29  A Community-Based Hip Fracture Registry: Population, Methods, and Outcomes.  Maria C. Hsiao; Ph.D; Jennifer M. Wiss, MD; Alex Mina, MD; Jessica J. Hartt, MD; Gary L. Zohman, MD; Elizabeth W. Paxton, MD

Cases of hip fracture recorded from 1/2009 to 1/2011 were ascertained using the Kaiser Permanente Hip Fracture Registry. The registry collects information on patient, procedure, surgeon, facility, and surgical outcomes. The population (N = 12,562) was predominately white, women, and older (≥75 years), and 32% had at least 1 comorbidity. The average length of follow-up was 1.1 years. Herniation/patella was the most common procedure (33.1%). Most fractures were treated by medium-volume surgeons at high-volume facilities. The 90-day readmission rate was 22.1%, and the mortality rate was 12.3%.

17 Utility of the Multinational Association for Supportive Care in Cancer (MASCC) Risk Index Score as a Criterion for Nonadmission in Febrile Neutropenic Patients with Solid Tumors. Roger A. Bitar, MD, MPH

Febrile neutropenic episodes in patients with solid tumors were identified electronically from 10/2008 to 11/2010. Inclusion criteria were met in 198 episodes. Sensitivity, specificity, and positive and negative predictive values of the MASCC risk index score vs. complications were, respectively, 84%, 29.6%, 57.7%, and 82%, and 89% risk index score ≥21 or >10, respectively. It could not be used as a criterion for “no complications” due to a low sensitivity and inability to set an exclusion criterion.

21 Getting off the Bus Closer to Your Destination! Patients’ Views about Pharmacogenetic Testing. Lauren Brown Trindall, MD, Tara B. Cut-ten, MD; Stephanie M. Fennell, DPh; James Kalten, MD, MPH; Carl J. Linnik, MD, PhD; Eric B. Larson, MD, MPH

The authors conducted focus groups with patients prescribed antidepressants, print session plus 3 focus groups, n = 27; patients prescribed carbamazepine (2 focus groups, n = 17); and healthy patients (2 focus groups, n = 17). Although participants understood the potential advantages of pharmacogenetic testing, many felt that the rules (administration, stigmatization, physician-teenager on genome results, and denial of certain medications) may outweigh the benefits. These concerns were shared across groups but were more strongly expressed among participants with chronic mental health diagnoses.
54 Relationship between Participation in Patient- and Family-Centered Care Training and Communication Adaptability among Medical Students: Changing Hearts, Changing Minds.
Lisa Kissignol, MA
A census of 43 third-year medical students at the University of New Mexico School of Medicine participated in Parents Reaching Out: Families as Faculty program during their pediatric rotation. Analysis of variance revealed statistical significance for the factor “appropriate disclosure” (meaning students have become more sensitive to the level of intimacy that the other person is seeking and the student is willing to offer more information). There was a positive correlation between pretest and posttests in social experience, wit, and social confirmation.

59 A Ten-Year Case-Control Study of Passive Smoke Exposure as a Risk Factor for Pertussis in Children.
Mark A Schmidt, PhD, MPH; Samantha K Kurosy, MS; John P Mullooly, PhD; Colleen Chun, MD; Sheila Weinmann, PhD
The authors conducted a matched case-control study of laboratory-confirmed pertussis cases, occurring from 1/1/1996 to 12/31/2005, in children up to 12 years of age who were members of a large managed care organization. Sixty-five laboratory-confirmed cases of pertussis were identified. Using multivariable conditional logistic regression analysis, the authors did not detect a statistically significant association between pertussis and household passive exposure to cigarette smoking.

Special Report
64 2014 Hypertension Guideline: Recommendation for a Change in Goal Systolic Blood Pressure.
Joel Handler, MD
The 2014 Kaiser Permanente Care Management Institute National Hypertension Guideline was developed to assist primary care physicians and other health care professionals in the outpatient treatment of uncomplicated hypertension in adult men and nonpregnant women aged 18 years and older. A major practice change is the recommendation for goal systolic blood pressure less than 150 mmHg in patients aged 60 years and older who are treated for hypertension in the absence of diabetes or chronic kidney disease. This article describes the reasons for, evidence for, and consequences of the change, and includes the guideline.

CASE REPORTS
74 Beer Potomania—An Unusual Cause of Hyponatremia. Dean A Kujubu, MD; Ardeshir Khosravi, MD
The first case of severe hyponatremia, since referred to as beer potomania, in a heavy beer drinker patient was reported in 1972. Excessive consumption of beer in particular, which has a low solute content, may result in severe hyponatremia. We report a case of severe hyponatremia that occurred in a patient who, owing to his underlying colon cancer, was drinking beer and ingesting little food.

CLINICAL MEDICINE
77 Dermatologic Diagnosis: Leukocytoclastic Vasculitis. Joseph Einhorn, MD; Joel T Levis, MD, PhD, FACEP, FAAEM
Leukocytoclastic vasculitis (LCV), also termed hypersensitivity vasculitis, is a small-vessel vasculitis. The skin is the organ most commonly involved in LCV. Typical presentation is a painful, burning rash predominantly in the lower extremities. The most common skin manifestation is palpable purpura. Other skin manifestations include maculopapular rash, bullae, papules, plaques, nodules, ulcers, and livedo reticularis.

79 ECG Diagnosis: Hyperacute T Waves. Joel T Levis, MD, PhD, FACEP, FAAEM
After QT prolongation, hyperacute T waves are the earliest-described electrocardiographic sign of acute ischemia, preceding ST-segment elevation. The principle entity to exclude is hyperkalemia—this T-wave morphology may be confused with the hyperacute T wave of early transmural myocardial infarction.

COMMENTARY
81 Does Consuming Sugar and Artificial Sweeteners Change Taste Preferences? Carole Bartolotto, MA, RD
Americans consume 22.3 teaspoons of added caloric sweeteners a day. Sweeteners range from 180 to 13,000 times sweeter than sugar. In summer 2014, 20 people from Kaiser Permanente California facilities cut out all added sugars and artificial sweeteners for 2 weeks: 95% of participants found that sweet foods and drinks tasted sweeter or too sweet, 75% found that other foods tasted sweeter, and 95% said moving forward they would use less or even no sugar. Additionally, 86.6% of participants stopped craving sugar after 6 days.

NARRATIVE MEDICINE
90 Suicide is a Baobab Tree: A Narrative Medicine Case Study. Adriano Machado Faciolli, PhD; Fábio Ferreira Amorim, MD, PhD; Karlo Jozefo Quadros de Almeida, MD; Eliana Mendonça Vilar Trindade, PhD
Like the baobab, when suicide or a suicide attempt occurs, suicidal ideations are well cultivated and have often already been repeatedly planted. Consequently, suicide is often difficult to prevent: once the death seed is planted; it is difficult to recreate life. Every year, more than 800,000 people die by suicide worldwide.

95 Why a Hanging Man Dances. Gurpreet Kaur Padam, MD
“Do you know why a hanging man dances?” asked Mr B. He was once an intensely independent man, now 80 years old and afflicted with end-stage lung disease. He appeared tired, repositioning himself with great effort to sitting at the edge of the bed, tightly holding onto the bed sheets as if clenching to a life that was slowly escaping him. “No. I don’t want anything that will make me live longer.”
Case Report: Pulmonary Papillomatosis

A 49-year-old man presented to the gastroenterology clinic with 2 weeks of worsening lower back pain. There was associated poor appetite, fatigue, night sweats, and chills. The patient’s medical history was significant for well-controlled hypertension and sigmoid diverticulosis. The thrombosis probably resulted from inflammation in the adjacent diverticulum.

BOOK REVIEW

The Body Keeps the Score: Brain, Mind, and Body in the Healing of Trauma.
Review by Albert Ray, MD

This book explores the ways that patients and healers can develop the skills to appropriately evaluate historic traumatic events and how to successfully begin treating them. From the scientifically oriented physician, the biochemical, physiological, and anatomic effects of trauma on the body are well explored in this detailed exposé. What is more important though is the invisible mark that is embedded permanently on the mind and body by past traumatic events.
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Characteristics of Newly Enrolled Members of an Integrated Delivery System after the Affordable Care Act

Elizabeth A Bayliss, MD, MSPH; Jennifer L Ellis, MSPH; Mary Jo Strobel, RN, MBA; Deanna B McQuillan, MA; Irena B Petsche, PhD; Jennifer C Barrow, MSPH; Arne Beck, PhD

ABSTRACT

Context: Little is known about the health status and care needs of new enrollees in health plans since implementation of the Affordable Care Act.

Objective: To describe characteristics of new members of an integrated delivery system during early phases of implementation of the act.

Design: Descriptive analysis of ongoing collection of operational data.

Main Outcome Measures: The 11-question Brief Health Questionnaire, which was administered to new members of Kaiser Permanente Colorado who had benefits effective on or after January 1, 2014. Bivariate analyses compared characteristics of new enrollees by benefit.

Results: Of 89,289 newly enrolled non-Medicare members, 22,548 (25.3%) completed the Brief Health Questionnaire between January 1, 2014, and August 31, 2014. Of these, 3593 respondents were insured through Medicaid, 9434 through the individual health exchange, and 9521 through primarily commercial plans. Of Medicaid, exchange, and commercial members, 19.5%, 7.1%, and 5.3%, respectively, self-reported fair or poor health; 12.9%, 2.0%, and 3.3% of each group self-reported 2 or more Emergency Department visits during the previous year; and 8.1%, 4.3%, and 4.4% self-reported an inpatient admission during the previous year. During the preceding year, 31.5% of Medicaid, 30.8% of exchange, and 12.6% of commercial members were uninsured longer than 8 months.

Conclusion: Systematic collection of patients’ self-reported information can enhance traditional approaches to initiating care, inform operational planning, and describe newly enrolled populations. Newly enrolled Medicaid beneficiaries may have more initial health care needs than new exchange or commercial members; however, health differences between the latter two groups are subtle.

INTRODUCTION

The first open enrollment period under the Affordable Care Act (ACA) resulted in an estimated eight million individuals gaining insurance coverage through exchanges and an additional six million through Medicaid expansions nationally. Published estimates of health status for those likely to gain new coverage under the ACA vary widely and are based on limited data.

Accurate and timely information on the care needs of individuals who are either newly insured or transitioning between care plans under the ACA are important because these needs will affect demand for a range of primary and specialty care services. Most methods for predicting health care resource needs rely on models that incorporate measures of previous service use, morbidity burden, and socioeconomic factors. These factors are strong predictors of future service needs, as are self-reported health and functional status. However, morbidity and utilization data are unavailable before engagement with the health care system. In the absence of preexisting information on newly enrolled individuals, real-time data collection on health-related characteristics can inform care delivery and resource planning. Operations leaders and researchers in Kaiser Permanente Colorado (KPCO) collaborated to develop a brief health screening questionnaire to anticipate the potential health care needs of newly enrolled members. The goal of the Brief Health Questionnaire (BHQ) is twofold: 1) to identify care needs that can be met before traditional primary care appointments and 2) to characterize the newly enrolled member population. This brief report describes characteristics of new KPCO members during early phases of the ACA implementation.

METHODS

A not-for-profit, integrated health care delivery system, KPCO provides services in Denver and other metropolitan areas along the Colorado “Front Range” to the north and south of Denver. New members were defined as individuals who had no previous enrollment in KPCO and had new benefits effective on or after January 1, 2014. For families with more than one new enrollee, each individual was eligible to respond to the BHQ. We defined insurance type as Medicaid, individual exchange, and all other (composed primarily of large- and small-group commercial members). New Medicare members were excluded. The 11-question BHQ addresses the following domains: general health status, specific chronic illnesses, prescription...
medications, depression screening, pregnancy, financial constraints, prior-year hospitalizations, Emergency Department (ED) use, and insurance coverage. The BHQ is provided in the Appendix: Brief Health Questionnaire (available online at: www.thepermanentejournal.org/files/Summer2015/Questionnaire.pdf). Before administration, the questionnaire was pilot tested on 35 new members to assess comprehension and completion time. Starting in late 2013, the BHQ was offered to any new non-Medicare member calling for an appointment and was accessible on the KPCO Web site. After scheduling of an appointment, new members were asked for permission to “route the call to a New Member Specialist for assistance with ‘onboarding.’” This specialist then asked the BHQ questions and entered responses into the member’s electronic health record (EHR).

