, MD

Dr Osman is formerly a physician from Group Health Permanente. 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 his Web site: www.osmanart.net.

CME credits available for this article — see page 95.

CASE STUDY

Does My Patient Have Asthma?

Eric Macy, MD, MS

Introduction

Physicians all know what asthma is. Southern California Kaiser Permanente (KP) physicians treated 211,350 patients during 458,868 encounters for asthma (International Classification of Diseases code = 493.xx) in 2009 (data from internal, password-protected KP research database). We do a great job of providing at least one inhaled steroid canister annually for every patient who meets the current Healthcare Effectiveness Data and Information Set (HEDIS) criteria for persistent asthma. We give them to virtually 100% of these patients. So why might this be a problem? Why ask: "Does my patient have asthma?"

Imagine if one-third of the individuals you treated for type 2 diabetes really had some other problem and did not really need or benefit from the medications that you gave them over the long term. This is essentially what often happens with asthma management. It is important to remember that asthma is a syndrome and that the diagnosis is often made clinically, based on wheezing and shortness of breath, but must be confirmed to justify long-term treatment with inhaled steroids with or without long-acting bronchodilators. Self-reported asthma symptoms and even physician-diagnosed "asthma" are more common with obesity, but reversible airflow obstruction is not.

Case Report

Now for the case:

Ms X, age 57 years, transferred her medical care to KP in late December 2009. She was initially seen in primary care on January 6, 2010, with a diagnosis of steroid-dependent "asthma," along with obesity, depression, reflux, sleep apnea, pollen allergy, hypertension, hyperlipidemia, and prediabetes. She was quickly referred to the Allergy Department where she was initially seen on January 11, 2010. She had been taking oral steroids daily since 2003, averaging about 20 mg of prednisone per day. She had episodically taken as much as 60 mg/d. Tapering had been tried in the past but was always stopped secondary to myalgias, shortness of breath, and depression. These symptoms would worsen markedly when dosage reached 10 mg/d. She was a 45-pack-year smoker who quit in 1998. Her shortness of breath did not start until 2002. She underwent environmental skin testing in 2002 and was noted to be allergic to pollens only. She had gained >27 kg in the decade before symptom onset. Her body mass index was 39.6. She underwent sinus surgery in 2003. She had no childhood history of asthma, and she had not undergone lung function tests to document reversible airflow obstruction before being seen at KP. She had not undergone a methacholine challenge. She had been getting poor-quality sleep for years. Sleep apnea was initially diagnosed in 2005, and she had been using continuous positive airway pressure (CPAP) when initially seen, but she did so irregularly because it did not seem to help.

When initially seen in the Allergy Department, she had normal spirometry results (forced vital capacity, 91%; forced expiratory volume in the first second of expiration, 96%; ratio of forced vital capacity to forced expiratory volume in the first second of expiration, 84%), without obstruction or restriction. She had a low normal fraction of exhaled nitric oxide (16 parts per billion). She had normal findings on sinus radiographs, with no air fluid levels. Steroids were initially tapered by 10 mg every other week. The combination steroid and long-acting bronchodilator she had been using was stopped. The leukotriene inhibitor she had been given was stopped. The angiotensin-converting enzyme (ACE) inhibitor that she had been taking was stopped, and she was given an angiotensin-receptor blocker instead. Her CPAP machine was retitrated, her anti-reflux therapy was reinforced, and she began an exercise and weight-loss program. She lost >18 kg by November 2010. When prednisone dosage was down to 10 mg/d, the taper was slowed to 1 mg every other week. When she caught viral infections, the steroid taper was slowed. She was no

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longer taking oral prednisone by early November 2010. Because the patient received help in controlling her weight, sleep apnea, iatrogenic cough, and reflux laryngitis, her "asthma" symptoms disappeared. She still coughs when she has viral infections, but with her assistance and understanding, her health care team is resisting future long-term treatment with oral steroids.

Discussion

Physicians learn in medical school that asthma is a chronic inflammatory lung disease. It is clinically characterized by shortness of breath and wheezing and physiologically verified by documenting reversible airflow obstruction or bronchial hyperreactivity. We know that there are many other conditions that will cause asthma-like symptoms, including obesity, heart failure, smoking, reflux laryngitis, viral infection, sinusitis, laryngeal dysfunction, use of ACE inhibitors, and aspiration pneumonia, but we still tend to rely on the clinical symptoms of coughing, wheezing, and shortness of breath to diagnose asthma. Asthma treatments are extremely effective in individuals with reversible airflow obstruction caused by small-airway inflammation. Overuse of bronchodilators can contribute to worsening cough, laryngitis, and reflux. Use of high-dose inhaled steroids increases the risk of diabetes.[1] Asthma treatments can seem to provide transient symptomatic relief of shortness of breath in individuals without asthma, and asthma medications are heavily advertised directly to consumers. We know there has been an epidemic of "asthma" diagnosed since the 1980s, but we still don't want to miss the diagnosis or fail to provide symptomatic therapy to our patients.

When my colleagues and I studied individuals in 2005 who were continuous long-term KP members and who met the HEDIS criteria for persistent asthma in any year between 1999 and 2002, a surprisingly high 48% of them met the criteria in only one of the four years. We found that in that four-year period, only 19% of them met the criteria every year.[2] Partly because of that study, the national HEDIS definition of persistent asthma was changed. Now we look at individuals who meet the criteria for at least two years in a row and see whether they are getting any preventive medication.

When we randomly sampled individuals in the KP Asthma Case Identification Database with a clinical diagnosis of asthma in San Diego in 2001, we found that more than one third of them had no evidence of reversible airflow obstruction or bronchial hyperreactivity when tested in 2003.[3] These patients' had carried a physician diagnosis of asthma for a mean of >22 years, yet before the study evaluation, only 13% of them had ever had undergone measurement of their forced expiratory volume in the first second of expiration pre- and postbronchodilator. This was surprising because 40% of them had been seen at least once by Allergy or Pulmonary Departments during their care at KP and almost 80% had at least one spirometry in their medical records. KP physicians are not the only clinicians who tend to over diagnose asthma. Similar findings have been published for large trials in Ontario, Canada.[4]

Most patients who currently have a diagnosis of asthma in their KP records have still never undergone pulmonary function testing to document reversible airflow obstruction. Among patients whose pulmonary function has been tested, many still have a diagnosis of asthma in their medical records and receive chronic asthma medications, even when the test findings were normal or negative. Methacholine challenges are done rarely to confirm bronchial hyperreactivity in individuals with clinical asthma symptoms yet repetitively normal findings on spirometry. Methacholine challenges are available in all KP medical centers, either in the Allergy Department or in the Pulmonary Laboratory, depending on the site. KP HealthConnect now can use flow sheets to track spirometry results obtained in Allergy Departments. Results for complete lung function tests done in the KP pulmonary laboratories are still generally available only as scanned reports or text.

… more than one third of them had no evidence of reversible airflow obstruction or bronchial hyperreactivity …

Patients "with asthma" who require chronic oral steroids for "control" frequently have one or more other chronic conditions that are their primary problems. They typically also have iatrogenic comorbidities. When these patients are assessed in-depth and their comorbidities are addressed, they rarely require daily oral steroids for symptom management. Some patients with true asthma will require recurrent oral steroids, but this is a rare exception, and these patients should all be treated in the Allergy or Pulmonary Department. Aspirin-exacerbated respiratory disease is often the cause of the need for oral steroids; it can be treated with aspirin desensitization.[5] Exhaled nitric oxide is a marker for eosinophilic inflammation, and a low fraction of exhaled nitric oxide argues against active asthma as the cause of shortness of breath in a person with normal spirometry findings.[6] Oral

steroids can help calm laryngeal irritation mimicking asthma, but at the price of greater obesity and severe somatic symptoms when withdrawn.

For all of the patients whose condition has been diagnosed as "asthma" and who take chronic inhaled steroids and long-acting bronchodilators or leukotriene inhibitors, the diagnosis should be confirmed by pulmonary function tests before and after bronchodilator use to document reversible airflow obstruction or should undergo a methacholine or mannitol challenge. For patients found to have normal lung function and no bronchial hyperreactivity, the other causes of their "asthma" symptoms should be addressed and treated. ❖

Disclosure Statement

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References

1. Suissa S, Kezouh A, Ernst P. Inhaled corticosteroids and the risks of diabetes onset and progression. Am J Med 2010 Nov;123(11):1001–6.
2. Mosen D, Macy E, Schatz M, et al. How well do the HEDIS asthma inclusion criteria identify persistent asthma? Am J Manag Care 2005 Oct;11(10):650–4.
3. Macy E, Schatz M, Gibbons C, Zeiger R. The prevalence of reversible airflow obstruction and/or methacholine hyperreactivity in random adult asthma patients identified by administrative data. J Asthma 2005 Apr;42(3):213–20.
4. Aaron SD, Vandemheen KL, Boulet LP, et al; Canadian Respiratory Clinical Research Consortium. Overdiagnosis of asthma in obese and nonobese adults. CMAJ 2008 Nov 18;179(11):1121–31. Erratum in: CMAJ 2008 Dec 2;179(12):1301.
5. Macy E, Bernstein JA, Castells MC, et al; Aspirin Desensitization Joint Task Force. Aspirin challenge and desensitization for aspirin-exacerbated respiratory disease: a practice paper. Ann Allergy Asthma Immunol 2007 Feb;98(2):172–4.
6. Schneider A, Tilemann L, Schermer T, et al. Diagnosing asthma in general practice with portable exhaled nitric oxide measurement—results of a prospective diagnostic study: FENO < or = 16 ppb better than FENO < or = 12 ppb to rule out mild and moderate to severe asthma [added]. Respir Res 2009 Mar 3;10(1):15. Erratum in: Respir Res 2009 Jul7;10(1):64.

Wheeze

All that wheezes is not asthma.

— Chevalier Jackson, 1865-1958, a laryngologist and pioneer of the modern science of endoscopy



"Tranquil Journey on the Yangtze"
Acrylic on canvas
9 4x4" canvases

Karen C Kwock, RN

Ms Kwock is a Nurse in the Neuroscience Department at the Moanalua Medical Center in Honolulu, HI. She studies painting at the Aiea Community School for Adults. This piece was painted from a photograph taken by Ms Kwock's son. With her extended family and 84-year-old father, they traveled to China to see the Yangtze River and the Three Gorges Dam.

CASE STUDY

Suppressed Wound Healing In a Patient with Rheumatoid Arthritis Taking Leflunomide (Arava)

D Miller Wise, MD

Abstract

Although patients with rheumatoid arthritis taking disease-modifying antirheumatic drugs (DMARDs) are monitored for various medication adverse events, DMARDs, and leflunomide in particular, have effects that are not observed clinically, specifically adverse effects on wound healing.

Introduction

Patients with rheumatoid arthritis (RA), while taking newer disease-modifying antirheumatic drugs (DMARDs), are examined clinically for decreases in morning stiffness, in joint swelling or tenderness, and for medication adverse effects. Unfortunately, DMARDs have adverse effects not seen clinically. I believe that DMARDs, and leflunomide (LEF) in particular, have adverse effects on wound healing.[1] When the patients with RA do not heal after surgery, a DMARD may be the cause. I report here the case of a patient with RA whose wound did not heal for three years, most likely because of LEF. Further study is needed to determine safe use of DMARDs for these patients when they undergo surgery.[2]

Case Report

A white woman, age 60 years, with RA of the back, shoulders, knees, and hands had obtained no benefit from nonsteroidal anti-inflammatory drugs, sulfasalazine (Azulfidine), methotrexate, prednisone, or hydroxychloroquine (Plaquenil), alone or combined. LEF (Arava) provided improved control of her RA.

A diagnosis of a large ovarian cyst in our patient led to a total abdominal hysterectomy by Pfannenstiel incision. The fascial repair would not heal, so a vacuum-assisted closure device was applied to her wound. However, an incisional hernia developed. During a period of 2 years, the hernia grew to 30 cm in diameter, and the fascia and skin wound would not heal, despite drainage procedures, mesh repair, mesh removal with repeated fascial repairs, or intermittent use of the vacuum device (Figure 1).

During review of medications and a search of the literature on LEF, I found reports of patients taking LEF for RA or autoimmune vasculitis who developed leg ulcers, poor wound healing, and complications[3–59] (Table 1). Furthermore, some patients' ulcers healed after LEF washout with cholestyramine.[4] A hypothesis grew: LEF is suppressing our patient's healing; stop it, wash it out, and she may heal.[4]

Data for serum LEF level were not available locally; distant results take time. It seemed imprudent to wait for data on serum level after repeated washout procedures and after the patient had lived with an enlarging hernia for more than two years. The patient and I agreed that the benefits of washouts outweighed the risks of waiting to confirm serum LEF level. I did two washouts of LEF with oral cholestyramine, each during a one-week period as described in the literature, and I scheduled a hernia repair with abdominal-wall reconstruction.[4–6]

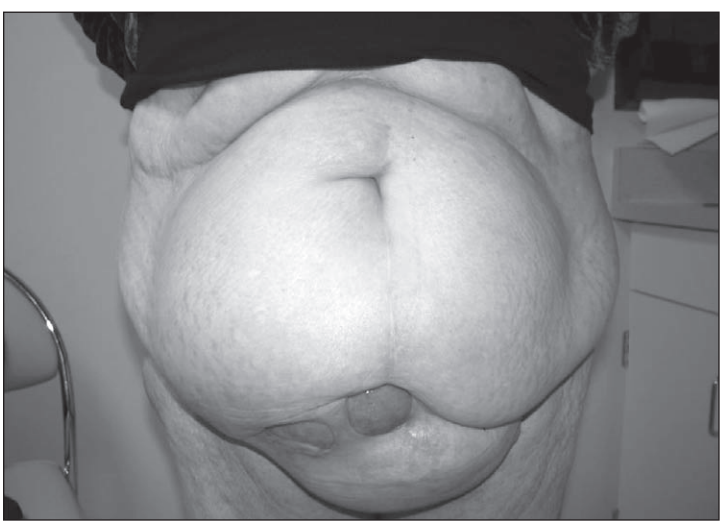


Figure 1. Appearance of wound over hernia at presentation.

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Within 10 days of the first washout, empiric evidence of healing appeared: The lower wound bled for the first time in 2 years, the granulation tissue was redder and thicker, and the lower epithelial wound border advanced 1 cm.