Data collection is ongoing and evolving for this operational project. For example, Community Specialists still reach out to new Medicaid members to assess health and community resource needs. Additionally, new members are now directed (via a welcome telephone call and mailed identification card insert) to a 1-stop shop for all their on-boarding needs, which include selecting a primary care physician, understanding benefits and care delivery options, registering on the KPCO Web site, and administration of the BHQ. This New Member Team is also responsible for outreach to new members within their first 90 days of coverage.

Table 1. Characteristics of new members responding to the Brief Health Questionnaire between January 1, 2014, and August 31, 2014 (N = 22,548)

<table>
<thead>
<tr>
<th>New member characteristic</th>
<th>Medicaid (n = 3593), No. (%)</th>
<th>Individual on exchange (n = 9434), No. (%)</th>
<th>Other (n = 9521), No. (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>2097 (58.4)</td>
<td>5511 (58.4)</td>
<td>5406 (56.8)</td>
<td>0.0414*</td>
</tr>
<tr>
<td>Male</td>
<td>1496 (41.6)</td>
<td>3923 (41.6)</td>
<td>4112 (43.2)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>0</td>
<td>3 (0)</td>
<td></td>
</tr>
<tr>
<td>Age group, years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-9</td>
<td>553 (15.4)</td>
<td>683 (7.2)</td>
<td>1865 (19.6)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>10-19</td>
<td>353 (9.8)</td>
<td>547 (5.8)</td>
<td>1104 (11.6)</td>
<td></td>
</tr>
<tr>
<td>20-29</td>
<td>567 (15.8)</td>
<td>1477 (15.7)</td>
<td>1832 (19.2)</td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>580 (16.1)</td>
<td>1715 (18.2)</td>
<td>1699 (17.8)</td>
<td></td>
</tr>
<tr>
<td>40-49</td>
<td>547 (15.2)</td>
<td>1477 (15.7)</td>
<td>1310 (13.8)</td>
<td></td>
</tr>
<tr>
<td>50-59</td>
<td>694 (19.3)</td>
<td>2160 (22.9)</td>
<td>1251 (13.1)</td>
<td></td>
</tr>
<tr>
<td>≥ 60</td>
<td>299 (8.3)</td>
<td>1375 (14.6)</td>
<td>460 (4.8)</td>
<td></td>
</tr>
<tr>
<td>Response format</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Web portal completion</td>
<td>111 (3.1)</td>
<td>98 (10.5)</td>
<td>918 (9.6)</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>Telephone completion</td>
<td>3482 (96.9)</td>
<td>8447 (89.5)</td>
<td>8603 (90.4)</td>
<td></td>
</tr>
<tr>
<td>Benefit start month</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>January</td>
<td>179 (5.0)</td>
<td>3094 (32.8)</td>
<td>3324 (34.9)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>February</td>
<td>365 (10.2)</td>
<td>710 (7.5)</td>
<td>986 (10.4)</td>
<td></td>
</tr>
<tr>
<td>March</td>
<td>495 (13.8)</td>
<td>1104 (11.7)</td>
<td>910 (9.6)</td>
<td></td>
</tr>
<tr>
<td>April</td>
<td>592 (16.5)</td>
<td>1357 (14.4)</td>
<td>985 (10.4)</td>
<td></td>
</tr>
<tr>
<td>May</td>
<td>586 (16.3)</td>
<td>2293 (24.3)</td>
<td>979 (10.3)</td>
<td></td>
</tr>
<tr>
<td>June</td>
<td>513 (14.3)</td>
<td>422 (4.5)</td>
<td>746 (7.8)</td>
<td></td>
</tr>
<tr>
<td>July</td>
<td>406 (11.3)</td>
<td>305 (3.2)</td>
<td>1098 (11.5)</td>
<td></td>
</tr>
<tr>
<td>August</td>
<td>457 (12.7)</td>
<td>149 (1.6)</td>
<td>493 (5.2)</td>
<td></td>
</tr>
</tbody>
</table>

* Some percentages may not total to 100% because of rounding.

† Nonsignificant differences between Medicaid and exchange: sex (p = 0.9664). Nonsignificant differences between Medicaid and other: sex (p = 0.1537).

If new members responded “yes” to any BHQ question, New Member Specialists made telephone appointments for follow-up encounters on the basis of prespecified rules. All BHQs completed on the KPCO Web site were automatically routed to appropriate EHR in-baskets for follow-up. Pharmacists contacted new members regarding refills on prescription medications; Nurse Care Managers assessed those reporting fair or poor health status, specific chronic conditions, a “positive” depression screen (a Patient Health Questionnaire-2 score of 3 or greater†), or potential high morbidity as indicated by hospitalization and emergency service use. Social workers and Community Specialists evaluated reports of financial and social needs. The Obstetrics Department arranged for necessary prenatal care. Documentation of follow-up encounters was entered in the EHR for use at the point of care. Use of the questionnaire is ongoing.

We compared demographic characteristics and BHQ responses across groups of new members (Medicaid, exchange, and other) using χ² tests. We also conducted two descriptive subanalyses comparing 1) individuals who reported having no insurance for more than eight months during the previous year with those insured for that entire year and 2) BHQ respondents and nonrespondents.

The KPCO institutional review board reviewed the protocol for the BHQ program and analyses, and determined that it met criteria for an operations intervention with intent to publish, rather than human subjects research.

RESULTS

A total of 89,289 members were newly enrolled between January 1, 2014, and August 31, 2014. Of these, 22,548 (25.3%) completed a BHQ by August 31, 2014. By insurance type, 3593 respondents were insured through Medicaid, 9434 through the individual health exchange, and 9521 through other mechanisms, primarily large and small group commercial plans. These responses represented 43.2% (3593/8318) of new Medicaid enrollees, 26.8% (9434/35,113) of new exchange enrollees, and 20.8% (9521/45,858) of
**Table 2. Responses to Brief Health Questionnaire between January 1, 2014, and August 31, 2014, by insurance category (N = 22,548)**

<table>
<thead>
<tr>
<th>Response</th>
<th>Medicaid (n = 3593), No. (%)</th>
<th>Individual on exchange (n = 9434), No. (%)</th>
<th>Other (n = 9521), No. (%)</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excellent</td>
<td>703 (19.6)</td>
<td>2893 (30.7)</td>
<td>3381 (35.5)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Very good</td>
<td>974 (27.1)</td>
<td>3370 (35.7)</td>
<td>3377 (35.5)</td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>1118 (31.1)</td>
<td>2421 (25.7)</td>
<td>2209 (23.2)</td>
<td></td>
</tr>
<tr>
<td>Fair</td>
<td>517 (14.4)</td>
<td>565 (6.0)</td>
<td>426 (4.5)</td>
<td></td>
</tr>
<tr>
<td>Poor</td>
<td>184 (5.1)</td>
<td>106 (1.1)</td>
<td>75 (0.8)</td>
<td></td>
</tr>
<tr>
<td>Missing/no answer</td>
<td>97 (2.7)</td>
<td>79 (0.8)</td>
<td>53 (0.6)</td>
<td></td>
</tr>
<tr>
<td><strong>Self-reported chronic conditions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>301 (8.4)</td>
<td>648 (6.9)</td>
<td>609 (6.4)</td>
<td>0.0003</td>
</tr>
<tr>
<td>Diabetes</td>
<td>207 (5.8)</td>
<td>439 (4.7)</td>
<td>290 (3.1)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Heart disease</td>
<td>95 (2.6)</td>
<td>213 (2.3)</td>
<td>149 (1.6)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>494 (13.8)</td>
<td>1239 (13.1)</td>
<td>778 (8.2)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Positive depression screen</td>
<td>424 (11.8)</td>
<td>441 (4.7)</td>
<td>325 (3.4)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td><strong>Other health considerations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>48 (1.3)</td>
<td>80 (0.9)</td>
<td>124 (1.3)</td>
<td>0.0048</td>
</tr>
<tr>
<td>Current prescription medications</td>
<td>1347 (37.5)</td>
<td>3847 (40.8)</td>
<td>3342 (35.1)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Health conditions interfere with daily activity</td>
<td>1102 (30.7)</td>
<td>1506 (16.0)</td>
<td>1280 (13.4)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td><strong>Emergency Department visits in past year</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>2322 (64.6)</td>
<td>8150 (86.4)</td>
<td>7927 (83.3)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>1 time</td>
<td>705 (19.6)</td>
<td>1007 (10.7)</td>
<td>1212 (12.7)</td>
<td></td>
</tr>
<tr>
<td>2+ times</td>
<td>462 (12.9)</td>
<td>191 (2.0)</td>
<td>316 (3.3)</td>
<td></td>
</tr>
<tr>
<td>Missing data</td>
<td>104 (2.9)</td>
<td>86 (0.9)</td>
<td>66 (0.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Inpatient admissions in past year</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>3199 (89.0)</td>
<td>8938 (94.7)</td>
<td>9035 (94.9)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>1 time</td>
<td>231 (6.4)</td>
<td>343 (3.6)</td>
<td>360 (3.8)</td>
<td></td>
</tr>
<tr>
<td>2+ times</td>
<td>59 (1.6)</td>
<td>60 (0.6)</td>
<td>60 (0.6)</td>
<td></td>
</tr>
<tr>
<td>Missing data</td>
<td>104 (2.9)</td>
<td>93 (1.0)</td>
<td>66 (0.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Insurance during year</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Had insurance for whole year</td>
<td>1132 (31.5)</td>
<td>3893 (41.3)</td>
<td>4499 (47.3)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>No insurance for 1-4 months</td>
<td>230 (6.4)</td>
<td>877 (9.3)</td>
<td>660 (6.9)</td>
<td></td>
</tr>
<tr>
<td>No insurance for 5-8 months</td>
<td>167 (4.7)</td>
<td>484 (5.1)</td>
<td>274 (2.9)</td>
<td></td>
</tr>
<tr>
<td>No insurance for &gt; 8 months</td>
<td>1132 (31.5)</td>
<td>2906 (30.8)</td>
<td>1199 (12.6)</td>
<td></td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>12 (0.3)</td>
<td>40 (0.4)</td>
<td>20 (0.2)</td>
<td></td>
</tr>
<tr>
<td>Missing data</td>
<td>920 (25.6)</td>
<td>1234 (13.1)</td>
<td>2869 (30.1)</td>
<td></td>
</tr>
<tr>
<td><strong>Reported financial constraint</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health affected by difficulty paying for food, medicine, rent, utilities</td>
<td>823 (22.9)</td>
<td>867 (9.2)</td>
<td>512 (5.4)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Any positive BHQ response</td>
<td>2185 (60.8)</td>
<td>5264 (55.8)</td>
<td>4630 (48.6)</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

*Some percentages may not total to 100% because of rounding.

*Nonsignificant differences between Medicaid and exchange: heart disease (p = 0.1947); high blood pressure (p = 0.3551). Nonsignificant differences between Medicaid and other: pregnancy (p = 0.8803). Nonsignificant differences between exchange and other: asthma (p = 0.1913); prior-year inpatient admissions (p = 0.1632). BHQ = Brief Health Questionnaire.

Table 2 summarizes responses to the BHQ questions across insurance groups. Fair or poor health was self-reported by 19.5%, 7.1%, and 5.3% of Medicaid, exchange, and other groups, respectively. A greater proportion of Medicaid enrollees (30.7%) reported physical functioning interfering with health, and a greater proportion of exchange enrollees (40.8%) reported prescription medication use. Of BHQ respondents, 11.8% of Medicaid, 4.7% of exchange, and 3.4% of other/commercial enrollees screened positive for possible depression. During the preceding year there was a greater difference in self-reported ED utilization across groups than in self-reported inpatient hospital admissions, with 12.9% of Medicaid enrollees reporting 2 or more ED visits (compared with 2.0% of exchange and 3.3% of other new members), but less than 2% of all groups reporting 2 or more inpatient admissions. Comparable percentages of Medicaid and exchange enrollees (just over 30%) reported no insurance during more than 8 months during the previous year, compared with 12.6% of other beneficiaries. All variable differences across groups of enrollees were significant at p < 0.001 except for sex, which was significant at p < 0.05. Of new Medicaid enrollees, 60.8% were referred for any additional services on the basis of BHQ responses, compared with 55.8% of new exchange enrollees and 48.6% of other enrollees (p < 0.001). The highest percentage of referrals across insurance groups was because of prescription medication use.
Table 3. Brief Health Questionnaire characteristics and responses (N = 14,761) by prior-year insurance: insured for entire year versus no insurance for more than 8 months

<table>
<thead>
<tr>
<th>Characteristic or response</th>
<th>Medicaid (n = 2264)</th>
<th>Individual on exchange (n = 6799)</th>
<th>Other (n = 5698)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Insured (n = 1132), No. (%)</td>
<td>Not insured (n = 1132), No. (%)</td>
<td>Insured (n = 3893), No. (%)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>768 (67.8)</td>
<td>638 (56.4)</td>
<td>2310 (59.3)</td>
</tr>
<tr>
<td>Male</td>
<td>364 (32.2)</td>
<td>494 (43.6)</td>
<td>1583 (40.7)</td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Age group, years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-9</td>
<td>1 (0.1)</td>
<td>0</td>
<td>3 (0.1)</td>
</tr>
<tr>
<td>10-19</td>
<td>48 (4.2)</td>
<td>9 (0.7)</td>
<td>43 (1.1)</td>
</tr>
<tr>
<td>20-29</td>
<td>262 (23.1)</td>
<td>208 (18.4)</td>
<td>624 (16.0)</td>
</tr>
<tr>
<td>30-39</td>
<td>260 (23.0)</td>
<td>202 (17.8)</td>
<td>737 (18.9)</td>
</tr>
<tr>
<td>40-49</td>
<td>200 (17.7)</td>
<td>246 (21.7)</td>
<td>676 (17.4)</td>
</tr>
<tr>
<td>50-59</td>
<td>233 (20.6)</td>
<td>340 (30.0)</td>
<td>1076 (27.6)</td>
</tr>
<tr>
<td>≥ 60</td>
<td>128 (11.3)</td>
<td>128 (11.3)</td>
<td>734 (18.9)</td>
</tr>
<tr>
<td>General health</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excellent</td>
<td>151 (13.3)</td>
<td>119 (10.5)</td>
<td>1151 (29.6)</td>
</tr>
<tr>
<td>Very good</td>
<td>323 (28.5)</td>
<td>282 (24.9)</td>
<td>1537 (39.5)</td>
</tr>
<tr>
<td>Good</td>
<td>406 (35.9)</td>
<td>436 (38.5)</td>
<td>974 (25.0)</td>
</tr>
<tr>
<td>Fair</td>
<td>174 (15.4)</td>
<td>218 (19.3)</td>
<td>201 (5.2)</td>
</tr>
<tr>
<td>Poor</td>
<td>77 (6.8)</td>
<td>75 (6.6)</td>
<td>24 (0.6)</td>
</tr>
<tr>
<td>Missing/no answer</td>
<td>1 (0.1)</td>
<td>2 (0.2)</td>
<td>6 (0.2)</td>
</tr>
<tr>
<td>Self-reported chronic condition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>124 (11.0)</td>
<td>126 (11.1)</td>
<td>319 (8.2)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>95 (8.4)</td>
<td>79 (7.0)</td>
<td>184 (4.7)</td>
</tr>
<tr>
<td>Heart disease</td>
<td>35 (3.1)</td>
<td>45 (4.0)</td>
<td>103 (2.7)</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>211 (18.6)</td>
<td>203 (17.9)</td>
<td>565 (14.5)</td>
</tr>
<tr>
<td>Other health considerations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current prescription medication</td>
<td>592 (52.3)</td>
<td>442 (39.1)</td>
<td>1957 (50.3)</td>
</tr>
<tr>
<td>Positive depression screen</td>
<td>132 (11.7)</td>
<td>209 (18.5)</td>
<td>155 (4.0)</td>
</tr>
<tr>
<td>Pregnant</td>
<td>22 (1.9)</td>
<td>13 (1.2)</td>
<td>36 (0.9)</td>
</tr>
<tr>
<td>Health condition interferes with daily activity</td>
<td>417 (36.8)</td>
<td>458 (40.5)</td>
<td>603 (15.5)</td>
</tr>
<tr>
<td>Emergency Department visits in past year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>716 (63.3)</td>
<td>742 (65.6)</td>
<td>3430 (88.1)</td>
</tr>
<tr>
<td>1 time</td>
<td>240 (21.2)</td>
<td>249 (22.0)</td>
<td>396 (10.2)</td>
</tr>
<tr>
<td>2+ times</td>
<td>176 (15.6)</td>
<td>139 (12.5)</td>
<td>65 (1.7)</td>
</tr>
<tr>
<td>Missing data</td>
<td>0</td>
<td>2 (0.2)</td>
<td>2 (0.1)</td>
</tr>
<tr>
<td>Inpatient admissions in past year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>1008 (89.1)</td>
<td>1041 (92.0)</td>
<td>3697 (95.0)</td>
</tr>
<tr>
<td>1 time</td>
<td>98 (8.6)</td>
<td>77 (6.6)</td>
<td>165 (4.2)</td>
</tr>
<tr>
<td>2+ times</td>
<td>24 (2.1)</td>
<td>13 (1.2)</td>
<td>28 (0.7)</td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (0.1)</td>
<td>1 (0.1)</td>
<td>3 (0.1)</td>
</tr>
<tr>
<td>Self-reported financial constraints</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health affected by difficulty paying for food, medicine, rent, utilities</td>
<td>218 (19.3)</td>
<td>452 (39.9)</td>
<td>196 (5.0)</td>
</tr>
</tbody>
</table>

*Insured is defined as reporting being insured for entire previous year; uninsured is defined as being uninsured for more than 8 months during the previous year. Sample for this subanalysis does not include respondents reporting either 1 to 4 months or 5 to 8 months without insurance during the previous year. Some percentages may not total to 100% because of rounding.
The pattern of new Medicaid enrollees having greater morbidity than new exchange or other new enrollees was also evident in proportions of self-reported chronic conditions. Asthma was reported by 6.9% of new Medicaid enrollees, 6.4% of new exchange enrollees, and 6.4% of new other enrollees (p = 0.003). Diabetes was reported by 5.8%, 4.7%, and 3.1% of each group, respectively; heart disease by 2.6%, 2.3%, and 1.6%; and high blood pressure by 13.8%, 13.1%, and 8.2% (p < 0.001 for all).

Descriptive subanalyses of new members previously uninsured for more than 8 months vs those insured for the entire year are listed in Table 3. In each benefit group, the previously uninsured individuals report slightly higher rates of fair or poor health, and of health interfering with daily activity, but they do not report greater rates of specific chronic conditions. A higher proportion of individuals in the previously uninsured subpopulations had a positive depression screen, and a higher proportion reported financial constraints.

Table 4 compares BHQ respondents vs nonrespondents. Compared with nonrespondents, respondents were significantly more likely to be female, to be older, and to carry Medicaid or exchange insurance (p < 0.001).

**Table 4. Brief Health Questionnaire (BHQ) new member respondents versus nonrespondents (N = 89,289)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No BHQ (n = 66,741), No. (%)</th>
<th>BHQ (n = 22,548), No. (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>31,743 (47.6)</td>
<td>13,014 (57.7)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Male</td>
<td>34,976 (52.4)</td>
<td>9531 (42.3)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>22 (0)</td>
<td>3 (0)</td>
<td></td>
</tr>
<tr>
<td><strong>Age group, years</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-9</td>
<td>11,031 (16.5)</td>
<td>3101 (13.8)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>10-19</td>
<td>6739 (10.1)</td>
<td>2004 (8.9)</td>
<td></td>
</tr>
<tr>
<td>20-29</td>
<td>13,312 (20.0)</td>
<td>3876 (17.2)</td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>12,029 (18.0)</td>
<td>3994 (17.7)</td>
<td></td>
</tr>
<tr>
<td>40-49</td>
<td>9202 (13.8)</td>
<td>3334 (14.8)</td>
<td></td>
</tr>
<tr>
<td>50-59</td>
<td>9749 (14.6)</td>
<td>4105 (18.2)</td>
<td></td>
</tr>
<tr>
<td>≥ 60</td>
<td>4679 (7.0)</td>
<td>2134 (9.5)</td>
<td></td>
</tr>
<tr>
<td><strong>Insurance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>4725 (7.1)</td>
<td>3593 (15.9)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Individual on exchange</td>
<td>25,679 (38.5)</td>
<td>9434 (41.6)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>36,337 (54.4)</td>
<td>9521 (42.2)</td>
<td></td>
</tr>
</tbody>
</table>

* Some percentages may not total to 100% because of rounding.

**DISCUSSION**

Accurate information on the health status and care needs of individuals enrolling in insurance plans during the early phases of the ACA implementation can help optimize care delivery for newly insured and transitioning populations. This snapshot of new members in an integrated delivery system in the Denver Front Range area suggests that new Medicaid enrollees are less healthy than new exchange and new commercial members are; however, differences between new exchange enrollees and new commercial members are more subtle.

We found that 19.5% of new Medicaid members and 7.1% of new exchange members overall had fair or poor health. In the smaller subsample of individuals without previous insurance, 25.9% of new Medicaid members and 11.4% of new exchange members reported fair or poor health. Our Medicaid findings are consistent with previous estimates8,29 that proportions of the ACA target population with fair or poor health would range from 10% to 25%, with the greater burden falling on individuals below 200% of the Federal Poverty Level. However, the general health status in new exchange enrollees in this population is somewhat better than these predictions.8,7,24 It is also somewhat better than a national population of nongroup enrollees (individuals who purchased their own insurance) surveyed after ACA implementation in Spring 2014, in which 14% reported fair or poor health.29 It is possible that our results reflect characteristics of Colorado residents—which may differ from a nationally representative sample—or that individuals enrolling in Year 1 of the ACA may have better health status than those who remain uninsured. Ongoing surveillance of health status among the newly insured will help clarify their health status and care needs and should inform service requirements for integrated and other delivery systems.

Rates of chronic disease are notoriously difficult to predict because individuals who are unable to access care may be unaware of diagnoses. Estimates of heart disease in our Medicaid and exchange sample to date (2% to 3%) are comparable to literature-based predictions, whereas the rate of asthma in BHQ respondents (6.4% to 8.4%) is comparable to rates in previously uninsured populations, but half of asthma rates in Medicaid populations.7,30 Published estimates suggest depression rates in the range of 2% to 17% for Medicaid and exchange enrollees.7,30 Although BHQ respondents had positive depression screens within this range, their diagnoses of depression require further evaluation.27

In 2011, the Kaiser Family Foundation predicted that 65% of exchange purchasers would have been previously uninsured.30 We found that previous insurance coverage was not comprehensive for any of the 3 groups, and that just over 30% of new Medicaid and exchange enrollees reported being uninsured for more than 8 months during the previous year. These proportions may be slightly skewed by missing data, but they are lower than the 57% national figure reported in a 2014 Kaiser Family Foundation survey.27 They may also reflect the insurance marketplace in Colorado and uptake of exchange plans by both insured and uninsured individuals. (Our sample does not include the small-business exchange.)

New Medicaid members reported greater past utilization of the ED than
did other respondents. Studies of Medicaid expansions suggest that this pattern may continue after obtaining insurance, although it may be modified by effective primary care relationships.\textsuperscript{23,31} In the longer term, gaining insurance benefits increases utilization of health care resources, improves mental and physical health, increases the use of preventive services, and decreases mortality for both Medicaid and non-Medicaid populations.\textsuperscript{28,32-34} Optimizing long-term health outcomes will require maximizing both informational and interpersonal continuity of care for patients who may move between Medicaid and exchange benefit categories and between being insured and uninsured.

Although patient-reported data on health status, physical function, emotional well-being, and other constructs are predictive of mortality and utilization, and can guide interventions to improve the quality of care, such measures have previously been used almost exclusively in the context of research rather than care delivery.\textsuperscript{10,35-38} Recently, health assessments have been incorporated into care delivery for defined populations such as seniors, employees, and Health Plan members.\textsuperscript{39} The BHQ assessment exemplifies how patient-reported data can be systematically collected to inform care delivery, especially in light of 2014 net growth of approximately 15%, compared with previous annual net growth rates in the range of 2% to 3% for the delivery system. To date, approximately 54% of all BHQ respondents have been referred for either care management or pharmacy services. Future retrospective analyses will determine whether referrals for early medication and care management affect more distal health outcomes such as hospitalization and disease-specific adverse events.