At surgery, the chronic wound was peeled off the bowel, and then the hernia was reduced with no enterotomies. Poorly vascularized abdominal skin was removed. We placed a single-layer underlay of AlloDerm acellular dermal matrix, with the reticular dermal side up against the peritoneum and musculofascial layer.[47–50] The AlloDerm was sutured under tension to the laterally pulling oblique muscles, taking tension off the midline closure. The rectus abdominis muscles and fascia were closed in the midline under mild tension, with no change in pulmonary compliance. Skin and subcutaneous tissue were closed without tension over suction drains.

After surgery we observed no loss of pulmonary domain, no oxygen desaturation, no supplemental oxygen need, early ambulation, no infection, no dehiscence, and no ileus. Within six months, the patient remained healed until, after minor activity, she felt a tearing in the pubic area and presented with a new suprapubic hernia.

Protein and iron stores, hemoglobin level, and hematocrit were all normal. Because LEF has been reported to leech out of bone and other tissues for up to two years after stopping the drug, and because of our empirical experience with healing during the first washouts, I elected to repeat cholestyramine washout two times, and then to repair the hernia.

During surgery, I found that the first AlloDerm repair was intact and reperitonealized with no adhesions. The new tear was several inches caudal to the AlloDerm at the rectus origin from the symphysis pubis. The repopulated AlloDerm was stronger than the rectus origin from bone. I created an underlay of another piece of AlloDerm secured into the symphysis periosteum and caudal rectus fascia, and then closed the musculofascial layer over the AlloDerm. The patient healed rapidly and has remained healed for five years (Figure 2). Unfortunately, hydroxychloroquine, etanercept (Enbrel), and newer DMARDs are now used for her severe RA.



Figure 2. After surgery, the patient remained healed.

Table 1: Reported adverse effects of leflunomide (Arava)

Hematologic
Leucopenia[59]
Anemia[59]
Pancytopenia[9,59]
Fever, thrombocytosis, leukocytosis, and relapsing polychondritis[10]
Potentiation of warfarin[11]
Dermatologic
"Skin disorder"[59]
Skin discoloration[59]
Maculopapular rash[59]
Skin ulcers[4–6,59]
Alopecia areata[12]
Erythema multiforme[13]
Exfoliative dermatitis[14]
Lichenoid eruptions[15,16]
Cutaneous lupus erythematosus[17–20]
Dermatomyositis[21]
Acute necrotizing vasculitis[7,46]
Nonhealing surgical wounds[3]
Pulmonary
Acute interstitial pneumonia, elevated liver enzymes, hypertension[59]
Lethal pneumonitis[22]
Pulmonary hypertension[23]
Pulmonary abscess[24]
Pulmonary aspergillosis[25]
Mycobacterium abscessus infection[26]
Pulmonary tuberculosis[27]
Rheumatoid lung nodulosis and osteopathy[28]
Atypical *Mycobacterium* pneumonia[29]
Infectious
Opportunistic infections[59]
Fatal sepsis[59]
Propionibacterium acnes endophthalmitis[30]
Pulmonary tuberculosis[27]
Brain abscess[31]
Postsurgical osteomyelitis[32]
Cardiovascular
Hypertension[59]
Hypertriglyceridemia[33]
Inhibition of neointima proliferation[34]
Gastrointestinal
Hepatotoxicity[59]
Diarrhea[59]
Acute, fatal hepatitis[35,36]
Liver failure[37]
Colitis[38]
Neurologic
Aseptic meningitis[39]
Brain abscess[31]
Cystoid macular edema[40]
Peripheral neuropathy[41–44]
Severe axonal sensorimotor polyneuropathy[44]
Musculoskeletal
Rhabdomyolysis[15]
Osteomyelitis[32]

Discussion

LEF, a potent anti-inflammatory, antiproliferative, and antineoplastic drug, is one of a new generation of DMARDs for use in patients with severe RA, a group of drugs that includes etanercept, infliximab (Remicade), and adalimumab (Humira).

Normal white blood cell (WBC) function and normal fibroblast function are necessary for a normal inflammatory response and wound healing. Multiple reports show that WBC and red blood cell precursor cell lines' intra- and intercellular biochemical reactions are blocked by LEF. LEF is reported to suppress or block proliferation of multiple normal WBC lines: leukocyte phagocytic antigen-presenting cells,[51] leukocyte dendritic cells,[52,53] and lymphocyte T-cells[54–57] (Figure 3). DMARDs should be considered immunosuppressive drugs, of a different class from corticosteroids.

Pyrimidine synthesis, blocked by LEF, is a key process in synovial cell production and in fibroblast collagen production. LEF therefore affects proliferation and functions of normal cell lines. LEF alters fibroblast-like synovial cell proliferation, halting progression of RA; it appears in this case to affect true fibroblasts the same way, blocking wound fibrosis and healing.

Milder adverse effects of LEF—that are not apparent clinically until the patient has a reported complication—may be treated by stopping and then restarting LEF once signs decrease.[58] However, stopping LEF is not enough to prevent suppression of wound healing after surgery. LEF leaches out of tissues for up to 2 years.[59] Surgeons should optimize conditions for wound healing, including cessation of smoking or harmful medications and the washout of suppressive DMARDs before surgery. Hernia recurrences increase with each hernia repair after the first.

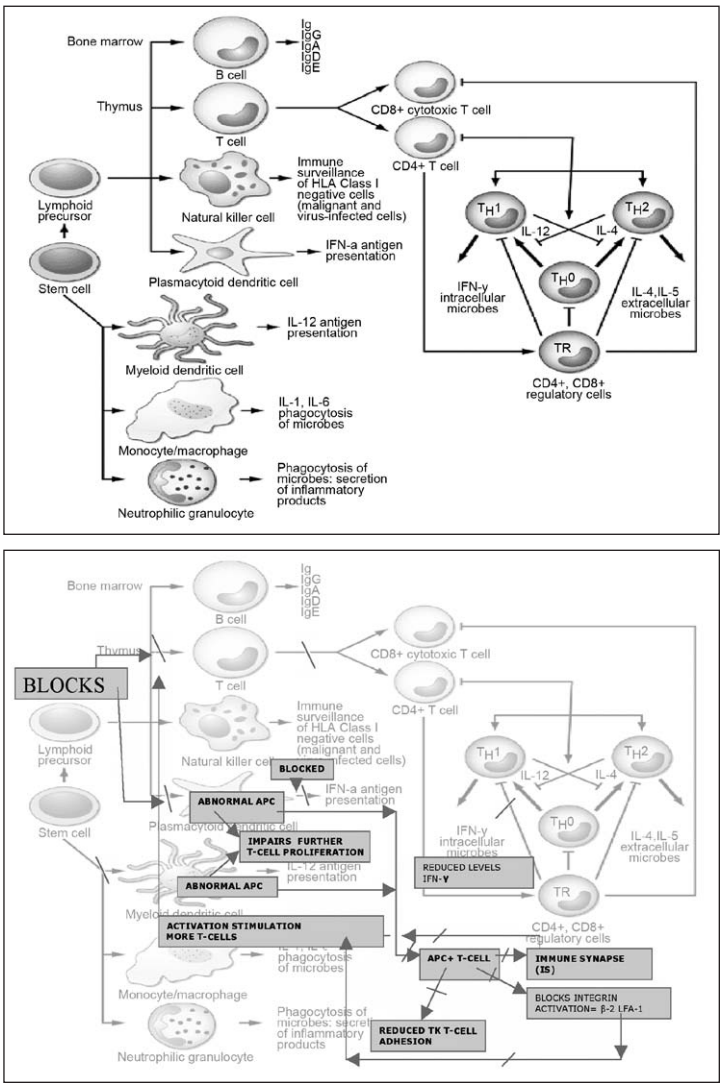


Figure 3. Normal cellular immune function (top) and adverse cellular effects of Arava (bottom).

APC = antigen-presenting cell; HLA = human leukocyte antigen; IFN = interferon; Ig = immunoglobulin; IL = interleukin; LFA = lymphocyte function-associated antigen. (Modified with permission from Part 13: disorders of the immune system, connective tissue, and joints. In: Kaspar DL, Braunwald E, Fauci AS, Hansen SL, Longo DL, Jameson JL, editors. Harrison's principles of internal medicine. 16th ed. New York: McGraw-Hill Professional; 2005. p 1923.)

Recurrence is even higher in patients with associated comorbidities such as smoking or chronic obstructive pulmonary disease, massive obesity (a body mass index >35 kg/m^2), and immunosuppression. This patient had no comorbidities other than RA treated with LEF. Her body mass index was 32 kg/m^2, and she did not smoke or have chronic obstructive pulmonary disease. She was immunocompromised by LEF.

Any patient taking DMARDs must be made aware of potentially fatal adverse effects, give informed consent, and then be closely monitored for hepatic, gastrointestinal, hematologic, infectious, pulmonary, dermatologic, and neurologic adverse effects.[3–46] The 59th edition (2005) of the *Physicians'*

Desk Reference provided little information on the adverse effects of LEF.[59] Serious adverse effects are typically learned from after-market reports[3–59] (Table 1). In 2010, the US Food and Drug Administration added a black-box warning to LEF about hepatic injury and failure. Box warnings of all serious adverse effects belong on data sheets of all DMARDs, similar to after-market warnings added in the past for chloramphenicol (marrow suppression) and for oral contraceptives (thromboembolism).

When a patient with RA needs surgery, how do the surgeon and rheumatologist manage medications to improve the likelihood of healing? The case I presented here is of a patient with RA whose lack of wound healing was most likely caused by the DMARD LEF. That hypothesis led to washout of LEF with cholestyramine. Clinical examination findings confirmed the effectiveness of LEF washout. Today, rapid local assays for serum LEF levels are available to confirm readiness for surgery.[60] I believe that further studies are needed both to define the effects of DMARDs on WBC cell lines, fibroblasts, and wound healing and to help guide the prudent management of DMARDs—or their washout—in these patients with complex needs who must undergo surgery.[2] ❖

Disclosure Statement

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

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References

1. Fuerst M, Möhl H, Baumgärtel K, Rüther W. Leflunomide increases the risk of early healing complications in patients with rheumatoid arthritis undergoing elective orthopedic surgery. Rheumatol Int 2006 Oct;26(12):1138–42.
2. Pieringer H, Stuby U, Biesenbach G. Patients with rheumatoid arthritis undergoing surgery: how should we deal with antirheumatic treatment? Semin Arthritis Rheum 2007 Apr;36(5):278–86.
3. Busti AJ, Hooper JS, Amaya CJ, Kazi S. Effects of perioperative antiinflammatory and immunomodulating therapy on surgical wound healing. Pharmacotherapy 2005 Nov;25(11):1566–91.
4. Knab J, Goos M, Dissemond J. Successful treatment of a leg ulcer occurring in a rheumatoid arthritis patient under leflunomide therapy. J Eur Acad Dermatol Venereol 2005 Mar;19(2):243–6.
5. Jakob A, Portsmann R, Rompel R. [Skin ulceration after leflunomide treatment in two patients with rheumatoid arthritis.] [article in German]. J Dtsch Dermatol Ges 2006 Apr;4(4):324–7.
6. McCoy CM. Leflunomide-associated skin ulceration. Ann Pharmacother 2002 Jun;36(6):1009–11.
7. Macdonald J, Zhong T, Lazarescu A, Gan BS, Harth M. Vasculitis associated with the use of leflunomide. J Rheumatol 2004 Oct;31(10):2076–8.
8. Chan AT, Bradlow A, McNally J. Leflunomide induced vasculitis—a dose-response relationship. Rheumatology (Oxford) 2003 Mar;42(3):492–3.
9. Chan J, Sanders DC, Du L, Pillans PI. Leflunomide-associated pancytopenia with or without methotrexate. Ann Pharmacother 2004 Jul–Aug;38(7–8):1206–11.
10. Koenig AS, Abruzzo JL. Leflunomide induced fevers, thrombocytosis, and leukocytosis in a patient with relapsing polychondritis. J Rheumatol 2002 Jan;29(1):192-4.
11. Lim V, Pande I. Leflunomide can potentiate the anticoagulant effect of warfarin. BMJ 2002 Dec 7;325(7376):1333. Erratum in: BMJ 2003 Feb 22;326(7386):432.
12. Gottenberg JE, Venancie PY, Mariette X. Alopecia areata in a patient with rheumatoid arthritis treated with leflunomide. J Rheumatol 2002 Aug;29(8):1806–7.
13. Fischer TW, Bauer HI, Graefe T, Barta U, Elsner P. Erythema multiforme–like drug eruption with oral involvement after intake of leflunomide. Dermatology 2003;207(4):386–9.
14. Bandyopadhyay D. Exfoliative dermatitis induced by leflunomide therapy. J Dermatol 2003 Nov;30(11):845–6.
15. Rivarola de Gutierrez E, Abaca H. Photodistributed lichenoid drug eruption with rhabdomyolysis occurring during leflunomide therapy. Dermatology 2004;208(3):232–3.
16. Schmutz JL, Barbaud A, Trechot P. [Drug-induced lichenoid eruptions]. [article in French]. Ann Dermatol Venereol 2006 Apr;133(4):409.
17. Elias AR, Tam CC, David-Bajar KM. Subacute cutaneous lupus erythematosus associated with leflunomide. Cutis 2005 Sep;76(3):189–92.
18. Chan SK, Hazleman BL, Burrows NP. Subacute cutaneous lupus erythematosus precipitated by leflunomide. Clin Exp Dermatol 2005 Nov;30(6):724–5.
19. Goëb V, Berthelot JM, Joly P, et al. Leflunomide-induced subacute cutaneous lupus erythematosus. Rheumatology (Oxford) 2005 Jun;44(6):823–4.
20. Kerr OA, Murray CS, Tidman MJ. Subacute cutaneous lupus erythematosus associated with leflunomide. Clin Exp Dermatol 2004 May;29(3):319–20.
21. Gómez Rodriguez N, Zulaica Garate A. [Development of dermatomyositis in a woman with rheumatoid arthritis treated with leflunomide]. [Article in Spanish]. An Med Interna 2005 Jun;22(6):300–1.
22. Vallbracht II, Popper HH, Rieber J, et al. Lethal pneumonitis under leflunomide therapy. Rheumatology (Oxford) 2005 Dec;44(12):1580–1.
23. Martinez-Taboada VM, Rodriguez-Valverde V, Gonzalez-Vilchez F, Armijo JA. Pulmonary hypertension in a patient with rheumatoid arthritis treated with leflunomide. Rheumatology (Oxford) 2004 Nov;43(11):1451–3.
24. Ulusoy H, Bilgici A, Kuru O, Celenk C. Pulmonary abscess due to leflunomide use in rheumatoid arthritis: a case report. Rheumatol Int 2005 Mar;25(2):139–42.
25. De Rosa FG, Shaz D, Campagna AC, Dellaripa PE, Khettry U, Craven DE. Invasive pulmonary aspergillosis soon after therapy with infliximab, a tumor necrosis factor-alpha-neutralizing antibody: a possible healthcare-associated case? Infect Control Hosp Epidemiol 2003 Jul;24(7):477–82.
26. Thomas JE, Taoka CR, Gibbs BT, Fraser SL. Fatal pulmonary Mycobacterium abscessus infection in a patient using etanercept. Hawaii Med J 2006 Jan;65(1):12–5.