Our study has several limitations. Medicaid enrollees enrolling in KPCO were a relatively small subset of all Colorado Medicaid beneficiaries. New KPCO exchange enrollees reflect an approximate 38% share of the Colorado exchange marketplace and only represent those who selected a single integrated delivery system. Newly enrolled patients in other delivery systems and settings will have different characteristics. This sample primarily reflects a subset of members who contacted the delivery system during the first 6 months of enrollment, and data collection was limited by the capacity of the call center’s service associates. As illustrated in Table 4, there were a number of demographic differences between BHQ respondents and nonrespondents. Respondents to the BHQ are also more likely to have used health care services. These comparisons support (but do not confirm) a hypothesis that new enrollees with higher morbidity were initial users of the delivery system and more likely to complete a BHQ. Finally, most of the responses were obtained via telephone; although responses obtained through the Web portal may be systematically different, Web-based responses represent a very small proportion of the total and are unlikely to bias the results. Our preliminary cross-sectional description must be supplemented with longitudinal assessments that link patient-reported BHQ responses with subsequent utilization patterns and that link all of these factors with robust health outcomes.

**CONCLUSION**

This description suggests that newly enrolled Medicaid beneficiaries may have more initial health care needs than either new exchange or commercial members; however, health differences between the latter 2 groups in this population sample are more subtle. The Congressional Budget Office estimates that by 2023, insurance will be obtained by 13 million individuals through Medicaid expansions and by 24 million through exchange-based plans.\textsuperscript{40} There is likely to be increasing movement of individuals across benefit categories, as well as increasing inclusion of previously insured populations in Medicaid and exchange insurance plans. Adequately informing care delivery for this changing landscape will require an understanding of which subpopulations are likely to transition between benefit categories and between delivery systems and settings, and which subpopulations risk adverse health outcomes as a function of these transitions. Further evaluation of needs assessments, such as the BHQ process, will inform the development of systematic interventions to optimize health outcomes in newly enrolled populations.

**Disclosure Statement**

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

**Acknowledgments**

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ABSTRACT
Context: Because institutions rely on rule-based alerts as an important component of their safety and quality strategies, they should determine whether the alerts achieve the expected benefit.

Objective: To develop and to test a method of reporting outcome metrics for rule-based electronic health record alerts on a large scale.

Methods: We empirically developed an action-oriented alerts taxonomy according to structure, actions, and implicit intended process outcomes using a set of 333 rule-based alerts at Kaiser Permanente Northwest. Next we developed a method for producing metrics reports for alert classes. Finally, we applied this method to alert taxa.

Main Outcome Measures: Outcome measures were the successful development of a rule-based alerts taxonomy and the demonstration of its application in a reporting strategy.

Results: We identified 9 major and 17 overall classes of alerts. We developed a specific metric approach for 5 of these classes, including the 3 most numerous ones in our institution, accounting for 224 (67%) of our alerts. Some alert classes do not readily lend themselves to this approach.

Conclusions: We developed a taxonomy for rule-based alerts and demonstrated its application in developing outcome metrics reports on a large scale. This information allows tuning or retiring alerts and may inform the need to develop complementary or alternative approaches to address organizational imperatives. A method that assigns alerts to classes each amenable to a particular reporting strategy could reduce the difficulty of producing metrics reports.

INTRODUCTION
Rule-based alerting within electronic health records (EHRs) is a common approach to addressing safety, quality, and workflow issues in health care. Most mature EHR installations have alerts of this type and some, including ours, have hundreds. Stage 2 of the Center for Medicare and Medicaid Services Meaningful Use incentive program requires that eligible providers and hospitals implement at least five clinical decision-support interventions, most of which will be rule-based alerts. Because institutions look to clinical decision support and rule-based alerts as an important component of their return-on-investment strategy for their EHR investment, it is imperative to know whether the alerts are not only “working” (firing as designed) but are achieving intended benefits. This understanding is fundamental to improving clinical decision support and may suggest the necessity for considering additional or alternative strategies to achieve strategic goals. A recent publication of the American Health Lawyers Association on minimizing EHR-related safety events specifically called out alert metrics beyond simply override rate as an important determinant of safety in these systems.

Knowledge engineers and builders of alerts typically believe, often with limited or no data, that the ones they deploy are functioning well, are well received by their target audience, and are achieving their intended goals. Tools within EHRs to evaluate these beliefs are generally very limited. Alert structures can be complex, and achieving an understanding of their performance characteristics and effectiveness can prove difficult. To develop a detailed understanding of the functioning and outcomes of an alert usually requires creating an individualized report. There are few reports of systematic approaches to monitoring alerts.

Objective
Our goal was to develop and test a framework for reporting performance metrics for rule-based EHR alerts at scale. Our intention was to achieve alert outcome reports that extend beyond basic metrics and include process outcomes. As a preliminary step we set out to develop a new action-oriented classification system or taxonomy of alerts on the basis of their structure, especially intended and optimized to facilitate outcomes metrics. Existing taxonomies would not suffice because they do not readily map to a measurement framework. We sought to generate metrics in sets rather than one by one to reduce the time and expense of developing and maintaining performance metrics for alerts.

Background
In a proposed five-level evaluation hierarchy of rule-based alert performance, “firing rates” are at the lowest and most commonly reported level. Rates by role such as nurse or physician, specialty such as family medicine or general surgery, site of care such as inpatient or ambulatory, department or unit such as intensive care or urgent care, time of day...
or week, and similar factors can extend this metric. The second level is “acceptance” and “override” rates. Proximate “action taken” by users in response to the alert is the next highest level. The fourth level is a measure of intermediate process goals or outcomes achievement. Finally, the highest level is a measure of patient health goals or outcomes or clinician goals or outcomes achievement. Each successive level in the evaluation hierarchy is more difficult to create. In this report we chose to focus on the fourth level, process goals and outcomes.

For most alerts, knowing that they fire frequently or infrequently and have a high or low acceptance rate yields only a limited understanding of whether their explicit recommendations were followed or if they were effective in achieving their intended goals. Was the safe practice followed or the unsafe practice avverted? Was the evidence-based treatment prescribed? Was the cost-effective choice made, the recommended documentation performed, the dose modified, the procedure ordered or performed? These are “level 4” questions in the hierarchy introduced above. Ultimately, was care improved and the desired health or clinician outcome achieved? These are “level 5” questions. For most alerts, firing, overriding, and proximate action-taken rates do not answer these higher-order questions because action on the alert may not be the same as action on the triggering event.

In EHRs, alerts may be built with a number of available user actions. In the Epic 2012 and earlier versions (Madison, WI) EHR, for example, standard controls include “accept” and “cancel” buttons that take these actions on the alert. However, there may be additional actions such as “open an order set,” “create an order,” or “navigate” to the Problem, Allergy, or Medication List activities to perform an operation, and such actions are intended to address the triggering condition. It is possible for users to “cancel” an alert yet still perform the recommended operation, such as order a laboratory procedure. Alternatively it is possible to “accept” the alert but fail to perform the operation. For example, the user can open an order set attached to an alert and choose not to sign the recommended order, or can navigate to an allergy or medication list and decide not to perform the recommended update. Thus reports that simply count these actions may generate inaccurate and misleading information about alert effectiveness and desired outcomes. In the end, what we want to know is whether the recommended operation was performed, regardless of whether it was done as a direct result of the alert.

A reporting strategy that disengages the outcome from a direct action of the alert creates the additional complexity of determining the optimal time frame for measurement. The measurement interval could be defined as immediately proximate to the alert firing (or viewing, in the case of alerts that do not pop up), as the less stringent “any time within the encounter” definition, or as another predefined interval (such as within eight hours of firing). In the first instance, “credit” is assigned to the alert only if the recommended action occurred as a direct result of or immediately following the alert. An order or action fulfilling the recommendation that was placed later in the same encounter would not count as alert “success.” In the second instance, any fulfilling order or action that was taken within the same encounter would count, even though it is not certain that the action taken was directly caused by the alert. In the inpatient setting, where the entire stay might be considered the encounter, this definition could cause difficulty in interpretation. Here the third approach, crediting actions that occurred within a specified time window, such as within an eight-hour shift, might be more meaningful. Conceptually, this requires an approach to metrics similar to an intention-to-treat analysis of a randomized control study.

Complete assessment of the appropriateness of a specific alert, the user’s response to that alert, or level five patient or clinician outcomes requires a broader analysis to include patient, user, and environmental factors. Because an automated batch processing of alerts cannot achieve that level of investigation, a more realistic goal is to develop a report that would allow categorizing alerts into those appearing to be “high,” “low,” and “intermediate” in performance. An institution might then, for example, choose to direct its efforts at improving, eliminating, or better understanding those alerts with “low” performance. To do so might require a more in-depth assessment, possibly including medical chart reviews. McCoy et al1 published a framework for evaluating alert appropriateness.

To develop a detailed model of alert metrics, it is necessary to have a common understanding of the structure or “anatomy” of an alert. There have been a number of clinical decision support and alert taxonomies developed for different purposes. In 2007, Wright et al at Partners Healthcare System developed a taxonomy for rule-based decision support. They included four functional components they termed triggers, input data, interventions, and offered choices. Later, the National Quality Forum Clinical Decision Support Expert Panel proposed a modification of this classification. They replaced “offered choices” with “action steps.” Triggers are the user actions that can invoke an alert. These actions might include, for example, entering or signing an order, opening a chart or a specific screen, or entering documentation. Input data are the elements in the record that might modify the alert performance. Input data might be information about the patient (eg, age, gender, diagnoses, preferences),
A Metrics Taxonomy and Reporting Strategy for Rule-Based Alerts

about the user (e.g., specialty, role, experience, preferences), or about the environment (e.g., time of day or week, unit, department, or setting). Interventions refer to computer-human interface actions and the manner in which the alert is displayed, such as via a pop-up message. In some cases the intervention might happen without user awareness, such as if the alert action is to set a modifier or to trigger an asynchronous alert (occurring at a remote time or place). Finally, action steps are recommended or permitted actions that a user can take as a direct result of the alert. Accepting, canceling, and overriding (with or without providing a reason) are the most common actions. Many more actions may also be available in alerts, including opening order sets, accepting an order, and navigating to another activity such as the medication, allergy, or problem list. The Sidebar: National Quality Forum Taxonomy: Selected EpicCare Examples illustrates these structural elements with a few examples from the EpicCare EHR. Most other EHR alerts have similar structure and comparable examples.

Combining available triggers, inputs, interventions, and action steps yields a very large number of possible alert forms, particularly since an alert may incorporate more than one element for each functional component. For example, one alert could have an enter-diagnosis and enter-order trigger, multiple data inputs, and both a pop-up display and an in-basket notification. Alerts may also have more than one permissible or recommended action step. This complexity is a major reason why it is difficult to create generalized alert outcome reports. For each alert it is necessary both to define its structure and to declare which actions constitute a desired outcome or “success.” Previous taxonomies are not classified by actions taken (such as create or modify an order) and do not attempt to address alert outcomes.

METHODS

This work was developed at Kaiser Permanente Northwest (KPNW), a Region of the Kaiser Permanente Health Care program located in Oregon and Southwest Washington. The Region employs approximately 1000 physicians and cares for approximately 500,000 Health Plan members. KPNW began implementation of EpicCare in 1994, and it was fully implemented in ambulatory clinics by 1997. The inpatient system was implemented in 2008. KPNW owns and operates 2 hospitals and about 40 outpatient clinic sites, most of which are large and multispecialty.

We took an empirical approach to developing the alert metrics taxonomy. Each of 333 active, production rule-based alerts in our system was assigned to a class on the basis of its structure and intended outcome. If an existing class did not adequately encompass the alert in question, a new class was added or an existing class was modified. This process was iteratively repeated until all alerts were assigned and the remaining classes were coherent. Where alerts had characteristics of more than one class, they were assigned on the basis of their apparent primary intention. For example, an alert that recommended substitution of a particular medication for another (a substitution action) but also facilitated documentation of allergy to the recommended choice via a link to the allergy activity (a documentation action) was classified according to the primary intention of substitution. In order to limit project scope, standard, vendor-supplied drug-drug and drug-allergy alerts were excluded from this analysis. This was deemed appropriate for several reasons. In the Epic EHR such alerts are presented with a different utility. Although they do conform to the same four-element National Quality Forum functional taxonomy, they have a different data and reporting structure and are very numerous. Moreover, for these alerts “acceptance” and “override” rates are more useful metrics because the valid action steps are fewer and more straightforward—the user either accepts or overrides the recommendation to avoid the drug-drug, drug-allergy, or drug-condition combination. Admittedly, that analysis would necessarily
be more complex if one considered the possible override reasons that may be required or optionally provided or the alternative actions such as updating medication or allergy lists.