27. Hocevar A, Rozman B, Praprotnik S, et al. Leflunomide-associated tuberculosis? Rheumatology (Oxford) 2006 Feb;45(2):228–9.
28. Rozin A, Yigla M, Guralnik L, et al. Rheumatoid lung nodulosis and osteopathy associated with leflunomide therapy. Clin Rheumatol 2006 May;25(3):384–8.
29 Takeishi M, Akiyama Y, Akiba H, Adachi D, Hirano M, Mimura T. Leflunomide induced acute interstitial pneumonia. J Rheumatol 2005 Jun;32(6):1160–3.
30. Montero JA, Ruiz-Moreno JM, Rodríguez AE, Ferrer C, Sanchis E, Alio JL. Endogenous endophthalmitis by Propionibacterium acnes associated with leflunomide and adalimumab therapy. Eur J Ophthalmol 2006 Mar–Apr;16(2):343–5.
31. Lee CS, Chang, CK. Brain abscess in rheumatoid arthritis. Ann Rheum Dis 2003 Jul;62(7):689–90.
32. Delank KS, Hansen T, Eysel P, Eckardt A. [Infections of the musculoskeletal system with chronic polyarthritis during a combination therapy with Methotrexate and Leflunomide]. [Article in German.] Z Orthop Ihre Grenzgeb 2002 Sep–Oct;140(5):555–60.
33. Laborde F, Loeuille D, Chary-Valckenaere I. Life-threatening hypertriglyceridemia during leflunomide therapy in a patient with rheumatoid arthritis. Arthritis Rheum 2004 Oct;50(10):3398.
34. Jahnke T, Schäfer FK, Bolte H, et al. 2005 Dr Gary J Becker Young Investigator Award: periprocedural oral administration of the leflunomide analogue FK778 inhibits neointima formation in a double-injury rat model of restenosis. J Vasc Interv Radiol 2005 Jul;16(7):903–10.
35. Sevilla-Mantilla C, Ortega L, Agúndez JA, Fernández-Gutiérrez B, Ladero JM, Diaz-Rubio M. Leflunomide-induced acute hepatitis. Dig Liver Dis 2004 Jan;36(1):82–4.
36. Legras A, Bergemer-Fouquet AM, Jonville-Bera AP. Fatal hepatitis with leflunomide and itraconazole. Am J Med 2002 Sep;113(4):352–3.
37. Thomasset SC, Ong SL, Large SR. Post-coronary artery bypass graft liver failure: a possible association with leflunomide. Ann Thorac Surg 2005 Feb;79(2):698–9.
38. Verschueren P, Vandooren AK, Westhovens R. Debilitating diarrhoea and weight loss due to colitis in two RA patients treated with leflunomide. Clin Rheumatol 2005 Feb;24(1):87–90.
39. Cohen JD, Jorgensen C, Sany J. Leflunomide-induced aseptic meningitis. Joint Bone Spine 2004 May;71(3):243–5.
40. Barak A, Morse LS, Schwab I. Leflunomide (Arava)-induced cystoid macular oedema. Rheumatology (Oxford) 2004 Feb;43(2):246–8.
41. Metzler C, Arlt AC, Gross WL, Brandt J. Peripheral neuropathy in patients with systemic rheumatic diseases treated with leflunomide. Ann Rheum Dis 2005 Dec;64(12):1798–800.
42. Kopp HG, Moerike K, Kanz L, Hartmann JT. Leflunomide and peripheral neuropathy: a potential interaction between uracil/tegafur and leflunomide. Clin Pharmacol Ther 2005 Jul;78(1):89–90. Erratum in: Clin Pharmacol Ther 2005 Sep;78(3):310.
43. Bonnel RA, Graham DJ. Peripheral neuropathy in patients treated with leflunomide. Clin Pharmacol Ther 2004 Jun;75(6):580–5.
44. Gabelle A, Antoine JC, Hillaire-Buys D, Coudeyre E, Camu W. [Leflunomide-related severe axonal neuropathy.] [Article in French.] Rev Neurol (Paris) 2005 Nov;161(11):1106–9.
45. Savage RL, Highton J, Boyd IW, Chapman P. Pneumonitis associated with leflunomide: a profile of New Zealand and Australian reports. Intern Med J 2006 Mar;36(3):162–9.
46. Holm EA, Balslev E, Jemec GB. Vasculitis occurring during leflunomide therapy. Dermatology 2001;203(3):258–9.
47. Scott BG, Feanny A, Hirshberg A. Early definitive closure of the open abdomen: a quiet revolution. Scand J Surg 2005;94(1):9–14.
48. McDonald MD, Weiss III CA. Human acellular dermis for recurrent hernia. Contemp Surg 2005;61:276–80.
49. Holton LH 3rd, Kim D, Silverman RP, Rodriguez ED, Singh N, Goldberg NH. Human acellular dermal matrix for repair of abdominal wall defects: review of clinical experience and experimental data. J Long Term Eff Med Implants 2005;15(5):547–58.
50. Kolker AR, Brown DJ, Redstone JS, Scarpinato VM, Wallack MK. Multilayer reconstruction of abdominal wall defects with acellular dermal allograft (AlloDerm) and component separation. Ann Plast Surg 2005 Jul;55(1):41–2.
51. Zeyda M, Poglitsch M, Geyeregger R, et al. Disruption of the interaction of T cells with antigen-presenting cells by the active leflunomide metabolite teriflunomide: involvement of impaired integrin activation and immunologic synapse formation. Arthritis Rheum 2005 Sep;52(9):2730–9.
52. Kirsch BM, Zeyda M, Stuhlmeier K, et al. The active metabolite of leflunomide, A77 1726, interferes with dendritic cell function. Arthritis Res Ther 2005;7(3):R694–703.
53. Zeyda M, Stuhlmeier K, Kirsch BM, Watschinger B, et al. The malononitrilamide FK778 inhibits activation of NF-kappaB in human dendritic cells. Transplant Proc 2005 May;37(4):1968–9.
54. Cherwinski HM, McCarley D, Schatzman R, Devens B, Ransom JT. The immunosuppressant leflunomide inhibits lymphocyte progression through cell cycle by a novel mechanism. J Pharmacol Exp Ther 1995 Jan;272(1):460–8.
55. Part 13: disorders of the immune system, connective tissue, and joints. In: Kaspar DL, Braunwald E, Fauci AS, Hansen SL, Longo DL, Jameson JL, editors. Harrison's principles of internal medicine. 16th ed. New York: McGraw-Hill Professional; 2005.
56. Austen KF, Frank MM, Atkinson JP, Cantor HI, editors. Samter's immunologic diseases, vol 1. 6th ed. Philadelphia: Lippincott Williams & Wilkins; 2001. p 53.
57. Austen KF, Frank MM, Atkinson JP, Cantor HI, editors. Samter's immunologic diseases, vol. 1. 6th ed. Philadelphia: Lippincott Williams & Wilkins; 2001. p. 55.
58. Fleischmann R. Safety and efficacy of disease modifying antirheumatic agents in rheumatoid arthritis and juvenile rheumatoid arthritis. Expert Opin Drug Saf 2003 Jul;2(4):347–65.
59. Physicians' desk reference. 59th ed. Montvale, NJ: Thomson PDR; 2005. p 673–99.
60. Sobhani K, Garrett DA, Liu DP, Rainey PM. A rapid and simple high-performance liquid chromatography assay for the leflunomide metabolite, teriflunomide (A77 1726), in renal transplant recipients. Am J Clin Pathol 2010 Mar;133(3):454-7.

ECG Diagnosis: Pulmonary Embolism

Joel T Levis, MD, PhD, FACEP, FAAEM

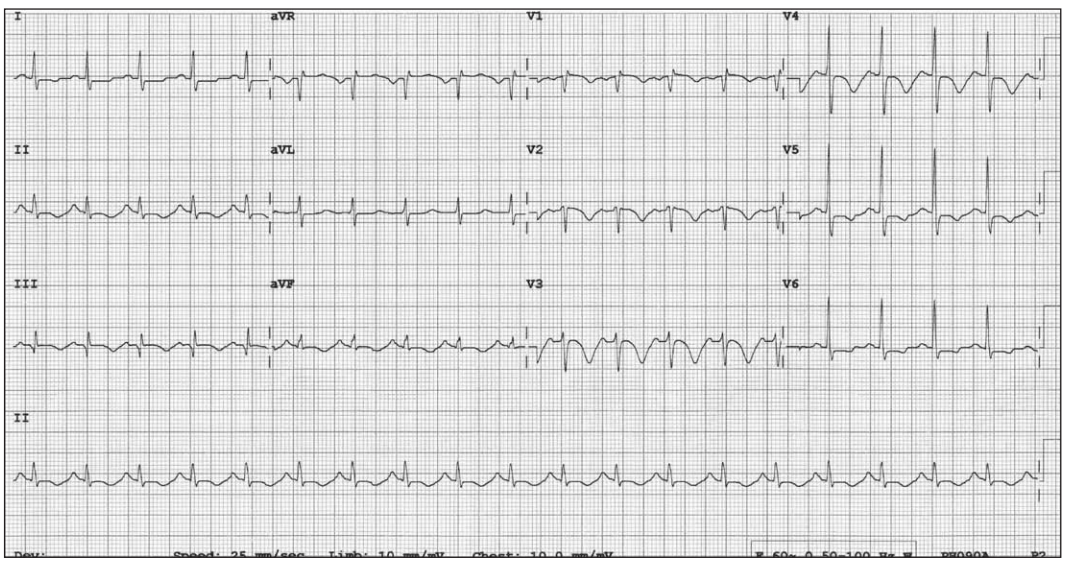


Figure 1. 12-lead ECG from a 68-year-old woman with new onset dyspnea on exertion.

Demonstrates sinus tachycardia, prominent S wave in lead I, with Q wave and T wave inversion in lead III ($S_1Q_3T_3$ sign), with inverted T waves in leads V_1-V_6. ST-segment elevation in leads aVR and V_1 is also present. A computed tomography angiogram of the chest was performed, which demonstrated multiple, bilateral pulmonary emboli (PE).

The $S_1Q_3T_3$ sign (prominent S wave in lead I, Q wave and inverted T wave in lead III) is a sign of *acute cor pulmonale* (acute pressure and volume overload of the right ventricle because of pulmonary hypertension) and reflects right ventricular strain.[1] This electrocardiogram (ECG) finding is present in 15% to 25% of patients ultimately diagnosed with pulmonary emboli (PE).[2] Any cause of *acute cor pulmonale* can result in the $S_1Q_3T_3$ findings on ECG, including PE, acute bronchospasms, pneumothorax, and other acute lung disorders. Other ECG findings noted during the acute phase of a PE include new right bundle branch block (complete or incomplete), rightward shift of the QRS axis, ST-segment elevation in V_1 and aVR, generalized low amplitude QRS complexes, atrial premature contractions, sinus tachycardia, atrial fibrillation/flutter, and T wave inversions in leads V_1-V_4.[2] The ECG is often abnormal in PE, but findings are neither sensitive nor specific for the diagnosis of PE.[3] The greatest utility of the ECG in a patient with suspected PE is ruling out other life-threatening diagnoses (eg, acute myocardial infarction). ❖

References

1. Chan TC, Vilke GM, Pollack M, Brady WJ. Electrocardiographic manifestations: pulmonary embolism. J Emerg Med 2001 Oct;21(3):263-70.
2. Ullman E, Brady WJ, Perron AD, Chan T, Mattu A. Electrocardiographic manifestations of pulmonary embolism. Am J Emerg Med 2001 Oct;19(6):514-9.
3. Rodger M, Makropoulos D, Turek M, et al. Diagnostic value of the electrocardiogram in suspected pulmonary embolism. Am J Cardiol 2000 Oct 1;86(7):807-9, A10.

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Dermatology Image: Erythema Multiforme

Joel T Levis, MD, PhD, FACEP, FAAEM



Figure 1. Erythema multiforme rash on the leg of a ten-year-old girl presenting with fevers, sore throat, and myalgias.

Erythema multiforme (EM) is a type of delayed hypersensitivity skin reaction triggered by infection or certain drugs.[1] It consists of a polymorphous eruption of macules, papules, and characteristics target lesions (central bullae or vesicle with surrounding concentric rash) distributed with a propensity for the distal extremities.[2] Although the more severe conditions of Steven-Johnson Syndrome and toxic epidermal necrolysis (TEN) may represent the same process, EM, with its minimal mucous membrane involvement and less than 10% epidermal detachment, now is accepted as a distinct condition.[2] Possible infectious causes of EM include herpes simplex virus (HSV), adenovirus, measles, mycobacterium, yersinia, and treponema pallidum.[1] Medications most often associated with EM include barbiturates, hydantoins, nonsteroidal anti-inflammatory drugs, penicillins, phenothiazines, and sulfonamides.[3] In more than 50% of cases of EM no underlying cause is found.[1] EM is a clinical diagnosis. Skin biopsy is not necessary when the clinical picture is clear, as biopsy findings in EM are nonspecific.[2] Management of EM involves determining the etiology, when possible, and treating the suspected infection or discontinuing the causal drug. Oral antihistamines and topical steroids may be used to provide symptom relief in mild cases of EM, whereas oral prednisone for one to two weeks followed by a taper may be used in patients with more severe presentations.[4] ❖

References

1. Loh KY. A 'target' skin lesion. Aust Fam Physician 2008 Nov;37(11):946.
2. Lamoreux MR, Sternbach MR, Hsu WT. Erythema multiforme. Am Fam Physician 2006 Dec;74(11):1883-8.
3. Volcheck GW. Clinical evaluation and management of drug hypersensitivity. Immunol Allergy Clin North Am 2004 Aug;24(3):357-71, v.
4. Habif TB. Hypersensitivity syndromes and vasculitis. In: Clinical Dermatology: A Color Guide to Diagnosis and Therapy. 4th ed. New York: Mosby, 2004:626-34.