Following development of an initial taxonomy, we turned attention to designing a report creation methodology. Starting with the classes with the largest number of members, we examined a representative alert from each class. For each, we developed a formulaic description of the triggering event and recommended outcome. Then we used the data model and data in Clarity, Epic’s analytical database, to create a report comparing initial with final conditions to determine alert outcome. We started with the appropriate trigger table in the reporting data warehouse. For example, we used one table for procedure triggers and another for generic medications. Next, we created a subquery that defines the recommended result, such as an order set or in an order attached directly to the alert. We joined this table to the triggered alert by its identifier, the alert locator ID. Next we created a subquery to determine whether the alert trigger and/or the recommended result was ordered or created in a valid time interval, as discussed above. For ambulatory alerts we defined this interval as within the particular patient encounter, usually an office visit or telephone call. Finally, we created a summary report.

RESULTS

Each alert is unique, owing to its complex structure and specific clinical or operational intention. Nevertheless, through empirical analysis, it appears that there are a manageable number of major structural classes for alert metrics, and these constitute the proposed taxonomy (see Sidebar: Alert Metrics Taxonomy). Each of these classes has a generalized structure that can be expressed in narrative. Substitution alerts, for example, are those in which a clinician orders a test, procedure, or treatment, or enters a diagnosis or finding and the alert recommends a second test, procedure, or finding instead, such as “Replace the order for ‘Chest X-ray AP/LAT’ with an order for ‘Chest X-ray two-views.’” The substitutions are usually of the same type (eg, test for test or diagnosis for diagnosis) but could be of mixed type (eg, medication for procedure). In this case, a trigger “X” causes the alert to recommend substituting an item or action “Y.” Corollary-type alerts are similar. In these cases, however, a trigger “X” generates a recommendation of an additional “Y.” For example, “In addition to the order for digoxin, please order a serum potassium and creatinine.” Corollary recommendations may be single or multiple (“Z” and “Y” and “Yn”), and like substitution alerts, the recommendations may be of the same or mixed type.

### Alert Metrics Taxonomy

<table>
<thead>
<tr>
<th>Substitution</th>
<th>Substitute-Order</th>
<th>Substitute-Medication</th>
<th>Substitute-Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corollary</td>
<td>Corollary-Order</td>
<td>Corollary-Medication</td>
<td>Corollary-Documentation</td>
</tr>
<tr>
<td>Modify</td>
<td>Modify-Order</td>
<td>Modify-Medication</td>
<td>Modify-Documentation</td>
</tr>
<tr>
<td>Create</td>
<td>Create-Order</td>
<td>Create-Medication</td>
<td>Create-Documentation</td>
</tr>
<tr>
<td>Create</td>
<td>Create-Communication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove</td>
<td>Remove-Order</td>
<td>Remove-Medication</td>
<td></td>
</tr>
<tr>
<td>Perform</td>
<td>Perform-Procedure</td>
<td>Perform-Documentation</td>
<td></td>
</tr>
<tr>
<td>Informational only</td>
<td>Send communication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FT4 = free thyroid; T4 = thyroid hormone; TSH = thyroid stimulating hormone; W = with.
The other alert classes follow similar patterns. Modify-type alerts recommend changes to new or existing orders or documentation—for example, “Decrease the dosage of digoxin on the basis of the patient’s serum creatinine.” Create alerts recommend new orders or documentation, such as “The patient is due for a mammogram. Please sign the attached mammogram order.” Remove alerts recommend that existing orders or documentation are canceled—for example, “It appears that the patient no longer requires a follow-up CT [computed tomography] scan. If this is correct, please cancel this order.” Perform alerts recommend the execution of specific actions, such as “Because of the elevated initial blood pressure, please repeat a blood pressure in 5 minutes and document in the chart.” Informational alerts provide a message without the expectation of a particular action that is captured within the system—for example, “There is a regionwide shortage of influenza vaccine.” Alerts might send communication through a variety of means including in-basket messages or messages to pagers, faxes, phones, or Internet-enabled devices. Because this taxonomy is not exhaustive, there is necessarily an Other category. In our analysis, the alerts that fell into this category were “one-offs” and did not lend themselves to additional characterization at this time. An example of such an alert is a single one that automatically adds a modifier or marker to the patient’s chart if he is a man older than 70 years.

<table>
<thead>
<tr>
<th>Alert_Description</th>
<th>Recommended #</th>
<th>Recommended %</th>
<th>Trigger #</th>
<th>Trigger %</th>
<th>Trigger+Recommended #</th>
<th>Trigger+Recommended %</th>
<th>None #</th>
<th>None %</th>
<th>Total #</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTRAST IMAGING AND NO PRIOR CREATININE</td>
<td>99</td>
<td>3.3%</td>
<td>938</td>
<td>30.9%</td>
<td>1790</td>
<td>59.0%</td>
<td>206</td>
<td>6.8%</td>
<td>3033</td>
</tr>
<tr>
<td>REF EKG</td>
<td>50</td>
<td>5.2%</td>
<td>133</td>
<td>13.7%</td>
<td>723</td>
<td>74.7%</td>
<td>62</td>
<td>6.4%</td>
<td>968</td>
</tr>
<tr>
<td>REF EKG WITHIN 30 DAYS</td>
<td>67</td>
<td>8.2%</td>
<td>112</td>
<td>13.7%</td>
<td>589</td>
<td>71.8%</td>
<td>52</td>
<td>6.3%</td>
<td>820</td>
</tr>
<tr>
<td>REF PATIENT OTHER</td>
<td>14</td>
<td>0.8%</td>
<td>732</td>
<td>42.9%</td>
<td>853</td>
<td>50.0%</td>
<td>107</td>
<td>6.3%</td>
<td>1706</td>
</tr>
<tr>
<td>LACTATE WITH BLOOD CULTURES ED</td>
<td>3</td>
<td>0.2%</td>
<td>125</td>
<td>8.5%</td>
<td>1337</td>
<td>91.0%</td>
<td>5</td>
<td>0.3%</td>
<td>1470</td>
</tr>
<tr>
<td>REF TSH NOT ON MEDS</td>
<td>10</td>
<td>1.5%</td>
<td>109</td>
<td>15.9%</td>
<td>551</td>
<td>80.2%</td>
<td>17</td>
<td>2.5%</td>
<td>687</td>
</tr>
<tr>
<td>REF TSH NOT ON MEDS WITHIN 2 YEARS</td>
<td>8</td>
<td>1.2%</td>
<td>72</td>
<td>10.8%</td>
<td>561</td>
<td>84.0%</td>
<td>27</td>
<td>4.0%</td>
<td>668</td>
</tr>
<tr>
<td>REF CBC 4 WEEKS</td>
<td>13</td>
<td>1.0%</td>
<td>138</td>
<td>10.2%</td>
<td>1166</td>
<td>86.4%</td>
<td>32</td>
<td>2.4%</td>
<td>1349</td>
</tr>
<tr>
<td>REF URIC ACI</td>
<td>22</td>
<td>5.4%</td>
<td>98</td>
<td>23.9%</td>
<td>240</td>
<td>58.5%</td>
<td>50</td>
<td>12.2%</td>
<td>410</td>
</tr>
<tr>
<td>REF URIC ACI WITHIN 6 WEEKS</td>
<td>25</td>
<td>7.1%</td>
<td>73</td>
<td>20.9%</td>
<td>207</td>
<td>59.1%</td>
<td>45</td>
<td>12.9%</td>
<td>350</td>
</tr>
<tr>
<td>REF PHOSPHORIOUS</td>
<td>21</td>
<td>5.3%</td>
<td>92</td>
<td>23.1%</td>
<td>234</td>
<td>58.7%</td>
<td>52</td>
<td>13.0%</td>
<td>399</td>
</tr>
<tr>
<td>Total/Average</td>
<td>332</td>
<td>2.8%</td>
<td>2622</td>
<td>22.1%</td>
<td>8251</td>
<td>69.6%</td>
<td>655</td>
<td>5.5%</td>
<td>11860</td>
</tr>
</tbody>
</table>

Figure 3. Corollary-type alerts and report. A referral to nephrology for evaluation of acid-base disturbance generated these alerts for tests recommended before the referral that have not been performed. In the report, “X” is the procedure that triggered the best-practice alert, “Y” the recommended additional order(s); “X+Y” represents encounters in which both tests were ordered: the desired result in this case. © 2014 Epic Systems Corporation. Used with permission.

BUN = blood urea nitrogen; CA = calcium; CBC = complete blood count; CL = chloride; CO2 = carbon dioxide; CR = creatinine; ED = Emergency Department; EKG = electrocardiogram; GLU = glucose; K = potassium; KPNW = Kaiser Permanente Northwest; NA = sodium; REF = referral; TSH = thyroid stimulating hormone; UA = urinalysis.
than age 65 years who has documentation that he is a current or ever-smoker. This marker, in turn, is used by a second alert that recommends screening for abdominal aortic aneurysm. We elected not to create new classes with only single members in our data set. The Sidebar: Alert Metrics Taxonomy also contains subcategories. More granular specification is important because the reporting logic differs for procedures, medications, and documentation.

We assigned each of 333 KPNW active, in-production, rule-based alerts to a class. Some alerts recommend or allow more than one action, such as substitute an order and perform documentation. As noted, for the purposes of report creation, simplification, and this initial stage of development, each was assigned to one class only on the basis of their primary or most impactful recommendation. In our system at this time, 3 of 18 categories accounted for more than 60% of all alerts, with Corollary Order, Substitute Medication, and Create Order contributing 106, 58, and 46 alerts, respectively (Figure 1). Categorizing alerts by class allowed us to develop a reporting strategy that works for all members of that class, or at least for those members who do not deviate too much from a prototypical class representative. The Substitution Order class offers an example of our approach. In this case, a user orders test or procedure “X” and the alert recommends substituting test or procedure “Y” (Figure 2). Regardless of whether the user accepted or canceled the alert, or opened or did not open an attached order set if present, what we want to know is, at the end of...
the measurement period (eg, encounter), which was ordered, “X” or “Y”? (Ordering both is also possible, which would usually not be a desired result, as is ordering neither, which might or might not be desirable depending on the situation.) What we need is a program that can determine for all alerts of this type, which order(s) were present in the “result set” at the end of the encounter. Figure 2 also shows an example of a report created for 2 alerts of the Substitution class. In these 2 alerts, the recommended result occurred 54.8% of the time on average.

Corollary Order alerts provide a second example. In these situations, a user orders test or procedure “X” and the alert recommends one or more additional test or procedure “Y” (Figure 3). In these cases, regardless of whether the user accepted or canceled the alert or performed other actions as a direct result of the alert, we want to know at the end of the encounter what was ordered, “X,” “Y,” both, or neither? Fortunately, the same approach and logic can be used to generate reports for these alerts. The structure is the same and what differs is the definition of success. In this case, what is desired is “X + Y” and not “X” or “Y” alone. Using this logic, a report for this class of alerts can be generated (Figure 3). In this example, the recommended result occurred in an average of 69.6% of cases.

The approach to medication-related alerts is similar but often more complex. It is unusual for there to be a one-to-one recommendation in medication substitutions. Usually a class of medications is contraindicated in a population defined by an age range, laboratory findings such as renal insufficiency, a specific genetic marker, or a diagnosis. The recommended substitution might depend on other factors including the initial reason for prescribing the triggering medication. Thus the recommended substitution values might be organized and contained in two or more groups. Furthermore, the valid medication alternatives themselves usually constitute a class rather than a single entity. The reporting program must be able to detect all the valid substitution values. Figure 4 illustrates a Substitute Medication alert. In this case a class of medications is relatively contraindicated in the elderly because of risks of insomnia, delirium, sedation, and cognitive impairment. Members of this medication class are prescribed for a variety of indications, and recommended alternatives depend on these reasons. Such condition-dependent alternatives can be offered within an order set.

Despite these complexities, it was possible to develop a program that can automatically detect the triggers and recommended substitutions for medication-related alerts, and produce a report (Figure 5). Using pharmaceutical classes and generic drugs facilitates this. We are also able to take advantage of naming conventions in our order set development where, for example, all groups that contain medications begin with the prefix MED. For the 15 alerts in this example, the average rate of prescribing the preferred medication is just 10% (range, 1.5%-54.3%). Because nonpharmacologic therapies may be very appropriate, prescribing “none” (neither the trigger nor the recommended alternative medications) might be considered a positive outcome. Taking the “none” and “Y” results together yields an overall average success rate of 24.8% (range, 9.4%-75.5%) for these alerts.