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Image Diagnosis: Ultrasound in Right Lower Quadrant Pain

L Paige Sokolsky, MD
Gus M Garmel, MD, FACEP, FAAEM

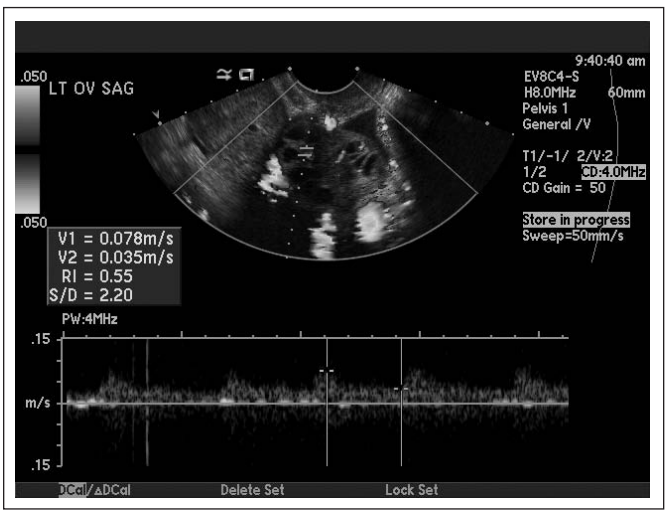


Figure 1.

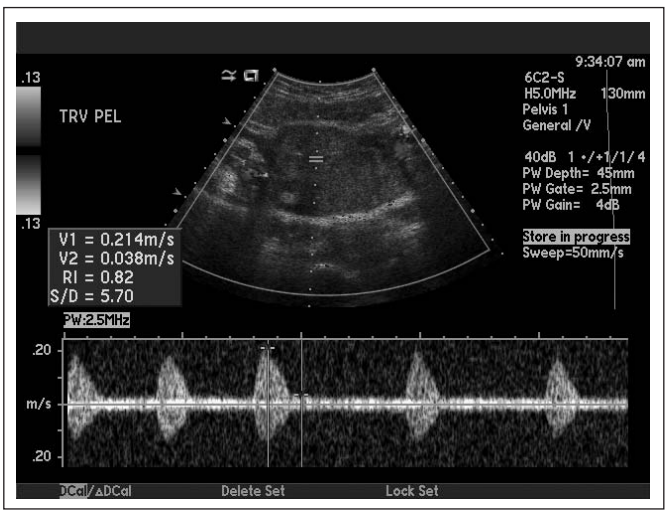


Figure 2.

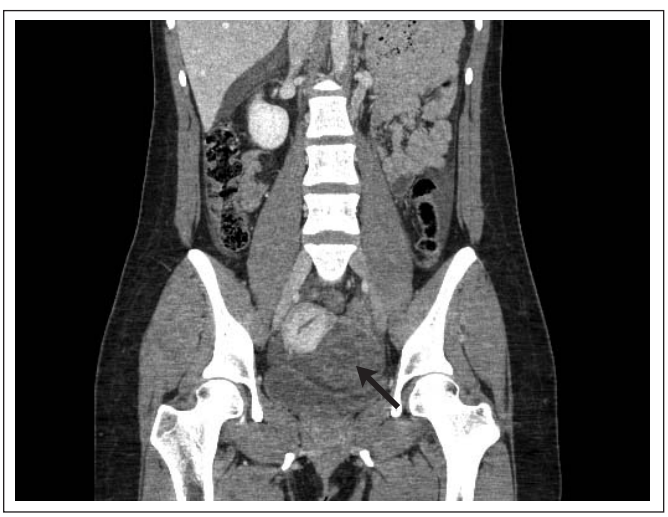


Figure 3.

Image Diagnosis: Ovarian Torsion

Ovarian torsion is classically described as an acute onset of severe lower quadrant abdominal pain, typically unilateral. Doppler ultrasound is the imaging modality of choice. Figure 1 demonstrates a normal ovary. The top half of the figure is a static gray-scale image with color Doppler; the bottom half has the corresponding spectral Doppler. Figure 2 is an enlarged, torsed ovary with peripherally displaced follicles because of vascular congestion. Because the ovary is supplied by both the ovarian and uterine arteries, a torsed ovary may have arterial flow. Resistive Index (RI), calculated as systolic flow minus diastolic flow (between 0 and 1), quantifies the resistance to blood flow in the ovary. The torsed ovary will have a high RI, close to 1, because of minimal diastolic flow, confirming the torsion. The coronal computed tomography (CT) scan (Figure 3), though not the appropriate test for diagnosis of ovarian torsion, illustrates medial displacement of the torsed and enlarged right ovary, and compression of the uterus and bladder.

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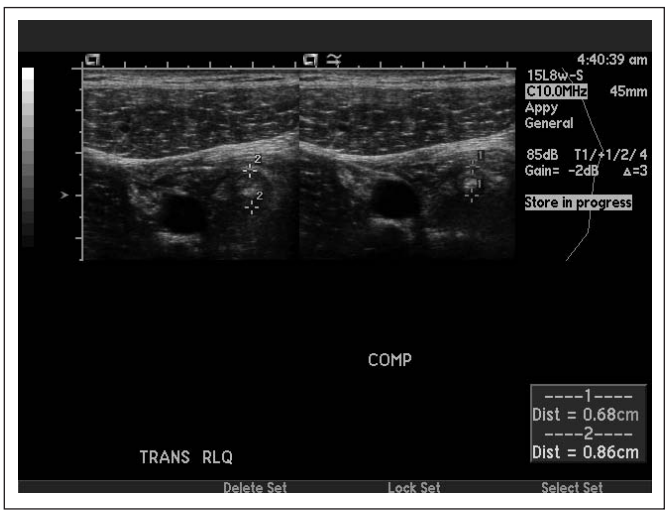


Figure 4.

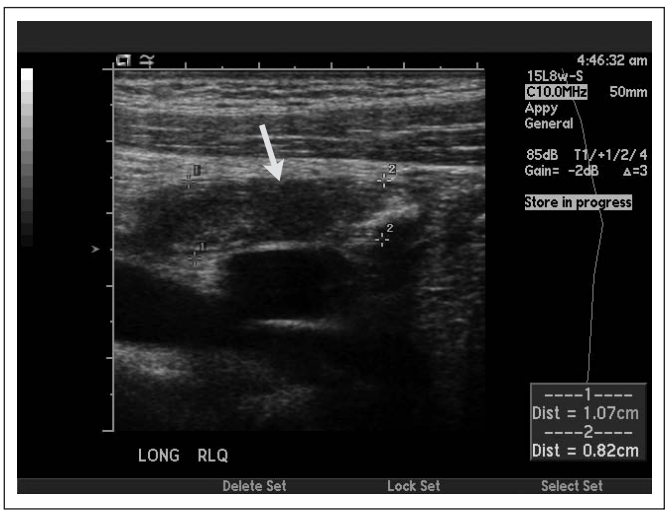


Figure 5.

Image Diagnosis: Appendicitis

In thin patients with clinical concern for appendicitis, ultrasound is an appropriate initial imaging technique. Figures 4 (axial) and 5 (transverse) depict a distended, incompressible structure at the point of the patient's maximal tenderness. Sonographic findings in acute appendicitis include appendiceal diameter greater than 6 mm, with inflamed mesentery surrounding a "target sign" lying anterior to the external iliac vessels. In Figure 6, a CT scan of the same patient confirms the ultrasound diagnosis of acute appendicitis. ❖



Figure 6.

COMMENTARY

Physician-Assisted Suicide and Euthanasia: Can You Even Imagine Teaching Medical Students How to End Their Patients' Lives?

J Donald Boudreau, MD

Abstract

The peer-reviewed literature includes numerous well-informed opinions on the topics of euthanasia and physician-assisted suicide. However, there is a paucity of commentary on the interface of these issues with medical education. This is surprising, given the universal assumption that in the event of the legalization of euthanasia, the individuals on whom society expects to confer the primary responsibility for carrying out these acts are members of the medical profession. Medical students and residents would inevitably and necessarily be implicated. It is my perspective that everyone in the profession, including those charged with educating future generations of physicians, has a critical interest in participating in this ongoing debate. I explore potential implications for medical education of a widespread sanctioning of physician-inflicted and physician-assisted death. My analysis, which uses a consequential-basis approach, leads me to conclude that euthanasia, when understood to include physician aid in hastening death, is incommensurate with humanism and the practice of medicine that considers healing as its overriding mandate. I ask readers to imagine the consequences of being required to teach students how to end their patients' lives and urge medical educators to remain cognizant of their responsibility in upholding long-entrenched and foundational professional values.

Humanism

If one accepts the definition of humanism as "a deep-seated personal conviction about one's obligation to others, especially others in need,"[1] its importance to medicine becomes incontestable. The literature is increasingly attentive to the roles of humanism in clinical practice.[2] In spite of the airtime devoted to the topic, little heed seems to have been paid to an issue, waiting in the wings, with the potential to reverberate at the very core of humanism in medicine. The issue is euthanasia. When I use the term *euthanasia* in this commentary, I am referring to "physician-inflicted death." In other words, I am asking the reader to consider a situation in which the physician is prepared to administer a lethal injection to a legally and factually competent patient who has given informed consent to the act. In many respects physician-assisted suicide raises many of the same ethical and professional issues as euthanasia because in both cases the physician is complicit in the patient's death.

There is extensive literature on the physician-assisted suicide debate. Proponents argue that physician-assisted suicide acknowledges the primacy of personal autonomy, promotes human dignity, and may represent a deeply humanizing act. Opponents raise the specter of the slippery slope, appeal to the notion that physicians must maintain an absolute repugnance to killing, and point out that autonomy and self-determination are rarely pressing concerns once people actually find themselves at the end of life.[3] This essay does not offer new empirical findings or a reconfigured conceptual framework for the debate. Rather, it anchors the dialogue explicitly in the educational context—a context in which there is a paucity of commentary on the interface of euthanasia with pedagogy. This contentious issue is not exclusively one of axiology. Pedagogic considerations are important. Regardless of which side of the argument one stands, an analysis of possible consequences on the professionalization of medical students and residents must not be neglected.

It is widely recognized that clinical educators contribute more to students' development than the acquisition of new knowledge and skills; they transmit values and participate in the forging of professional identities. They are "professionalizers." Collectively, they instill, insinuate, and instantiate a way of seeing, thinking, acting, and being in the clinical world. The socialization and

… clinical educators contribute more to students' development than the acquisition of new knowledge and skills …

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formative process is powerful and pervasive; it leads inevitably to clashes for influence over the hearts and minds of learners. It is thus not surprising that a 2008 review on the teaching of humanism emphasized the importance of role-modeling of reflection and focused mentorships.[4] Students are required to delve into many issues that are permeated with personal values and situated within belief systems. Controversies such as abortion, reproductive technologies, alternative and complementary medicine—all of these and many more—can readily challenge entrenched explanatory models and worldviews. To that list has now been added the "right to a dignified death."

Right to a Dignified Death

Discussion of this topic has become prominent in the public squares of many communities. Two recent examples are the Death with Dignity Act in Washington State in the US and bill C-384 that was before the Canadian federal government in 2010. The latter, if enacted, would have legalized euthanasia, stating, "A medical practitioner does not commit homicide if he or she aids a person to die with dignity … ."[5] It was debated in the parliament—and defeated. Whether or not it is considered part of the formal curriculum, the topic of dying with dignity—its definition(s), clinical correlates, scope, access, moral dimensions, and political overtones—has become a salient feature of the ecology of medical schools.

Euthanasia

In Western societies—often described as secular, pluralistic, liberal, and tolerant—there is a predilection to equating assisted suicide with ensuring a "good" death. In contrast, for some members of the medical profession, a more apt synonym might be *assisted self-murder.* A source of conflict may be the word *euthanasia*. Some clinicians, frustrated with lack of semantic clarity, have recommended that it be abandoned.[6] Its meaning in English has evolved. The *Oxford English Dictionary* defines the noun as "a gentle and easy death."[7] The concept of euthanasia has fluctuated since it was used in writing by Suetonius, the Roman historian. In the 19th century, it came to be understood as "the care of the dying." An 1826 Latin manuscript referred to medical euthanasia as the "skillful alleviation of suffering."[8] The physician was expected to provide for conditions that would facilitate a gentle death and was admonished: "… and least of all should he be permitted, prompted either by other people's request or his own sense of mercy, to end the patient's pitiful condition by purposefully and deliberately hastening death."[8] Euthanasia made reference to a state—a condition—at the time of death. Recently, it has acquired the notion of performance—the act of inducing a gentle and easy death. Mirroring this evolution, the words *euthanize* and *euthanatize* have been coined and are newcomers in our lexicon. The first sample sentence given by the *Oxford English Dictionary* to illustrate the use of the transitive verb *euthanize* dates to 1975.[7] The notion of physician aid in dying has accreted to the word *euthanasia* through time; it stands at a considerable distance from the word's original meaning and intention. Given the plasticity and adaptability of language, one can foresee the eventual appearance of a new noun, one that will represent the individual who performs acts of euthanasia. I refer here to that person as a "euthanatrician." The term *euthanizer* has been used.[9] Other neologisms such as *euthanologist* or *euthanasist* may eventually prevail.

Few would argue against a death characterized by gentleness. The comments that follow thus revolve around *euthanasia* cloaked in its contemporary connotation, that of hastening death—death where, when, and in the manner the patient chooses, within the customarily accepted bounds of unremitting suffering, terminal illness, and informed and voluntary consent. It has been referred to as "requested death."[10] To advance the discussion, I am prompted to consider medicine's relation with the other end of the life cycle—birth. The paper by Cane refers to "euthanasia" as "obstetrics of the soul."[8] Although there are obvious limitations to the analogy of euthanasia as delivery of the soul, it may be useful in illustrating a critical distinction. It is self-evident that an obstetrician may facilitate and be a witness to birth; however, an obstetrician can now also induce labor and delivery. Similarly, the euthanatrician could, on one hand, limit the range of action to facilitating care of the dying patient or, on the other hand, extend the scope of interventions by applying strategies to induce death. The obstetrician has a relationship to life, just as our imagined euthanatrician might have to death.