**DISCUSSION**

It is difficult to understand or to improve what isn’t measured or at least examined. To comprehend which alerts achieve their intended goals, one needs more than only rates of firing,

<table>
<thead>
<tr>
<th>Alert Description</th>
<th>Order Type</th>
<th>None</th>
<th>“X”</th>
<th>“Y”</th>
<th>“X+Y”</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELDERLY AND BENZODIAZEPINES</td>
<td>SmartSet</td>
<td>9.7%</td>
<td>36.9%</td>
<td>6.5%</td>
<td>46.9%</td>
<td>6898</td>
</tr>
<tr>
<td>ELDERLY AND SKELETAL MUSCLE RELAXANTS</td>
<td>SmartSet</td>
<td>19.9%</td>
<td>59.4%</td>
<td>8.2%</td>
<td>12.4%</td>
<td>1723</td>
</tr>
<tr>
<td>ELDERLY AND Z DRUG SLEEP AGENTS</td>
<td>SmartSet</td>
<td>9.6%</td>
<td>71.5%</td>
<td>11.6%</td>
<td>7.3%</td>
<td>1545</td>
</tr>
<tr>
<td>ELDERLY AND ANTIHISTAMINES/ANTICHOLINERGICS</td>
<td>SmartSet</td>
<td>21.8%</td>
<td>51.5%</td>
<td>14.6%</td>
<td>12.1%</td>
<td>1540</td>
</tr>
<tr>
<td>ELDERLY FALL RISK AND ANTI PSYCHOTICS/SLEEP MEDICATIONS</td>
<td>SmartSet</td>
<td>11.6%</td>
<td>63.5%</td>
<td>4.5%</td>
<td>20.5%</td>
<td>978</td>
</tr>
<tr>
<td>ELDERLY AND LORAZEPAM OR OXAZEPAM</td>
<td>SmartSet</td>
<td>7.7%</td>
<td>83.0%</td>
<td>1.7%</td>
<td>7.7%</td>
<td>951</td>
</tr>
<tr>
<td>DRUG INTERACTION CLOPIDOGREL+PO ESOMEPRAZOLE OR OMEPRAZOLE</td>
<td>SingOrd</td>
<td>5.6%</td>
<td>25.9%</td>
<td>20.2%</td>
<td>48.3%</td>
<td>752</td>
</tr>
<tr>
<td>ELDERLY FALL RISK OR DEMENTIA+TCA/PROCHLORPERAZINE</td>
<td>SmartSet</td>
<td>29.7%</td>
<td>49.6%</td>
<td>6.6%</td>
<td>14.1%</td>
<td>708</td>
</tr>
<tr>
<td>ELDERLY TERTIARY TRICYCLIC ANTIDEPRESSANTS</td>
<td>SmartSet</td>
<td>45.0%</td>
<td>43.9%</td>
<td>4.2%</td>
<td>6.9%</td>
<td>642</td>
</tr>
<tr>
<td>ELDERLY AND PROMETHAZINE</td>
<td>SmartSet</td>
<td>20.0%</td>
<td>49.2%</td>
<td>21.1%</td>
<td>9.8%</td>
<td>551</td>
</tr>
<tr>
<td>DRUG INTERACTION WARFARIN+SULFA</td>
<td>SmartSet</td>
<td>21.3%</td>
<td>17.7%</td>
<td>54.3%</td>
<td>6.8%</td>
<td>503</td>
</tr>
<tr>
<td>DRUG INTERACTION STATIN+GEMFIBROZIL</td>
<td>SmartSet</td>
<td>36.8%</td>
<td>36.2%</td>
<td>22.7%</td>
<td>4.3%</td>
<td>163</td>
</tr>
<tr>
<td>ELDERLY AND BUTALBITAL</td>
<td>SmartSet</td>
<td>25.8%</td>
<td>60.6%</td>
<td>8.3%</td>
<td>5.3%</td>
<td>132</td>
</tr>
<tr>
<td>ELDERLY AND DISOCUCATED THYROID</td>
<td>SmartSet</td>
<td>11.1%</td>
<td>86.1%</td>
<td>2.8%</td>
<td>0.0%</td>
<td>72</td>
</tr>
<tr>
<td>ELDERLY AND INDOMETHANINE</td>
<td>SmartSet</td>
<td>18.5%</td>
<td>76.9%</td>
<td>1.5%</td>
<td>3.1%</td>
<td>65</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>14.8%</td>
<td>48.2%</td>
<td>10.0%</td>
<td>27.0%</td>
<td>17314</td>
</tr>
</tbody>
</table>

Figure 5. Substitute Medication Alerts with results. “X” is the medication that triggered the alert, “Y” is the recommended substitution medication, “X+Y” represents encounters in which both medications were ordered. This report also indicated whether the medication was ordered via an ambulatory order set or via an attached single order (SingOrd).

PO = by mouth; TCA = tricyclic antidepressant.
acceptance, and override. First, one needs an explicit understanding and articulation of the goal. Next, one needs to determine whether that goal was achieved. To make this a realistic endeavor on a large scale, one needs a systematic approach.

We developed a classification system that allows development of batch reports on alert process outcomes or goals. Our initial approach was empiric and influenced heavily by the existing alerts in our system. We simplified the classification system by assigning alerts to only a single class, even though some alerts have features of more than one class. For these reasons, this taxonomy is certainly not exhaustive. Other classes of alerts no doubt exist in other systems today and will exist within our system in the future. We next created batch reports for some classes of alerts.

To date, we have developed reports for the Corollary-Order, Corollary-Medication, Create-Order, Substitute-Order, and Substitute-Medication classes of alerts. These represent the top three plus two less-frequent classes of alerts at KPNW, accounting for fully two-thirds of our current alerts. The fourth most common class, Informational Only, is not amenable to reporting of this nature because there is no measurable outcome event. Creating outcomes reports for several other classes, including those related to documentation, may also prove difficult and require special techniques, structured data entry, Concept Unique Identifiers, or natural language processing.

In some systems, certain alerts are designed to allow overrides with rationales, usually selected from a list, with or without the ability to add free text comments. We have very few of these in our system, except in the standard drug-drug and drug-allergy alerting activity. A challenging metrics issue is how to handle such alerts. Examples of overrides include “patient refused,” “benefit outweighs risk,” “no good alternative,” “postponed for medical indications,” or “doubtful allergy.” When a valid override or postpone reason is selected, this might be counted as alert success or at least not failure, but this assumes that only valid reasons are available for the given alert and that the reasons are selected with fidelity. In practice, some alerts are overridden, often at a very high rate, because the alert is a “false positive” based on incomplete or faulty data, incorrect alert logic, or inaccurate knowledge synthesis. A complete evaluation of the effectiveness of such an alert could thus require examining the selected override or postpone reasons in light of the actual clinical data to determine whether the reasons were applied appropriately.

We provided examples of metrics for three classes of alerts. For the Substitution-Order, Corollary-Order, and Substitution-Medication alerts we measured in this way, the desired outcome was achieved on average 54.8%, 69.6%, and 24.8% of the time, respectively. Running the same report with different alerts, or perhaps even the same alerts after the alert or the alerting environment was modified, would probably yield different numbers. An alert might be modified, for example, by developing a clearer message, making it more specific by incorporating exceptions in the logic, or adding a more useful action step. Examples of modifying the alerting environment would be decreasing the overall number of alerts, providing user education, or changing incentives.

Alert success results such as in our Substitute-Medication report (Figure 5) may seem low and disappointing to some people but likely will not surprise those experienced with alert acceptance and override rates. The value in having such data is first that it allows identification and examination of alerts that appear to be underperforming. Viewing this data also allows a better understanding of actual alert performance more generally and might encourage quality and safety officers, decision-support developers, and leaders to plan more realistic and comprehensive safety and quality strategies, rather than blithely assuming success from alerts alone. Findings such as these suggest that alerts may be part of such a strategy but often will not be sufficient. The main outcomes of this study were the successful development of a rule-based alerts taxonomy and the demonstration of its application in a reporting strategy. The full-scale application of this strategy with detailed outcomes to a corpus of alerts was out of the scope for this article and could itself justify a report. However, even preliminary and partial review of our alerts using this approach resulted in the elimination of several poorly performing alerts and the modification of others.

Our approach decreases the time and effort to produce alert process performance metrics reports, making it more feasible to run them regularly, and this in turn results in a more complete and dynamic representation of alert functioning. Because increased complexity makes measurement more difficult and costly, alert developers may want to add complexity and to use extra options and actions more thoughtfully and only where they add significant value.

This study has some limitations. A single author developed and determined the taxonomy and assigned alerts to the taxa. Although the primary intention and contribution of this work was to develop a reporting framework and approach rather than a broadly applicable and validated taxonomy, it would be useful to do this in the future. Two or more individuals making assignments with a reported interrater agreement would add confidence. We examined alerts in only a single institution using a single EHR, and we know we have not exploited all potential alert actions. There are no doubt alert classes that we did not identify, and we chose not to create an alert class containing only a single member in our data set. Furthermore, we assigned alerts to a single class, although some have actions that might place them in more than one. Alerts assigned to the Other category underline that the current taxonomy is not exhaustive. Further study with additional alerts and at different institutions should result in more classes. The specifics of our reporting approach will be generalizable only to a certain extent because each EHR has its own structure.
and data model, although most EHRs will have similar components. Finally, this report did not attempt to address the highest level in the evaluation hierarchy of rule-based alerts performance, whether patient or clinician goals or outcomes were achieved.

CONCLUSION

We developed a taxonomy for rule-based alerts and demonstrated its application in developing outcome metrics reports on a large scale.

CLINICAL RELEVANCE STATEMENT

Understanding whether clinical decision alerts achieve their intended function is fundamental to developing effective alerts and realizing the safety, quality, and resource benefits of EHRs. To reach this understanding, individuals and groups charged with developing and maintaining alerts need enhanced tools and reports. The approach presented here allows nuanced effectiveness reports on a large scale.

Disclosure Statement

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

Acknowledgments

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References


Our Wit Languisheth

Yet when we content ourselves with their discoveries [ie, those of ancient Greece], and calmly believe (which is mere sleepiness) that there is now no more place for new inventions, the spritely edge of our own wit languisheth, and we extinguish the lamp which they lighted to our hands.

— William Harvey, MD, 1578-1657, English physician, first to describe the circulatory system
This image was captured outside the Denver Art Museum. The sun was aligned behind the building, and the photograph was later processed in Photoshop to give the final result. The Denver Art Museum is a must-visit location in Denver, CO.

Dr McDowell is a Plastic Surgeon at the Denver Medical Office in CO.
More of his photography can be viewed online at: www.diversityofvision.com.
ORIGI NAL RESEARCH & CONTRIBUTIONS

“Getting off the Bus Closer to Your Destination”: Patients’ Views about Pharmacogenetic Testing

Susan Brown Trinidad, MA; Tara B Coffin, MEd; Stephanie M Fullerton, DPhil;
James Ralston, MD, MPH; Gail P Jarvik, MD, PhD; Eric B Larson, MD, MPH

ABSTRACT

Context: Pharmacogenetic testing, a form of precision medicine, has the potential to optimize medication choice and dosing. Yet, relatively little is known about the views of patients—particularly those with chronic psychiatric conditions—with respect to such testing.

Objective: To explore patients’ beliefs and attitudes regarding pharmacogenetic testing, with the goal of informing policy development and implementation.

Design: Qualitative study design using semistructured focus groups with adults enrolled in Group Health Cooperative, a large health maintenance organization in the Pacific Northwest. We conducted focus groups with patients prescribed antidepressants (pilot session plus 2 focus groups, n = 27); patients prescribed carbamazepine (2 focus groups, n = 17); and healthy patients (2 focus groups, n = 17).

Results: Although participants understood the potential advantages of pharmacogenetic testing, many felt that the risks (discrimination, stigmatization, physician overreliance on genomic results, and denial of certain medications) may outweigh the benefits. These concerns were shared across groups but were more strongly expressed among participants with chronic mental health diagnoses.

Conclusion: Clinical implementation of pharmacogenetic testing must address patient concerns about privacy, discrimination, quality of care, and erosion of the physician-patient relationship.

INTRODUCTION

The existence of interindividual differences in medication response is well known: variability exists among patients in terms of drug efficacy, dosage requirements, and susceptibility to adverse drug reactions. Pharmacogenetics, the study of how genetic factors influence pharmacokinetics and drug clearance, was first envisioned by Motulsky in 1957, has a growing role in providing clinically useful prescribing guidance. The US Food and Drug Administration currently lists 139 approved drugs with pharmacogenomic information in their labeling, with categories ranging from information about clinical pharmacology to contraindications, information for patient counseling, and dosing considerations. Boxed warnings, indicating the potential for serious injury or death for individuals with specific genotypes, are in place for select drugs in anesthesiology (codeine), cardiology (clopidogrel), hematology (lenalidomide), infectious disease (abacavir), oncology ( arsenic trioxide, everolimus, rasburicase), and neurology ( carbamazepine, valproic acid). The hope is that appropriate clinical use of pharmacogenetic testing will contribute to the “triple aim” of improving population health, enhancing patient care, and controlling medical costs. Pharmacogenomics, along with related advances in cancer genomic testing, has received new attention with the launch by President Obama of a new Precision Medicine Initiative.

The value of pharmacogenetic testing will depend in part on its acceptability to physicians and patients. The literature contains some data regarding physicians’ views of pharmacogenetic testing and others have explored the views of the general public, but less is known about patients’ perceptions. The objective of this study was to explore the views of patients with and without chronic conditions regarding pharmacogenetic testing.

METHODS

Setting and Study Design

This study is part of the Electronic Medical Records and Genomics Network, a consortium funded by the National Human Genome Research Institute to develop approaches to and investigate the utility of the clinical integration of genomic information. Our project is a collaboration between investigators at the Group Health Research Institute and the University of Washington, with study participants at Group Health Cooperative, an integrated health care delivery system that serves more than 600,000 enrollees in Washington and Idaho.

We selected a focus group method because interactive discussions are optimal for exploring questions of acceptability, particularly for topics about which participants may feel underqualified to opine; participants may feel more comfortable sharing potentially negative views because the group format can provide a feeling of “safety in numbers” for

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participants. The study was reviewed and approved by the Group Health Research Institute Human Subjects Review Committee, and written informed consent was obtained from all participants.

**Sampling Strategy and Recruitment**

Prospective participants were English-speaking adults age 18 years and older identified through Group Health administrative records. To learn about the perspectives of different “types” of patients, we defined 3 patient cohorts (Table 1). As a proxy for patients who were likely to have had personal experiences with trial and error in medication selection, we selected Group Health enrollees who had been (sequentially) prescribed multiple antidepressant medications. To elicit the views of patients for whom pharmacogenetic testing could possibly help to avoid adverse drug events, we identified individuals who had been prescribed carbamazepine. Carbamazepine has been associated with Stevens-Johnson syndrome (toxic epidermal necrolysis) in patients with the HLA-B*1502 allelic variant of the HLA-B gene, which is more common in people of Southeast Asian ancestry; for this reason, we oversampled for Asian ancestry in this group. For comparison purposes, we identified a third cohort of patients with no particular pharmaceutical concerns or chronic conditions.

We mailed 4303 letters to prospective participants describing the study and inviting them to call to enroll; 61 did so, for a total response rate of 1.4%.

**Data Collection**

In May 2012, we held a pilot session and 2 semistructured focus groups with the antidepressant cohort and 2 focus groups with patients prescribed carbamazepine. In July 2012, we conducted 2 focus groups with patients without chronic illnesses. The investigators used a written discussion guide in all sessions (Table 2). Each discussion was cofacilitated by 2 members of the study team (SBT and SMF, who introduced themselves as researchers from the University of Washington) and lasted 2 hours. A court transcriptionist attended each session. We provided an informal buffet dinner and paid parking, and each participant was given $50 in cash at the end of each session.

**Data Analysis**

Our analytic goal was to produce a qualitative description of participants’ perceptions of pharmacogenetic testing. We used thematic analysis and a constant comparison approach to coding. Two members of the study team performed several close readings.

**Table 1. Focus group composition**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Antidepressant cohort</th>
<th>Carbamazepine cohort</th>
<th>Healthy cohort</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligibility criteria</td>
<td>Prescribed ≥ 2</td>
<td>Currently prescribed</td>
<td>GHC enrollees for at least 2 years; ≤ 2 current prescriptions; exclusions: mental health diagnoses, current antidepressant or carbamazepine prescription, n = 17, No. (%)</td>
<td>n = 61, No. (%)</td>
</tr>
<tr>
<td></td>
<td>antidepressants in previous 2 years; new antidepressant prescription within past 3 months, n = 27, No. (%)</td>
<td>carbamazepine; oversampled for Asian ethnicity, n = 17, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10 (37)</td>
<td>5 (29)</td>
<td>7 (41)</td>
<td>22 (36)</td>
</tr>
<tr>
<td>Female</td>
<td>17 (63)</td>
<td>12 (71)</td>
<td>10 (59)</td>
<td>39 (64)</td>
</tr>
<tr>
<td>Age, years</td>
<td>22-78</td>
<td>21-73</td>
<td>21-78</td>
<td>21-78</td>
</tr>
<tr>
<td>Mean</td>
<td>54</td>
<td>50</td>
<td>50</td>
<td>51</td>
</tr>
<tr>
<td>Race and ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>23 (85)</td>
<td>11 (65)</td>
<td>15 (88)</td>
<td>49 (80)</td>
</tr>
<tr>
<td>Black</td>
<td>1 (4)</td>
<td>1 (6)</td>
<td>0</td>
<td>2 (3)</td>
</tr>
<tr>
<td>American Indian</td>
<td>1 (4)</td>
<td>0</td>
<td>0</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (4)</td>
<td>2 (12)</td>
<td>0</td>
<td>3 (5)</td>
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<tr>
<td>Pacific Islander</td>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hispanic</td>
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<td>2 (12)</td>
<td>2 (12)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (4)</td>
<td>3 (18)</td>
<td>2 (12)</td>
<td>6 (10)</td>
</tr>
<tr>
<td>Educational attainment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some high school</td>
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<td>0</td>
<td>1 (6)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>High school or GED</td>
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<td>3 (18)</td>
<td>0</td>
<td>5 (8)</td>
</tr>
<tr>
<td>Some college</td>
<td>6 (22)</td>
<td>2 (12)</td>
<td>0</td>
<td>8 (13)</td>
</tr>
<tr>
<td>Associate degree</td>
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<td>2 (12)</td>
<td>0</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>9 (33)</td>
<td>5 (29)</td>
<td>8 (47)</td>
<td>22 (36)</td>
</tr>
<tr>
<td>Master’s degree</td>
<td>8 (30)</td>
<td>4 (24)</td>
<td>7 (41)</td>
<td>19 (31)</td>
</tr>
<tr>
<td>PhD</td>
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<td>0</td>
<td>0</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Other advanced degree</td>
<td>0</td>
<td>1 (6)</td>
<td>1 (6)</td>
<td>2 (3)</td>
</tr>
</tbody>
</table>

GED = general equivalency diploma; GHC = Group Health Cooperative.
of the de-identified transcripts. The lead analyst drafted a codebook of the major themes, which was revised over several meetings of the analytic team. Transcripts and codes were uploaded into Dedoose (www.dedoose.com), an online software application for qualitative analysis. The codebook went through two substantive revisions before final coding, including independent coding of four transcripts by two team members. The lead analyst performed final coding, with review by a second member of the team.

RESULTS

Participants were aware of inter-individual differences in medication response. Many shared stories about medications that did not work, caused side effects, or were “too strong” or not strong enough. Several related having felt like “guinea pigs” or, in one case, “a test-tube baby” during a process of therapeutic trial and error. A participant in one of the antidepressant groups said, “Sometimes I’ve been prescribed a medication and then find out it’s not maybe doing the job. So we go to the next medication down the list, whereas, for some people, that first one works just fine.” The idea that genetics could make a difference in drug response was less familiar, but some participants believed that medication response could be inherited or shared within families.

Participants Believed Pharmacogenetic Testing Could Be Beneficial

Upon introduction to the topic, participants understood the potential of pharmacogenetic testing to optimize prescribing decisions, and they could imagine clear benefits from its use. As one participant put it, “I think it’s a great idea. Who wouldn’t want more information about the proper medication to take?” Another compared pharmacogenetic testing to riding a bus: “You could jump off anywhere downtown and get to a store, but you want to get off closer to the store you’re going to.” The value of the test could be even greater in high-stakes situations: a participant who reported that her child was currently awaiting a liver transplant said, “You get the liver, and you’re on medication for a long time. If there was a test that would show us which medications are going to work for him, we’d be on that so fast! Because that’s a huge life-or-death deal.”

Participants in the antidepressant and carbamazepine groups seemed particularly sensitized to the challenges patients can face in finding the right medication and avoiding side effects: many related stories of trial-and-error in the therapeutic odyssey. One person, a participant in one of the depression groups, shared her frustration with prior medication experiences and emphasized the value of identifying the optimal drug more quickly:

Even if it takes six months [to get pharmacogenetic test results], I have had—looking back, it’s like, you know, gee, do you think that that particular drug was what took like four years out of my life? Yeah. If somebody could go in there and figure it out in four months, yeah, that would be better.

A participant in one of the carbamazepine discussions said, “The idea that a genetic test—I know there’s some controversy there—but that it could help limit, or define, [the best] medication, that’s very appealing. I mean, I have had bad years on the wrong thing.” Another participant in the same session commented, “If I were taking lithium, or Depakote, or some medicine with a lot of side effects, and this test could say, well, those aren’t going to help me, I would want to be taken off of those. So I think there could be a benefit to having a complete workup of the information.”

Table 2. Focus group discussion topics

<table>
<thead>
<tr>
<th>Step</th>
<th>Goals/subtopics</th>
<th>Sample questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warm-up and orientation</td>
<td>- Establish rapport within the group</td>
<td>Different people respond differently to medications. For example, codeine—a commonly prescribed pain medication—just doesn’t work for some people. And some people may have severe reactions to medications that work just fine for others. Have you ever heard of anything like this before? Have you ever heard that genes might play a role in such differences?</td>
</tr>
<tr>
<td>Directed pharmacogenetic testing (for specific medication or class)</td>
<td>- Informed consent</td>
<td>Would you want to know if your doctor planned to order a genetic test before prescribing medication? Would you want this kind of test if you could find out the drug might not work for you? Would you want information suggesting that you may react similarly to related drugs (in addition to the one the doctor wished to prescribe for your current condition)?</td>
</tr>
<tr>
<td></td>
<td>- Pros and cons</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Factors influencing decision making</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Information desired about results</td>
<td></td>
</tr>
<tr>
<td>Whole-genome sequencing (including pharmacogenomic indication)</td>
<td>- Informed consent</td>
<td>Would you be willing to undergo sequencing before being prescribed a specific medication (e.g., at your annual physical examination)? What would you want to know about the way(s) in which your additional genetic test information might be stored? Eventually such comprehensive genetic testing might include all genes in the genome, not just those most relevant to drug prescribing. This might mean that other information relevant to your current or future health status would also be generated. What are your impressions about this possibility?</td>
</tr>
<tr>
<td></td>
<td>- Pros and cons</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Factors influencing decision making</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Data security</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Information desired about results</td>
<td></td>
</tr>
</tbody>
</table>
Potential Negative Effects on Quality of Care and the Physician-Patient Relationship

Some participants felt that physicians might rely too heavily on genetic results and fail to give due consideration to all possible factors; others worried that physicians might not understand how to use this new information appropriately. A participant in one of the sessions with healthy patients said, “I can see this testing as a protection for doctors, kind of a cop-out. They won’t have to work quite as hard to dig and find out, ‘What shall I prescribe this person and how is your genome, and the way medication problems had not been taken seriously or were actually contradicted. The following exchange, which took place in one of the antidepressant groups, illustrates several participants’ views:

PARTICIPANT 4: I want to say that again, what really bothers me the most: you have something static, which is your genome, and the way medication reacts is all different. And all other kinds of physical situations that may affect that medication. And because [the genome is] static, would the doctor be more inclined to say … “I’m sorry, that’s what the test says”?

PARTICIPANT 1: And look at you very authoritatively and say, “This must be in your mind. For all the other patients, it works fantastically.”

PARTICIPANT 6: It’s not the only piece of information. If you have had [gastrointestinal] surgery, for example, and you can’t absorb a medication, that’s not something that’s going to show up on your genetic profile.

PARTICIPANT 7: If you have multiple illnesses, and you take multiple medications, that’s not going to necessarily show up there either.

Participants voiced concern about the potential for genetic information to curtail interaction and reduce trust between physicians and patients. In addition to wanting physicians to listen to their concerns and take them into consideration in decision making, participants sought assurance that, in delivering genetic results, the physician would assess the patient’s need for support:

Doctors have all this [genetic] information, and you have to look at a person’s mental state. Can they handle certain information, or does that send them off to suicide? Or what’s it going to do? I was told one time I was getting tested for cancer, and then the doctor walked out of the room. I’m like, “What? What? Who?” I’m sitting there all by myself. “You’re testing for cancer??” So how can you deal with this information? How is that going to be handled?