Education of a Medical Act

What might the adoption of euthanasia *as a medical act* bring into medical education, and how might it influence the nurturing of humanism? The literature is sparse concerning this issue. One can ferret out empirical studies conducted to understand the perspectives of physicians.[11,12] The attitude of medical students

toward euthanasia has been aptly described.[13,14] Investigators in locations where physician-assisted suicide has been legalized have chronicled the experiences of professionals and institutions.[15,16] Not surprisingly, there are articles on the teaching of euthanasia in veterinary medicine.[17,18] However, consideration of consequences for medical education is largely absent from the literature. With the goal of consciousness-raising, I will suggest what these may consist.

Medical schools, which are expected to be socially responsive, would have to respond with targeted initiatives. Although one might anticipate residency education to be more directly affected, impacts throughout the education continuum can be anticipated. Modules in euthanasia would be proposed, and notwithstanding traditional arguments that curricula are overburdened with content, an academic home would be found. The process would necessitate the identification of specific objectives in knowledge, skills, and attitudinal domains. The call for integration of basic sciences (eg, physiology of dying) with clinical concerns (eg, advanced communication-skills training in end-of-life talk) would be inevitable. There would be negotiations between academic units for leadership, and bioethicists would be commandeered into service roles. Ethicists would surely be in demand to help uncover moral boundaries and, as is evident in veterinary medicine, be called on to negotiate ethical tensions.[19] Conceivably, internecine battles would erupt in certain institutions. Sources of conflicts and distress have already been outlined by a palliative-care team in a Swiss hospital.[20] Diametrically opposed viewpoints, even between colleagues within the same medical specialty, have been recorded in the peer-reviewed literature.[21,22]

For competency-based programs, there would be an impetus to clarify "competency" in euthanasia. Because this approach rests on a foundation of unambiguous, measurable, and enabling outcomes,[23] the idea of proficiency in expediting death would have to be explored. Leaders in undergraduate education would have to decide whether to accept it as a core competency and resolve whether medical students' responsibility should be confined to the communicative and decision-making process with patients and families or whether it should include procedural skills. If it were considered most appropriate to limit medical students' involvement to ethical discussions, clinical supervisors could in theory deploy emergent clinical practice guidelines. An eight-step approach of potential use to physicians facing requests for physician-assisted suicide has already been published.[24] One can foresee a need for addressing issues such as assessment of performance, level of competency in euthanasia based on levels of training, graded responsibility for resident teaching in the skill of "euthanizing," and requirements (eg, numbers of procedures observed and/or performed) for maintenance of competence. As unimaginable as these notions may appear, euthanasia could not—indeed should not—be exempt from standard discussions attendant to any new curricular objective. Parallel to the deployment of modified educational programs, the clinical discipline would become increasingly complex. It is hardly far-fetched to envision the emergence of evidence of best practices. Accreditation bodies would likely be subject to efforts by various stakeholder groups to formulate additional standards relating to physician aid in hastening death. Developments would inevitably mirror the experiences of academic institutions with respect to the issue of abortions. For example, the Accreditation Council for Graduate Medical Education has set forth guidelines mandating that residencies in obstetrics and gynecology must include learner experiences in induced abortion.[25] The Association of Professors of Gynecologists and Obstetricians has listed abortion as a core objective for medical students.[26] A long-established volunteer group, Medical Students for Choice, has successfully lobbied academic centers to expand abortion training.[27]

A New Corpus?

Finally, as preposterous as it may appear at first glance, credentialing bodies might be pressured to confer recognition on a new corpus. Given the unceasing pressure for specialization, the profession might witness the birth of a new discipline. I refer to it here as "euthanatrics." The notion of a new specialty for assisting in death is not an original concept; in an argument in favor of conferring the responsibility for euthanizing on the legal profession, it was called "legistrothanatry."[28]

Laws legalizing euthanasia and/or physician assistance in dying have been enacted in the US in Oregon, Washington, and Montana and in the Netherlands and Belgium. Early reports of the impacts of evolving jurisprudence have identified areas of concern. One account examining the transcript of a conversation between a patient requesting assisted suicide and her physician identifies lacunae in the consent-seeking process.[29] A formal assessment by the Dutch Ministries of Health and Justice of their 2002 law recommended

that "[p]hysicians should be further educated on the effects and side effects of morphine and benzodiazepines so that they can *select the correct medicines* if life termination is the envisaged objective"[15] (emphasis added). In the report's "Quality Improvement" section, the regional euthanasia review committees are described as having the option of inviting physicians whose adherence to standards of due care are deemed lacking for an "instructive talk."[15] Although this is a somewhat overbearing reformulation of formative feedback, it does presage quality-assurance issues that the profession will be required to address if obliged to prepare itself for delivery of services related to physician-assisted suicide.

... two of the desired behavioral characteristics of the healer include "presence" and "accompaniment."

Is this trajectory toward euthanatrics desirable? Do we wish to embrace a discipline that has the induction of death as one of its defining clinical acts? How would undergraduate programs, such as the one I am affiliated with, currently renewing itself on the assumption that the primary mandate of medicine is healing,[30] reconcile its foundational premise with the goal of physician-assisted suicide? As much as the original conception of euthanasia—the skillful relief of suffering—is harmonious with an emphasis on healing, its evolving meaning is (arguably) in conflict. I would predict that many physicians would recoil at the prospect of being called on to become authentic role models for euthanatricians. Attempts at integrating "intentional hastening of death" into the clinical methods taught in many schools might call their cohesive force into question. For example, at our school two of the desired behavioral characteristics of the healer include "presence" and "accompaniment."[31] In the context of physician-assisted suicide, would these attributes then come to be seen as facultative or of secondary importance? To accept euthanatrics and much of what it entails (eg, the obligation to select the correct medication for life termination) as core content risks undermining the curriculum's conceptual framework. This development has the potential to erode commitments to whole-person care, which many believe includes the potential for a transformational, perhaps transcendental, movement toward personal integrity—even in the face of death.

Healing and Euthanizing—Miscible?

My personal belief is that healing and euthanizing are simply not miscible. I believe it to be expressly true in medical schools, which are crucibles of professional identity formation. However, it must be acknowledged that divergent viewpoints exist. For example, it is intriguing that the institutional motto for the medical school of the Oregon Health & Science University is "Where healing, teaching and discovery come together."[32] Though it is located in a US state with legislation that permits physician-assisted suicide, and presumably the school's programs have addressed issues related to Oregon's Death with Dignity Act, it continues to fly the banner of healing. This situation points either to the existence of alternative perspectives or to conflicting values (the latter perhaps unrecognized or ignored). The presence of ethical tensions within hospices in Oregon, as they face the challenge of respecting the Death with Dignity Act while simultaneously striving to adhere to their institutional values, has already been documented.[33] It is therefore not a flight of fancy to speculate that similar tensions may be experienced by members of the academic community in that jurisdiction. Regardless of one's personal beliefs, it is incumbent on medical educators to consider the consequences of teaching euthanasia—that is, as the word is understood today—of teaching an act intended to hasten death.

Surely, all readers would agree that we need to teach *eu*-thanasia, euthanasia as described in 1826: compassionate, competent, and consummate care of the dying. A more debatable point is: To what extent should we, as a profession inextricable from humanism, travel down the road toward euthanatrics? Responses to this question must take into account both professional and personal values.

Undeniably, physicians endorsing pro-euthanasia legislation have honorable intentions, motivated by humane considerations grounded in prima facie ethical principles such as respect for dignity (even though there are deeply conflicting views on what such respect requires). Whatever the views in this regard, it is nonetheless plausible that proponents of euthanasia may be blind to unintended harmful consequences, especially at institutional and societal levels. What would legalizing physician-assisted suicide do to the institutions of medicine and law, to the medical profession, and to fundamental societal values, in particular respect for each individual human life and human life in general? Ethicist Margaret Somerville has argued that in secular societies, medicine and law are the principal carriers of these values. She describes the medical profession and its related institutions as "value-creating, value-carrying and consensus-forming for society as a whole"[34] As a consequence, it should be obvious

that we share a profound obligation to consider the implications of our actions on this value-laden system. In the case of legalized physician-mediated suicide, harm may be done to the profession and to those charged with replenishing its membership.

A physician's assistance in suicide can indeed be construed as helping the patient: helping in the sense of being an ally in the patient's quest to fulfill personal goals, or helping by buttressing individual autonomy. However, there are also features of such action that can be qualified as harmful: harmful by sowing confusion in trainees about the conceptual core of traditional clinical methods, or harmful by eroding respect for absolute moral values such as "do not kill."[35]

The phrase *primum non nocere* is greatly cherished by the profession. It is the first "golden rule" that we transmit to our junior colleagues. Another related but less well known phrase, used by medical luminaries such as Thomas Syndenham[36] and James Makittrick Adair[37] is *juvantia et laedenti*. It is derived from the Latin verbs *iuvo* ("help") and *laedo* ("hurt"). I propose that in our deliberations about euthanasia, we keep in our collective imagination the notion of *juvantia et laedentia*: "things that [can] help and things that [can] harm." ❖

Disclosure Statement

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References

1. Cohen JJ. Viewpoint: linking professionalism to humanism: what it means, why it matters. Acad Med 2007 Nov;82(11):1029–32.
2. Miller SZ, Schmidt HJ. The habit of humanism: a framework for making humanistic care a reflexive clinical skill. Acad Med 1999 Jul;74(7):800–3.
3. Cook M. From a doctor who changed her mind [Web log on the Internet]. Sydney, Australia: MercatorNet—New Media Foundation, Ltd: Careful!; 2011 Apr 9 [cited 2011 Sep 28]. Available from: www.mercatornet.com/careful/view/8965.
4. Stern DT, Cohen JJ, Bruder A, Packer B, Sole A. Teaching humanism. Perspect Biol Med 2008 Autumn;51(4):495–507.
5. Bill C-384. Parliament of Canada, Bill C-384, No: 40-2, Hansard-57 (May 13, 2009).
6. Kuiper M, Whetstine LM, Holmes JL, et al. Euthanasia: a word no longer to be used or abused. Intensive Care Med 2007 Mar;33(3):549–50.
7. Oxford English Dictionary [dictionary on the Internet]. Oxford, UK: Oxford University Press. © 2011 [cited 2009 Dec 10]. Available from: www.oed.com.
8. Cane W. "Medical euthanasia"; a paper, published in Latin in 1826, translated and reintroduced to the medical profession. J Hist Med Allied Sci 1952;7(4):401–16.
9. Veatch RM. The impossibility of a morality internal to medicine. J Med Philos 2001 Dec;26(6):621–42.
10. McInerney F. "Requested death": a new social movement. Soc Sci Med 2000 Jan;50(1):137–54.
11. Curlin FA, Lawrence RE, Chin MH, Lantos JD. Religion, conscience, and controversial clinical practices. N Engl J Med 2007 Feb 8;356(6):593–600.
12. Peretti-Watel P, Bendiane MK, Galinier A, et al. French physicians' attitudes toward legislation of euthanasia and the ambiguous relationship between euthanasia and palliative care. J Palliat Care 2003 Winter;19(4):271–7.
13. Clemens KE, Klein E, Jaspers B, Klaschik E. Attitudes toward active euthanasia among medical students at two German universities. Support Care Can 2008 Jun;16(6):539–45.
14. Karlsson M, Strang P, Milberg A. Attitudes toward euthanasia among Swedish medical students. Palliat Med 2007 Oct;21(7):615–22.
15. Gevers S. Evaluation of the Dutch legislation on euthanasia and assisted suicide. Eur J Health Law 2007 Dec;14(4):369–79.
16. Ganzini L, Harvath TA, Jackson A, Goy ER, Miller LL, Delorit MA. Experiences of Oregon nurses and social workers with hospice patients who requested assistance with suicide. N Engl J Med 2002 Aug 22;347(8):582–8.
17. Cohen-Salter C, Folmer-Brown S, Hogrefe KM, Brosnahan M. A model euthanasia workshop: one class's experience at Tufts University. J Vet Med Ed 2004 Spring;31(1):72–5.
18. Martin F, Ruby KL, Deking TM, Tauton AE. Factors associated with client, staff, and student satisfaction regarding small animal euthanasia procedures at a veterinary teaching hospital. J Am Vet Med Assoc 2004 Jun 1;224(11):1774–9.
19. Morgan CA, McDonald M. Ethical dilemmas in veterinary medicine. Vet Clin North Am Small Anim Pract 2007 Jan;37(1):165–79; abstract x.
20. Pereira J, Anwar D, Pralong G, Pralong J, Mazzocato C, Bigler JM. Assisted suicide and euthanasia should not be practiced in palliative care units. J Palliat Med 2008 Oct;11(8):1074–6.
21. Hamilton NG, Hamilton CA. Competing paradigms of response to assisted suicide requests in Oregon. Am J Psychiatry 2005 Jun;162(6):1060–5.
22. Ganzini L. Physician-assisted suicide. Am J Psychiatry 2006 Jun;163(6):1109–10; author reply 1110.

23. Albanese MA, Mejicano G, Mullan P, Kokotailo P, Gruppen L. Defining characteristics of educational competencies. Med Educ 2008 Mar;42(3):248–55.
24. Emanuel LL. Facing requests for physician-assisted suicide: toward a practical and principled clinical skill set. JAMA 1998 Aug 19;280(7):643–7.
25. ACGME Program Requirements for Graduate Medical Education in Obstetrics and Gynecology [monograph on the Internet]. Chicago: Accreditation Council for Graduate Medical Education; effective 2008 [updated 2011 Jul 1] [cited 2011 Sep 28]. Available from: www.acgme.org/acWebsite/downloads/RRC_progReq/220obstetricsandgynecology01012008.pdf.
26. Epsey E, Ogburn T, Leeman L, Nguyen T, Gill G. Abortion education in the medical curriculum: a survey of student attitudes. Contraception 2008 Mar;77(3):205–8.
27. Steinauer J, LaRochelle F, Rowh M, Backus L, Sandahl Y, Foster A. First impressions: what are preclinical medical students in the US and Canada learning about sexual and reproductive health? Contraception 2009 Jul;80(1):74–80.
28. Sade RM, Marshall MF. Legistrothanatry: a new specialty for assisting in death. Perspect Biol Med 1996 Summer;39(4):547–9.
29. Foley K, Hendin H. The Oregon report. Don't ask, don't tell. Hastings Cent Rep 1999 May–Jun;29(3):37–42.
30. Boudreau JD, Cassell EJ, Fuks A. A healing curriculum. Med Educ 2007 Dec;41(12):1193–201.
31. Boudreau JD, Cruess SR, Cruess RL. Physicianship: Educating for professionalism in the post-Flexnerian era. Perspect Biol Med 2011 Winter;54(1):89–105.
32. Oregon Health & Science University School of Medicine [homepage on the Internet]. Portland (OR): Oregon Health & Science University; © 2001–2011 [cited 2010 Oct 1]. Available from: www.ohsu.edu/xd/education/schools/school-of-medicine/.
33. Campbell CS, Cox JC. Hospice and physician-assisted death: collaboration, compliance, and complicity. Hastings Center Rep 2010 Sep–Oct;40(5):26–35.
34. Somerville M. When doctors swear to do no harm, it is implied that they should take no lives [monograph on the Internet]. Toronto, Ontario, Cananda: The Mark; 2009 Nov 10 (updated 2010) [cited 2011 Oct 1]. Available from: www.themarknews.com/articles/655-why-euthanasia-is-bad-for-doctors.
35. Pellegrino ED. Some things ought never to be done: moral absolutes in clinical ethics. Theor Med Bioeth 2005;26(6):469–86.
36. Sydneham T. The works of Thomas Sydenham, MD. [1883] Translated from the Latin edition of Dr Greenhill with a life of the author by R.G Latham. Birmingham (AL): Classics of Medicine Library; 1979. p 362.
37. Adair JM. Commentaries on the principles and practice of physic. London: J Balfour, at Edinburgh [1772]. Farmington Hills (MI): Gale Eighteenth Century Collections Online; 2010.

Mercy

Lord Verulam [Sir Francis Bacon] blames physicians for not making the euthanasia a part of their studies: and surely though the recovery of the patient be the grand aim of their profession, yet where that cannot be attained, they should try to disarm death of some of its terrors, and if they cannot make him quit his prey, and the life must be lost, they may still prevail to have it taken away in the most merciful manner.

— Commentaries on the History and Cure of Diseases*, Ch 51, William Heberden, 1710-1801, English physician*

COMMENTARY

Bridging Physician-Patient Perspectives Following an Adverse Medical Outcome

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"Human error and systems conditions periodically align and combine to contribute to unanticipated adverse outcomes for patients. What is most important is the manner in which we handle these adverse outcomes. Patient safety and clinician welfare will be best served if we are honest about unanticipated adverse outcomes with our patients, open with our colleagues and ourselves, and able to handle such occurrences with sympathy and empathy for our patients and our colleagues."

— Kaiser Permanente's Statement of Principle, from the Implementation Guidelines for Communicating Unanticipated Adverse Outcomes, October 2002[1]

During the course of physician-patient interactions in today's increasingly complex health care environment, conflict inevitably arises. Advances brought on by modern medical technology—effective drugs, accurate tests and diagnoses, physiological processes mapped and documented in electronic medical records—have raised the bar for consumer expectations of health care professionals. Physicians are held to very high standards, sometimes leaving them and their patients ill-equipped to cope with medical complications and unexpected outcomes. In the aftermath of an unanticipated adverse outcome, how health care professionals deal with errors has gained greater importance and attention, and has led to the creation of Kaiser Permanente's (KP) HealthCare Ombudsman/Mediator (HCOM) program in 2003.[2,3] (See sidebar: HealthCare Ombudsman/Mediator Program: Overview.)

The HCOM is involved in a variety of cases, ranging from unanticipated adverse outcomes and medical errors to physician-patient communication breakdown and patient dissatisfaction with treatment outcome or quality of care. Anyone who has an interest in the medical care of a patient may make a referral to the HCOM. To support better physician-patient communication, the HCOM actively listens to patient concerns, makes informal inquiries within the health organization, seeks answers to those concerns, and facilitates frank and transparent discussions between patients and physicians. In preparation for these conversations, the HCOM will help physicians deal with their own reactions to these events and help frame thoughtful responses, particularly when an apology is warranted.

The following case is based upon a true story and presented to illustrate how divergent physician and patient perspectives can be bridged following an adverse outcome. The patient's daughter provides insight into her mother's experience and how it affected their family. The physician offers his point of view and thought process before initiating a disclosure conversation. The HCOM's role is to understand the parties' competing perspectives, find commonality in their objectives, unite them in overcoming earlier mistrusts and fears, and ensure that both parties emerge with a better understanding of the other's intentions.

The Patient's Story

Until my mother went through this experience, it never occurred to me how much medical professionals ask of us. Our family was asked to entrust the care of our loved one to strangers, her life and health to a system that sometimes creates barriers for the sake of efficiency. Then in the face of an error we are expected to stay quiet and accept this devastating impact on our loved one.

My 75-year old mother was plagued with multiple medical problems and consequently, I was very involved in her care. My mother was not a complainer and tolerated more pain than necessary. So, when she began complaining of pain in her left knee, we knew surgery might be imminent. However, as other medical problems needed resolution, she waited a long time for her total knee replacement.

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Finally, the surgery occurred, leaving us with the hope my mother's knee pain would resolve. Two weeks into her recuperation, however, her surgeon informed us that something had gone wrong. They inserted the wrong part in my mother's knee during surgery. I couldn't believe it. I was afraid once my mother was admitted for surgery she would become a number, no longer a person but a body part awaiting repair. My worst fears were realized. Worse yet, I was the one who talked my mother into getting this surgery. Although I appreciated his honesty, this was not the outcome my mother expected. And why did he wait two weeks to admit his error?

I felt somehow responsible. I had advocated for my mother to have this surgery. How could I have let this happen on my watch? Now she needed a second surgery and I worried that she may not be comforted by my advice. How was she ever going to trust her doctor again after all that had happened? This experience left us reeling and we didn't know who to turn to.

Working with the HCOM was initially not a consideration; however, the HCOM explained her role as a neutral mediator who could facilitate our meeting with the doctor to address our many unanswered questions. Although I was still angry and frustrated and unsure the HCOM's involvement would lead to a productive conversation, it seemed the only way we were to get some answers and get mom the care she needed.

When my mother and I finally met with the physician, I sensed he was nervous and tentative, worried about how we were going to react to what he would share with us. He talked us through the surgery in detail, even showing us models of parts he used during surgery and explaining the function of each. He did so with patience and kindness, reminding me why we trusted him in the first place. He was a well-intended doctor having my mother's best interests at heart; a human being who simply had made a mistake. He thoughtfully offered to assist us in choosing another surgeon if we preferred not to have him perform my mother's repeat surgery. Although I anticipated my mother's anxiety, I knew there would be no other physician she would trust. It felt as though we had been on a long and difficult journey with him and it made sense for us to continue to travel this road together.

My mother and I really valued meeting with her physician who gave us a better understanding of the events surrounding her surgery. I recall how hesitant we were to bring forward our initial concerns, fearing we could compromise my mother's future care. I feel fortunate to have found a resource in the HCOM; she was honest, genuine and treated our entire family with respect and dignity, particularly during those times when we felt isolated and alone. Ultimately, it was the HCOM who reached out and supported us, helping to restore our faith in the physician's integrity and KP's efforts to prevent this error from happening to others. From the beginning we have said we believe things happen for a reason. My mom was chosen as she was strong enough to survive and because of what happened to her, care will be safer for other patients.

The Physician's Story

As a trained, experienced orthopedic surgeon having performed hundreds of knee arthroplasties in my career, I know surgical misadventures are an inherent risk of invasive surgery. But inserting a wrong femoral component into a patient is not something I'd ever done before. How could I have made such an obvious mistake? I recounted all the events of that day, retraced every step and wondered, and perhaps hoped it was someone else's misstep that caused the error. Even if that were true, I knew as primary surgeon I

HealthCare Ombudsman/Mediator Program: Overview

The HealthCare Ombudsman/Mediator (HCOM) Program was established within Kaiser Permanente (KP) in 2003. There are 28 HCOMs serving KP in both Northern and Southern California. Although the primary HCOM focus is to resolve patient disputes regarding the quality of care, for which there is over a 90% satisfaction rate among clinicians and staff, significant time (hundreds of hours) is spent educating physicians and clinicians how to:

- communicate unanticipated adverse outcomes or medical error
- better listen and appreciate a patient's perspective of an adverse event
- facilitate a sincere apology when warranted
- re-establish clinician-patient trust through transparent communication regarding medical care.

The HCOM program is but one aspect of a fully integrated approach in handling unanticipated adverse outcomes. This approach also includes the Situation Management Team (SMT), Medical Legal and Early Resolution Payments (ERP), Communicating Unanticipated Adverse Outcomes (CUAO) training programs and formal processes contained within Quality, Risk Management and Member Services.

had to assume responsibility for what had happened and others would hold me accountable as well. Then I worried how this would affect my reputation, if I had put my medical license and livelihood at risk? How would I explain myself to a peer review? Then I had a rescuing thought; inserting the wrong prosthesis can be an incidental episode that happens during surgery without necessarily affecting the overall outcome. I decided to wait and see how the patient responded to the procedure. If she responded well, I saw no reason to worry her needlessly.

As days passed, then a week, I struggled with my decision to withhold this information from the patient and her family. I sought reassurance in medical literature and discussed the event with colleagues, still hoping the wrong prosthesis wouldn't cause a problem. Yet, the more information I discovered, the more I became aware that my patient may endure unexpected complications and require a second operation. One colleague suggested I speak confidentially with the HCOM. I was reticent to share my story with a nonphysician but did so anyway not knowing what to expect.

I approached the HCOM and asked if she thought I needed to disclose the error to the patient. She advised exactly that which I feared most—disclosure. Observing my hesitancy, she advised I consult with the Assistant Physician-in-Chief of Risk who also counseled disclosure. The decision was now clear; the way to go about it was not.

Fearing the disappointment and anger my patient and family would likely show me, the HCOM prepared me for this conversation, suggesting I use my anatomy model and sample surgical parts to help explain the wrong prosthesis inserted and its possible consequences. She also advised me to let the patient and family know this error is being taken very seriously and we are looking into how this happened so we can make sure it doesn't happen to someone else.

Two weeks had passed since the surgery and I anxiously waited to meet with the patient and family to discuss my surgical mishap. As I did so, I awkwardly felt a sense of relief in telling the truth and apologizing for any harm I may have caused, even as I feared the backlash of anger that was sure to follow. However, the patient became only tearful and disheartened as I explained the need for a revision surgery. The family consoled her and appreciated my honesty, although clearly disappointed with the news. I offered, for the patient's consideration, the option of choosing another surgeon for her second operation.

Days later, the family informed me of their wish that I perform the corrective surgery. My patient expressed her trust in me, noting the importance of our long-standing relationship to her successful knee repair and recovery. I had graciously been given a second chance and looked forward to performing her surgical repair. As the surgery day arrived, the patient's daughter told me how difficult it was to persuade her mother to undergo a second surgery; I again experienced a pang of conscience simultaneously with a resolve to set things right. The surgery, in fact, did go well. I remained vigilant if not anxious to see if my patient would recover without complication, which she did. Thereafter, I followed-up with my patient and her family, explaining the systemic changes made to prevent a wrong part from ever being introduced during a surgical procedure.

This process of explaining myself, opening me up to colleague scrutiny and patient disappointment, was by no means easy. Nevertheless, I know the price paid was infinitely less than living with the thought I had caused harm to a patient and did nothing to remedy it with a truthful disclosure and a heartfelt apology.

The orthopedic surgeon in our story, not unlike the patient's daughter, experiences mental anguish and soul-searching. As commonly occurs, this physician questions his competence, relentlessly revisiting details of his patient's surgery in his awakened mind and sleepless nights. Nothing prepares physicians for how to appropriately respond to errors, as an atmosphere of mastery, precision, and competency pervades their rigorous medical education and training. The competitive nature underlying one's medical training does not encourage physicians to easily share guilt, fear, and uncertainty with colleagues.[4] Moreover, a medical error of this import may thrust the physician into the unfamiliar and intimidating medical legal world, further isolating him and threatening his medical reputation.

Physicians are healers who have taken a sacred oath to "do no harm." … Going back and picking up communication that has been dropped can bring healing to a difficult situation.

Physicians are healers who have taken a sacred oath to "do no harm." To the physician, it can be demoralizing when years of rigorous education and training, all designed to help the patient, result in harm. The initial impulse may be to turn away from the patient who was harmed, even though this is the time they need their physician the most.[4] Obviously, a medical error is devastating, but in its aftermath, miscalculating what is important to the patient and the family can

make things worse. Going back and picking up communication that has been dropped can bring healing to a difficult situation. Stepping closer to the flame is counterintuitive, but it is exactly what is needed. This physician and patient were courageous enough to take that step.

It is an HCOM's responsibility to connect these two very different stories in a way that creates a new story of collaboration and relatedness. Stories such as these take on a life of their own and become the road map for everything that befalls the patient and the physician. The more the stories are retold, the more divergent the different perspectives become. Yet, the common theme between these two stories is humanness. The physician and the family both feel guilt for their role in what occurred, each feeling accountable and invested in the patient's well-being. An HCOM's intervention is instrumental in assisting physicians and patients to restore a trusting relationship. Re-established communication following an unanticipated adverse outcome often yields a deeper, more meaningful relationship than existed before: a relationship built on collaboration, understanding, and respect.[5] Highly skilled and expertly trained HCOMs draw upon their diverse backgrounds and disciplines to identify participants' differing perspectives, share individual feelings and draw parallels between their common experiences and intentions. Participants are moved beyond their respective roles as physician and family to embrace their shared humanity and concern for a better outcome, not just for this patient but for others who follow.

Ultimately, the HCOM's goal is to help the patient, family, and care team inhabit their best version of themselves by being honest and transparent in their communications. Donald Berwick, MD, Administrator for the Centers for Medicare and Medicaid Services and former President and CEO of the Institute for Healthcare Improvement writes, "… extend transparency to all aspects of care, including science, costs, outcomes, processes, and errors. Apologize when things go wrong."[6] Through skillful shuttle diplomacy and face-to-face mediation, the HCOM process allows both physicians and patients to gain insight into the other's inner narrative, moving ever closer to resolution. ❖

References

1. Regional support capabilities: Quality, service, and performance improvement—risk management and patient safety: Communicating unanticipated adverse outcomes and situation management teams (CUAO/SMT) [Web page on the Internet]. Oakland, CA: The Permanente Federation; 2011 [cited 2011 Jul 24]. Available from: http://kpnet.kp.org/permfed/support/improvement/risk/cuoa.html.
2. When things go wrong: responding to adverse events. A consensus statement of the Harvard hospitals [monograph on the Internet]. Boston, MA: Massachusetts Coalition for the Prevention of Medical Errors; March 2006 [cited 2011 Jul 20]. Available from: www.macoalition.org/documents/respondingToAdverseEvents.pdf.
3. Department of Care and Service Quality: Healthcare Ombudsman/Mediator [homepage on the Internet]. Oakland, CA: Kaiser Permanente; updated 2011 [cited 2011 Jul 20]. Available from: http://kpnet.kp.org/qrrm/risk/HCOM3/hcom_index.htm.
4. Delbanco T, Bell SK. Guilty, afraid, and alone—struggling with medical error. N Engl J Med 2007 Oct 25;357(17):1682-3.
5. Winslade J, Monk G. Narrative mediation: a new approach to conflict resolution. San Francisco, CA: Jossey-Bass: 2000.
6. Berwick D. What 'patient-centered' should mean: confessions of an extremist. Health Aff (Millwood) 2009 Jul-Aug;28(4):w555-65.

Suggested Reading

1. Clark K. Advocacy in health care: a sample of state and private systems. Dispute Resolution Magazine 2010 Spring;16(3):10-12. Available from: www.servantlawyership.com/my_slideshow/Advocacy%20in%20Health%20Care.ABA%20DR%20magazine.4.2010.pdf
2. Liebman C, Hyman CS. A mediation skills model to manage disclosure of errors and adverse events to patients. Health Aff (Millwood) 2004 Jul-Aug;23(4):22-32.
3. Disclosing errors and examining mistakes: Kaiser Permanente keeps patients informed and involved. Joint Commission Perspectives on Patient Safety 2006 Sep;6(9):9-10.
4. Hardee J. An overview of empathy. Perm J 2003 Fall;7(4):51-4.
5. Leape LL. Full disclosure and apology—an idea whose time has come. The Physician Exec 2006 Mar-Apr;32(2):16-8.
6. Scott SD, Hirschinger LE, Cox KR, McCoig M, Brandt J, Hall LW. The natural history of recovery for the healthcare provider "second victim" after adverse patient events. Qual Saf Health Care 2009 Oct;18(5):325–30.
7. Leape L. Understanding the power of apology: How saying "I'm sorry" helps heal patients and caregivers. Focus on Patient Safety 2005;8(4):1-3.
8. Weber D. Who's sorry now. Physician Exec 2006 Mar-Apr;32(2):11-4.
9. Healing the Healer [video on the Internet]. Oakland, CA: Kaiser Permanente; 2011 [cited 2011 Jul 20]. Available from: http://kpnet.kp.org/qrrm/risk/HCOM3/hcom_index.htm#healing.
10. Formanek R, Bonacum D. "The other side of the fence": A geriatric surgical case study of error disclosure. Perm J 2008 Winter;12(1):39-45.

EDITORIAL

Patient-Centered Research from Electronic Medical Records

Mikel Aickin, PhD

Many important scientific discoveries were made not by minor modifications of previous research, but by rethinking fundamentals. At the turn of the past century, Albert Einstein (and a number of others) considered what would happen if we discarded our age-old idea that time and space were absolute, and the result was a revolution in physics. There are many examples in medicine where the previous worldview was overthrown along the way to the germ theory of disease. Charles Darwin struggled with the doctrine that species were created suddenly at one point in time, and arrived at one of the most powerful ideas in the world of biology.

At this time many areas of biomedical research seem to be stalled, or at least only slowly progressing. Despite the National Heart, Blood, and Lung Institute's two-generation campaign to reduce salt consumption in the American population, our best research seems to be ambiguous, if not discouraging, about the extent to which sodium restriction would prevent cardiovascular disease and death. Although some claim that obesity is a national epidemic with serious consequences for a range of diseases, and ultimately death, others say that the results of lowering weight are scarcely measurable at the individual level, and that the truly effective preventive strategies lie elsewhere. One can go on to list conditions for which the consensus view about effective treatment is that there is no consensus view or effective treatment.

Under Researched

Perhaps the current largest collection of unresolved or poorly resolved medical issues have to do with the kinds of patients that primary care physicians see most often. For example, one can find articles over the past 30 years complaining about the basic lack of progress in the treatment of the patient with chronic pain, and the situation does not appear to be improving. As the Institute of Medicine has recently observed,[1] there is no National Institute of Pain, so why should we expect to see a comprehensive national research policy in that area? But another reason for not doing clinical research on pain is that the causes are often obscure, the choice of effective therapies is cloudy, and patients with chronic pain tend to bring with them comorbidity profiles that greatly complicate research designs. Although pain may be the primary example, there are many others.

It is a strange situation that many of the routine problems that annoy clinicians are underresearched—the paradox that the most prevalent conditions are also the research orphans. One obvious explanation is that it is so difficult to do randomized clinical trials for these conditions, aggravated by the increasingly evident fact that such trials suffer from a lack of generalizability to clinical populations. In casting around for a research alternative, the obvious thing to try is medical research from existing electronic medical records (EMR). Surely there is a treasure-trove of useful data locked up in EMR systems, just waiting to be liberated.

Electronic Medical Record

It would, however, be equally true to say that there are virtually unlimited supplies of fresh water locked up in the polar ice caps, just waiting to be liberated. The trick is how to do it. Conventional wisdom in biomedical research is that one must rely on randomized clinical trials for the best evidence in any area of medicine. The practical result of this belief is that the efforts even to try to use EMR-based data have been few and far between. Funding has been virtually nonexistent, but the suspicion is that researchers likely see no benefit in preparing proposals for EMR-based research.

In a recent literature review of EMR-based studies,[2] it was found that nearly all were published in specialty journals, and for the most part the designs were attempts to import the methods of randomized clinical trials into the EMR data setting. From the titles one would judge that almost all of these studies were narrowly conceived, being concerned with a special slice of the patient population, or a highly specific point on some nuance of a disease process. On the one hand, there are good reasons to doubt that this path (mimicking clinical trials) will be successful, but on the other hand, a substantial number of new techniques for dealing with nonintervention designs has been developed.[3]

To return to the idea that intro-

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duced this essay, the conventional belief is that randomized clinical trials are the primary way to progress in treating disease. Virtually all of our statistical methods are oriented toward this approach. Methods for dealing with nonintervention dilemmas exist but are disused, and we are not making progress in employing them to solve large problems in our delivery of health care. The fundamental that we need to rethink is whether, unlike the polar ice caps, the information in EMRs is not beyond our grasp, and that all we need to do is to reach.

Even if funding were available, and researchers were willing to try it, there is still a large problem doing EMR-based research: finding a place to publish the results. Nearly all biomedical journals expect, or often demand, that articles be in a format that is uniquely tailored for clinical trials. Moreover, they expect conclusions be framed using recognized statistical methods that have been ritualized over decades of debate. It is not unreasonable to anticipate that EMR-based research submitted to existing journals would probably not survive to the review stage.

For this reason, the editors of *The Permanente Journal* (*TPJ*) have undertaken an experiment to lower the barrier to publication of EMR-based research to develop the quality and scope of this nontraditional approach. The editors recognize that EMR-based research has features that require modifications in the usual publication format. Chief among these is a succinct report in the usual paper-based form in the *Journal* itself, backed up by a far less restrictive electronic form, including aspects that are too difficult or expensive to print—for example, large databases and complex graphics.

In 2012, *TPJ* will open a new section dedicated to the publication of research that makes fundamental use of medical records data to generate knowledge about therapeutic outcomes. Submissions to this section will be peer-reviewed like all other submissions, but articles that are accepted will appear only in the *TPJ's* open-access e-journal—the official journal of record (www.thepermanentejournal.org)—with notices in the print journal.

In addition to the reasons noted above for this addition to *TPJ,* intervention research is too expensive to shoulder the entire burden of evidence-based medicine. There are simply too many conditions and types of patients for us to be able to rely on the clinical trial as the main source of therapeutic knowledge. Even if we could afford to do all the trials that need to be done it is not always obvious that a therapy administered in the setting of a trial is the same as would be administered in usual care. Yet there is still a need to assess and compare therapies based on observation of the individual patient.

Electronic Medical Record Information

There is an immense store of information in existing EMRs, and this storage is planned to increase in size over the coming years. In the past, EMR systems have been used for practice management, to facilitate patient care, and to improve the quality of health care delivery. They have not, however, been used very often for therapeutic medical research. There is a real barrier to this usage—EMR systems have always been designed for uses other than research. This means that some data that would be required for the purposes of high-quality research is either not collected or not stored. It does not mean, however, that the data collected cannot contribute anything to therapeutic research.

The national clinical research enterprise has concentrated its time and money so completely in the intervention-based clinical trial, that EMR-based research has been largely ignored. This has had two consequences. Methods of analysis that deal with the biases caused by lack of a research intervention have not been developed to the same degree as methods for intervention trials. With a perceived lack of methodology, and an actual lack of funding, nonintervention research has not produced the successful studies that form the basis for a larger share of the national research agenda. Thus the information locked away in EMR systems remains there, because of lack of adequate tools for its extraction, and inadequate funding to do the work.

Electronic Medical Record Article Characteristics

The intent of the section is to encourage articles with the following characteristics:

- fundamental use of data from EMRs
- assessment of therapies as they are actually provided
- inclusion of all relevant patients, without narrow exclusion criteria
- development of analytical methods that address the weaknesses of nonintervention studies
- portrayal of the complexity of clinical science.

These criteria are not intended to be definitive. Other areas of appropriate research have to do with (in no particular order):

- description of patient populations, from presenting characteristics through outcomes
- longitudinal studies of trajectories of care and outcome

- methods of extracting or recoding data for research
- qualitative research from EMR narratives
- potential appearance of long-term adverse consequences associated with various therapies
- methods for visualizing patterns in complex administrative data
- changes in the use of therapies over time
- involvement of medical students and residents in EMR-based clinical science
- inadequacies of existing EMR systems for research purposes, with recommendations for future changes
- comparisons of EMR-based research with intervention-based research
- studies based on non-EMR systems.

Topics of lesser interest for this particular section include:

- health care service delivery
- physician adherence to practice guidelines
- application of intervention trial methods to EMR data
- study of therapies that would not be used in practice (such as placebos)
- therapeutic effectiveness assessed without treatment comparisons
- epidemiologic studies.

The articles in this new section will appear on the Internet to eliminate restrictions on manuscript length and on numbers of tables and (colored) figures, and to open the possibility of including data files, computer programs, or other nontraditional materials. The intent is to provide enough space to deal with the complexity of clinic-based research without arbitrary technical limits.

This initiative is consistent with several recent recommendations regarding the national system of clinical research. For example, an Agency for Healthcare Research and Quality (AHRQ) study[4] has promoted the creation of patient registries for specific conditions, which would be primarily based on EMR. The Institute of Medicine has visualized health record data as a vastly underutilized information resource, and set the goal of an expanded learning health care system substantially based on clinical records.[5] Prokosh and Ganslandt have provided a careful outline of the challenges that follow from these recommendations along with some potential solutions.[6]

We welcome your comments and EMR research. Instructions for authors relevant to this new section can be found at www.thepermanentejournal.org. ❖

References

1. Institute of Medicine. Relieving pain in America: A blueprint for transforming prevention, care, education, and research. Washington DC: The National Academies Press, 2011.
2. Dean BB, Lam J, Natoli JL, Butler Q, Aguilar D, Nordyke RJ. Review: Use of electronic medical records for health outcomes research: a literature review. Med Care Res Rev 2009;66(6):611-38.
3. Guo S, Fraser MW. Propensity score analysis: statistical methods and applications. Thousand Oaks, CA: Sage Publications, 2010.
4. Gliklich RE, Dreyer NA, eds. Registries for evaluating patient outcomes: a user's guide. 2nd ed. (Prepared by Outcome DEcIDE Center [Outcome Sciences, Inc d/b/a Outcome] under Contract No.HHSA29020050035I TO3.) AHRQ Publication No.10-EHC049. Rockville, MD: Agency for Healthcare Research and Quality. 2010 Sep.
5. Institute of Medicine. Clinical data as the basic staple of health learning: Creating and protecting a public good: workshop summary. Washington, DC: The National Academies Press, 2010.
6. Prokosch HU, Ganslandt T. Perspectives for medical informatics. Reusing the electronic medical record for clinical research. Methods Inf Med;2009;48(1):38-44.

Data

In research, data speak.

— Clinical Trials Dictionary: Terminology and Usage Recommendations.

Curtis L Meinert, PhD, Professor in the Departments of Epidemiology and Biostatistics at Johns Hopkins Bloomberg School of Public Health

Humanity before Science: Narrative Medicine, Clinical Practice, and Medical Education

Samir Johna, MD
Simi Rahman, MD

A patient saw a physician for the first time. The physician wanted to learn everything about the new patient, and listened attentively without interruption. The patient paused after a while and wept. When asked why, "No one let me do this before," was the response.[1]

There is growing public opinion that the current medical care has lost its human aspects, widening the gap between patients' expectations and physicians' performance. Many forces today restrict physicians' ability to reflect on their clinical experiences and relationships. The marketplace speeds up medical work, interrupts continuity with patients, and erodes the autonomy of the physician-patient relationship.[2] The current revolution in technology of medical informatics complicates matters further. The *cut-and-paste* functions of electronic medical records undermine the psychological and therapeutic value of face-to-face personal and compassionate encounters between physicians and their patients.

This transformation in the physician-patient relationship did not take place overnight. Modern American medical education in charge of preparing future physicians was transformed by Flexner's report in 1910. Flexner was chosen by the Carnegie Foundation for the Advancement of Teaching to head up a commission to assess medical education in the US.[3] Flexner narrowly defined the proper goals of medicine as the "attempt to fight the battle against disease."[4] He argued that the future of pathology, therapeutics, and medicine depends upon those trained in the methods of natural science. Clinicians must be "impregnated with the fundamental truths of biology," ignoring the human aspects of the disease in favor of biology and natural science.

But we know that patients are not just bodies, organs, and tissues. They live meaning-centered lives, and they have complicated emotional and historical relationships with their bodies.[5] Flexner's vision of medical education created physicians richly sophisticated in biologic variables and interventions, but all too often they lost touch with the human aspects of health care and the basic tenets of clinical encounters with their patients.[5]

To understand the gap between patients' expectations and physicians' performance, one must make a distinction between *disease* and *illness*.[6] Medical philosophers turned to "phenomenology" to better understand the meaning of illness and the moral core of healing.[5] Illness is the innately human experience of symptoms and suffering, whereas disease is the clinical perspective of the problem. Flexner's model addresses the alteration in biologic structure and/or function, ie, *disease* without addressing the psychological and social variables of a disease, ie, *illness*. This fact was already well recognized in the 1970s when resistance to the Flexner's report started to surface.

Wounded Humanity

As such, illness, as explained by Pellegrino, is an altered state of existence arising out of an ontologic assault on the humanity of the person, resulting in the "*wounded humanity*."[7] An ill person suffers four elements: the loss of freedom to act because of bodily impairment, the lack of needed knowledge to make rational steps toward recovery, the loss of some degree of autonomy resulting in more dependence on others, and the transformation of self-image to adapt to the new situation. The patient's wounded humanity, rather than being a secondary aspect of the clinical encounter, must become the cornerstone of the healing relationship. The only way the physician can legitimately enter into a healing relationship is through the understanding of wounded humanity. Tending to biologic variables is one, and only one, part of it. To Pellegrino, "if the professional does not consciously remedy the four deficiencies that impair the patient's expression of humanity, his 'profession' is inauthentic."[8]

The wounded humanity is the core of any healing relationship between physicians and their patients. Physicians have recognized the need for patient-

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centered care, which they have attempted to address through various forums. The Schwartz Center Rounds is one example that fosters enhanced communication, teamwork, and provider support.[9] The impact on measured outcomes increased with the number of rounds attended. Such rounds may enhance relationship between physicians and their patients.[9] Another example is the Balint group, which probes into what evokes unexpected feelings among patients such as anger, fear, frustration, irritation, etc. Such discussion may facilitate an understanding of the physician-patient relationship.[10]

Narrative Medicine

Narrative Medicine on the other hand, is born through contemporary efforts to rehumanize medicine; to counterbalance the many problems of Flexner's model; and to recognize, absorb, interpret, and be moved by stories of illness.[11] The human capacity to understand the meaning and significance of stories is being recognized as critical for effective medical practice. Both patients and physicians find some comfort in storytelling. Patients find words very helpful to contain the chaos of illness and enable them to endure it better.[12] Physicians, on the other hand, find writing about patients and themselves confers on medical practice a new understanding that is otherwise unobtainable.[13] No wonder Narrative Medicine has been thriving over the past several years and is currently reflected in many genres. Stories from medical practice published in reputable medical journals such as "On Being a Doctor" in the *Annals of Internal Medicine,* and "A Piece of My Mind" in the *Journal of American Medical Association.* Other genres include writing exercises of medical training, medical fiction, lay exposition, and medical autobiography.[2]

But does Narrative Medicine hold the answer to the current crisis in the physician-patient relationship? Does storytelling really work? What evidence, if any, supports the positive impact of Narrative Medicine on patient care, clinical practice, and medical education?

There is a growing body of literature, though mostly qualitative, suggesting that Narrative Medicine does affect patient care. When a physician practices medicine with narrative competence, s/he can quickly and accurately hear and interpret what a patient is trying to say. Such a physician uses the time of a clinical interaction efficiently, wringing all possible medical knowledge from what a patient conveys about the experience of illness and how s/he conveys it. Also, as physicians describe the emotional and personal aspects of the care they deliver to particular patients, it helps them to comprehend their patients' ordeals as well as their own lives with the sick.[1,14]

In the effort to help physicians understand what they and their patients experience in the presence of illness, medical educators have been paying increasing attention to narrative competence, defined as the set of skills required to recognize, absorb, interpret, and be moved by stories. Unfortunately, as early in medical training as anatomy class, students learn that patients are predominantly defined by their bodies whereas physicians are defined by their scientific minds. It is also in the training process that such attitudes as professional detachment are learned. Although the field of medicine is dedicated to the examination, diagnosis, and treatment of bodies, the relationship of physicians to their own physicality is poorly understood, if not willfully ignored.[15]

DasGupta and Charon argue that traditional medical training teaches students that what lies below their white coats is irrelevant to their physicianhood.[15] Furthermore, a physician whose body becomes relevant may risk losing his or her identity as a physician. In the case of physicians who are themselves struggling with illness, "the dichotomy of being both a doctor and patient threatens the integrity of the club. To this fraternity of healers, being ill is tantamount to treachery."[16] Physicians' literature is rife with descriptions of physicians continuing to perform medicine while ill themselves. Yet, there is an alternate literature of physicians' transformations through personal illness in which these physicians' experiences were not only because of the physical reality of illness itself but also to the role-reversal that forcibly thrust the hitherto mind-defined physicians into their very real bodies. In the process of witnessing, interpreting, and translating their own illness experiences, these physicians become better able to listen empathically for the stories of their patients.[17]

Physicians … find writing about patients and themselves confers on medical practice a new understanding that is otherwise unobtainable.

Empathy

One of the most challenging tasks of medical education is teaching empathy. Empathy consists of three distinct components: a cognitive component in which the physician "enters" the perspective of the patient, an emotional component in which the physician puts himself or herself in the place of the patient, and finally, an action component in which the physician communicates understanding by checking back with the patient.[17] In a small study involving medical students, DasGupta and Charon demonstrated that writing "personal illness narratives" allowed participants to benefit from reflec-

tive writing in a new way. Rather than maintaining a clinician's point of view, or adopting the point of view of an "other," such narrative writings allow medical students to explore subjective experiences of illness. Furthermore, such experiences may critically inform the nature of students' professional caregiving. [15]

Pearson et al tested the value of narrative writings during surgical residency. They demonstrated in a small study that the use of a narrative-based approach in surgical resident education has the potential to capture and measure the general competencies of system-based practice, practice-based learning, communication skills, and professionalism.[18]

Levine et al explored the value of prompted narrative writing in internal medicine residency. They concluded from a small study among interns that writing throughout the year resulted in reflection and encouraged interns to reconsider their core values and priorities. Some found that the exercise promoted greater self-awareness and provided an emotional outlet. Writing about difficult experiences coupled with reflection motivated some interns to want to improve.[19]

It seems from the available literature that Narrative Medicine is promising in addressing some of the flaws of Flexner's model of medical education, and may be the answer to the current crisis in the physician-patient relationship. Its impact extends beyond empathic and compassionate delivery of care to patients; it extends well into physicians' own wellness. Medical educators should consider incorporating narrative writings as early as medical school education and all the way into residency and fellowship education. ❖

Disclosure Statement

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

References

1. Charon R. Narrative and medicine. N Engl J Med 2004 Feb 26;350(9):862-4.
2. Charon R. Narrative medicine: form, function, and ethics. Ann Intern Med 2001 Jan 2;134(1):83-7.
3. Starr P. The social transformation of American medicine. New York: Basic Books; 1982. p 118-21.
4. Flexner A. Medical Education in the United States and Canada. A report to the Carnegie Foundation for the Advancement of Science. New York: Carnegie Foundation for the Advancement of Teaching; 1910. p 23.
5. Lewis BE. Narrative medicine and healthcare reform. J Med Humanit 2011 Mar;32(1):9-20.
6. Kleinman A. The illness narrative: suffering, healing and the human condition. New York: Basic Books; 1988. p 3.
7. Pellegrino ED. Being ill and being healed: some reflections on the grounding of medical morality. Bull N Y Acad Med 1981 Jan-Feb;57(1):70-9.
8. Pellegrino ED. Humanism and the physician. Knoxville, TN: University of Tennessee Press; 1979. p 127.
9. Lown BA, Manning CF. The Schwartz Center Rounds: evaluation of an interdisciplinary approach to enhancing patient-centered communication, teamwork, and provider support. Acad Med 2010 Jun;85(6):1073-81.
10. Wilson H. Reflecting on the 'difficult' patient. N Z Med J 2005 Apr 1;118(1212):U1384.
11. Charon R. The narrative road to empathy. In: Spiro HM, Curene MG, Peschel E, St. James D, eds. Empathy and the practice of medicine: beyond pills and the scapel. New Haven, CT: Yale University Press; 1993. p 147-59.
12. Smyth JM, Stone AA, Hurewitz A, Kaell A. Effects of writing about successful experiences on symptom reduction in patients with asthma or rheumatoid arthritis: a randomized trial. JAMA 1999 Apr 14;281(14):1304-9.
13. Verghese A. My own country: a doctor's story of a town and its people in the age of AIDS. New York: Simon & Schuster; 1994.
14. Valenti MP, Mehl-Madrona L. Humanizing patients through narrative approaches: the case of Murphy, the "motor-mouth." Perm J 2010 Summer;14(2):47-50.
15. DasGupta S, Charon R. Personal illness narratives: using reflective writing to teach empathy. Acad Med 2004 Apr;79(4):351-6.
16. Rabin D, Rabin PL, Rabin R. Occasional notes. Compounding the ordeal of ALS: Isolation from my fellow physicians. N Eng J Med 1982 Aug 19;307(8):506-9.
17. Coulehan JL, Platt FW, Egener B, et al. "Let me see if I have this right ...": words that build empathy. Ann Intern Med 2001 Aug 7;135(3):221-7.
18. Pearson AS, McTigue AP, Tarpley JL. Narrative medicine in surgical education. J Surg Educ 2008 Mar-Apr;65(2):99-100.
19. Levine RB, Kern DE, Wright SM. The impact of a prompted narrative writing during internship on reflective practice: a qualitative study. Adv Health Sci Educ Theory Pract 2008 Dec;13(5):723-33.

Indivisible

Body and soul cannot be separated for purposes of treatment,
for they are one and indivisible. Sick minds must be healed as well as sick bodies.

— C Jeff Miller, MD, 1874-1936, American gynecologist

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Section A.

Article 1. (page 12)

Napa Immunization Study: Immunization Rates for Children with Publicly Funded Insurance Compared with those with Private Health Insurance in a Suburban Medical Office

Which of the following statements is correct?

a. children in affluent communities do not have barriers to immunization
b. it is reasonable to delay childhood immunizations for a child with an upper respiratory infection
c. health insurance and access to care are the most important factors in successful childhood immunization
d. it is a good practice to delay some immunizations in order to save the child the trauma of multiple injections

Which of the following elements of a successful immunization practice is incorrect?

a. the presence of a medical home
b. immunization schedules have become simpler over time
c. access to public or private health insurance
d. attention to and reduction of family fears

Article 2. (page 30)

Early Detection of Colon Cancer—The Kaiser Permanente Northwest 30-Year History: How Do We Measure Success? Is It the Test, the Number of Tests, the Stage, or the Percentage of Screen-Detected Patients?

The most important element of a successful colorectal cancer screening program is:

a. screening the high-risk population
b. having inreach and outreach programs to increase the populations to be tested
c. offering colonoscopy, which everyone knows is the "best test"
d. removing all colon polyps to prevent colorectal cancer

We will be able to prevent all colorectal cancer with enough screening and polyp removal?

a. True
b. False

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Article 3. (page 42)

Regional Expansion of Minimally Invasive Surgery for Hysterectomy: Implementation and Methodology in a Large Multispecialty Group

From 2005 to 2010 in the Southern California Permanente Medical Group, the following statements are correct, EXCEPT:

a. the rate of non-open hysterectomies has increased 120%
b. the length of stay of both open and non-open hysterectomies has decreased equally
c. in 2009, the rates of each of the four types of non-open hysterectomy were about the same
d. confounding variables included new hire and retiring physicians

In the following statements, which is NOT correct?
To improve attendance at the minimally invasive surgery (MIS) hysterectomy course

a. the presenters travelled to each medical center
b. attendees could use their weekly education time to attend
c. the $100,000 for equipment was covered by attendee fees of $250,000
d. the Chiefs of OB/GYN across the Region were included early in the planning and first to be exposed to the MIS program

Article 4. (page 66)

Does My Patient Have Asthma?

Among Kaiser Permanente patients who had four years of continuous health care coverage between 1999 and 2002 and met the HEDIS criteria for "persistent asthma" in any one of these four years, about how many met the HEDIS criteria for persistent asthma in all four years?

a. 20%
b. 40%
c. 60%
d. 80%

Common conditions misdiagnosed as asthma include:

a. laryngeal reflux or dysfunction
b. chronic obstructive pulmonary disease
c. post-viral infection-associated cough
d. A and C
e. All of the above

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.	☐☐☐☐☐		☐☐☐☐☐		☐☐☐☐☐		☐☐☐☐☐	

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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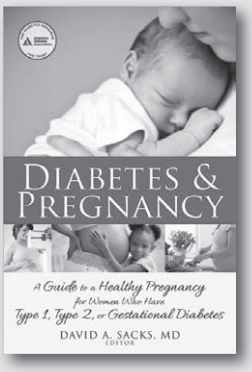
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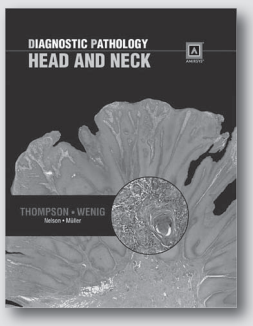
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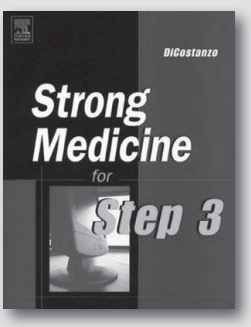
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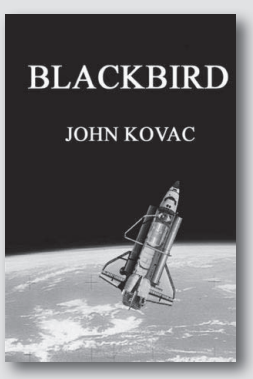
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