In contrast, a single participant in the antidepressant group envisioned pharmacogenetic testing as an important step toward what he considered the ideal: “the doctor robot,” which would make all clinical decisions on the basis of objective data.

Some participants viewed the use of pharmacogenetic information to deny a particular “good” medication as a form of unfair discrimination, as in this example: “The only thing I don’t like about [pharmacogenetic testing is], because of certain percentages, you might not be good on a certain drug, maybe, and they make this whole list of all these good drugs you can’t have. So they would refuse certain medicines to you, your whole life.” Another participant stated that if there were only one medication available to treat a particular, serious condition, and a pharmacogenetic test indicated that the medication could cause harm, it should be up to the patient—not the physician—to decide whether to take the risk.

Concerns about Access to Genetic Information

Notwithstanding their belief in the value of pharmacogenetic testing, participants identified potential drawbacks to its implementation in the clinic. Concerns about the potential for genetic information to be accessed and (mis)used by unauthorized persons were expressed in all groups. Breach of confidentiality; discrimination in eligibility and coverage for health insurance, long-term care insurance, and disability insurance; employment discrimination; being targeted for pharmaceutical marketing campaigns; and possible misuse by law enforcement agencies were of concern to participants.

Discrimination risks were more readily and more strongly expressed in the antidepressant and carbamazepine groups, together with concerns about social stigma associated with mental health diagnoses, as in this example from the carbamazepine group:

I already have concerns just about electronic keeping of my records, compared to the way it used to be [when] it was on all on paper. I have already experienced the lack of privacy with my primary doctor … I have mental health issues, so sometimes without even asking—they are supposed to be kept separate—my regular doctor, … just access[es] the mental health thing, and start[s] reading this. And they have already abused it . . . . That’s why I have a lot of privacy issues, because I have seen how it’s easily taken advantage of.

Participants were uncomfortable with the potential for genetic information to be shared legally beyond the health care system, such as with law enforcement agencies or in legal proceedings (eg, for disability determinations). A participant in the antidepressant cohort said:

I wouldn’t mind it so much as part of my medical record, if my medical record didn’t go to other people. Like applying for disability insurance, they go through medical records, and what they decide and they define it and interpret it in their own way. So I would be concerned about if they got ahold of genetic

Of greatest concern to participants across all sessions was the possibility that physicians might rely exclusively on pharmacogenetic test results and disregard patients’ reports about how a medication is working (or failing to work).
information and what they would do to you this time.

Participants across all three cohorts also expressed concern about access to pharmacogenetic information within the health care system. Participants suggested that genetic information should be restricted to clinicians with a clear need to know, and that access should be limited to data relevant to a current clinical concern, as in this comment: “If I could have it on a microchip somewhere and say, okay, ‘If I’m unconscious, you know, I give medical permission to read this.’ Yeah, I probably would go for that. But at the same time, I might say, ‘Well, I don’t necessarily want it in the chart where the person who’s making my appointment can look at it.’” Several other participants suggested that genetic information be given directly to the patient, who would be responsible for determining when it should be shared. One participant commented, “It’s us having power over the information. We still want to be a very important part of the equation. And that we get to make some decisions about how it’s used.”

Patients’ Understanding of “Genetic Testing” Is Discordant with Clinicians’ Definition

As designed, the focus group guide progressed from discussion of a narrow, single-indication pharmacogenetic test—looking at a small portion of the genome specific to a particular medication—to discussion of whole-genome sequencing, which would include pharmacogenetic results. In each of the sessions, however, we had substantial difficulty focusing participants’ conversation on the less comprehensive test scenario. In other words, participants considered “genetic testing” to refer to examination of the entire genome, and most understood the purpose of genetic testing to be predicting one’s susceptibility to heritable illness. For example, one participant in the healthy cohort said, “I came in with the idea that this is a testing of your genes, your genetic makeup, to find out if you are more predisposed for a certain disease …. Life-threatening things, that’s what I thought it was all about.” Overall, participants evinced little understanding of the distinction between single-gene tests, panels, and whole-genome sequencing. Participants felt that payers (and to a lesser extent, physicians) would prefer more comprehensive testing approaches for reasons of efficiency and cost-effectiveness.

Whole-Genome Sequencing Was Viewed Differently from Narrower Tests

Once we had explained the differences among single-indication testing, pharmacogenomic panels, and whole-genome sequencing, many participants told us that they regarded whole-genome sequencing as a riskier undertaking than a more narrowly focused test, even if pharmacogenetic information were the primary goal of sequencing. With the generation of additional information, participants believed, the potential for misuse and discrimination would increase as well. One participant stated:

“I kind of want to know how much information they can get from that blood sample. And will they then be able to go back and use other pieces of that test in an unrelated way that [doesn’t] have anything to do with the specific treatment I need at that moment? And I also want to know, after it’s been utilized for something specific, if it can be taken out of my medical record, or once it’s there, is it there forever? If I’m using it for something very, very specific, that sort of works, but they are also getting information about my IQ, my willingness to work Monday through Friday, or my need to call in for a vacation day every three weeks, or three days? I don’t want that in there.”

Several participants pointed to the 1997 science-fiction film GATTACA,23 in which the government constrains individuals’ life choices on the basis of their genomes, as a depiction of what could go wrong if laws and social standards fail to provide appropriate privacy protections.

Some participants said that comprehensive sequencing would also be more likely to generate information they might not want, particularly for serious health risks they “couldn’t do anything about.” The potential risks to other family members, given that genetic information about one person says something about their first-degree relatives, were also of concern.

On the other hand, whole-genome sequencing was very attractive to a few participants who reported many seemingly unrelated health problems in themselves and in their families. One such participant said:

“For me, I would find it beneficial, because I suffer from a lot of different ailments. I would definitely be like, “Yeah, give me that test,” because it could show that they are treating symptoms of a different ailment. So it doesn’t add up unless you come in with a sheet this long [gestures], by the way, all of this happens. So I think a test like that could rule out what you are treating and actually show what you have … . I would find this would be something very important to have in my records for my family to see, simply because of my family history. My daughter is autistic. And then on my mom’s side, we have tremors, don’t know what causes those. So it’s definitely something I’m very interested in.

These individuals expressed great interest in comprehensive testing, which they thought could provide a coherent explanation for the multitude of challenges they face.

DISCUSSION

Prior studies on patient views of pharmacogenetic testing have focused on the general public and have generally presented hypothetical scenarios with limited personal relevance to participants.23,24 Others have explored the perceptions and values of patients undergoing treatment of life-threatening conditions, who generally express strong support for treatment-focused genetic testing and markedly less concern about the potential risks of discrimination and breach of privacy.25-27

This study adds to the perspectives of individuals diagnosed with chronic mental-health conditions. In speaking with participants in the carbamazepine cohort, we learned that many had been prescribed carbamazepine for bipolar disorder rather than seizure disorders (a common indication for this
In this study, participants in our antidepressant and carbamazepine groups voiced especially strong concerns about the potential for stigmatization, discrimination, and mistreatment resulting from pharmacogenetic testing and unauthorized access to results. Although these findings may not generalize across entire populations, they highlight an underrepresented perspective that is of particular relevance to ongoing pharmacogenetic research in neuropsychiatry.2,30,31 Our passive recruitment strategy may have generated a greater than usual selection bias.

Pharmacogenetics has often been described as among the most straightforward and near-term applications of genetic information in personalized medicine.5,31-34 An important finding of this study is that some patients who could potentially benefit from pharmacogenetic testing have substantial, deeply held concerns about the tradeoffs involved in allowing genetic information to be generated about them and maintained outside their control. Our participants were not naive patients; they were very interested in reducing the time to optimal treatment, and many told us they had personally experienced negative effects from current pharmaceutical therapies. Even so, they did not consider pharmacogenetic testing of clear benefit. Our findings are consistent with the results of an Australian study in which chronically ill patients endorsed the potential value of pharmacogenetic testing but emphasized the need for antidiscrimination measures and a holistic approach to diagnosis and prescribing.35 Avoiding a life-threatening drug reaction is obviously a good thing, but when the benefits are less compelling, patients with chronic illnesses—and perhaps especially those with potentially stigmatizing diagnoses—may decide that the risks of pharmacogenetic testing outweigh the benefits.

We were struck by the strength and prevalence of participants’ worries that physicians might overvalue genetic results to the exclusion of patient reports and the detriment of the therapeutic alliance. Although patients understood that such information could be useful in achieving optimal treatment outcomes, they nonetheless expressed misgivings about the possibility that physicians would privilege genetic results over patients’ lived experience. This message represents an important counterpoint to the enthusiastic discourse surrounding next-generation sequencing and personalized medicine. If personalized medicine is to be fully embraced by patients, it will be important to ensure that physicians’ enactment of “personalization” includes responding to the patient as an individual and not merely a collection of genomic data.36

Despite the proposed central role of genetics in the coming era of data-driven health care, some patients see pharmacogenetic testing as a potential threat to communication, health care quality, and the physician-patient relationship. Participants in this study wanted pharmacogenetic testing and whole-genome sequencing to complement, not replace, other information about medication response.

CONCLUSIONS

The success of precision medicine, or the provision of “the right drug at the right dose to the right patient,” will rely on the broad acceptability of genomic testing by diverse patient cohorts.5 Our findings suggest that pharmacogenetic solutions designed around the needs and preferences of patients who are basically well may fail to meet the needs of patients with mental health diagnoses or other chronic conditions that may carry social stigma. Health systems and physician practices considering implementation of pharmacogenetic testing must address patient concerns about privacy, discrimination, overreliance on genomic results, and erosion of the physician-patient relationship through public outreach, physician education, and accountable oversight procedures and governance.

Disclosure Statement

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10. Dorfman EH, Brown Trinidad S, Morales CT, Howlett K, Burke W, Woodshil EL. Pharmacogenomics in diverse practice settings: implementation beyond major metropolitan areas. Pharmacogen-


Life-Histories

We would wish that ... life-histories were found in every family, showing the health and diseases of its different members. We might thus in time find evidences of pathological connections and morbid liabilities now not suspected.

— Sir William Withey Gull, MD, 1st Baronet of Brook Street, 1816-1890, English physician, Fullerton Professor of Physiology, and President of the Clinical Society
This photograph was taken in Seville, Andalusia, Spain in November 2012. Founded in the 8th century, Seville has been governed by Roman, Muslim, and Christian sovereigns. The city served as a major economic hub during the centuries of Spanish imperialism, and it remains an important European center for culture and the arts.

Dr. Glassner is an Emergency Physician at the Walnut Creek Medical Center in CA.
ORIGINAL RESEARCH & CONTRIBUTIONS

A Community-Based Hip Fracture Registry: Population, Methods, and Outcomes

Maria C S Inacio, PhD; Jennifer M Weiss, MD; Alex Miric, MD; Jessica J Hunt, MA; Gary L Zohman, MD; Elizabeth W Paxton, MA

ABSTRACT

Introduction: Hip fracture is associated with substantial morbidity and mortality. A large integrated health care system developed a registry to characterize its current patient population with hip fractures. This report describes the population, methods used, and outcomes of patients registered during the initial three years (2009-2011).

Methods: Cases of hip fracture recorded from January 2009 through December 2011 were ascertained using the Kaiser Permanente Hip Fracture Registry. The registry collects information on patient, procedure, surgeon, facility, and surgical outcomes. Outcomes monitored included length of stay, readmissions, mortality, revisions, surgical site infections, deep vein thrombosis, pulmonary embolism, pneumonia, pressure ulcers, dislocations, and myocardial infarction.

Results: The population (N = 12,562) was predominantly white (77.8%), women (68.6%), and older (71.6% aged ≥ 75 years), and 32% had at least 5 comorbidities. The average length of follow-up was 1.1 years (standard deviation = 0.9). The most prevalent comorbidities were hypertension (70.8%) and anemia (29.4%). Femoral neck fractures (54.6%) were the most common fracture type. Hemiarthroplasty was the most common procedure (33.1%). Most fractures were treated by medium-volume (10 to 29 cases per year) surgeons (68.4% of cases). The 90-day readmission rate was 22.1%, and the mortality rate was 12.3%. The most common postoperative complications were pneumonia (11.4%) and pressure ulcers (2.9%). There were 2.2 revisions per 100 observation years.

Conclusion: A hip fracture registry provides important information regarding patient characteristics, intraoperative practices, and postoperative outcomes, which can be analyzed, interpreted, and used to reduce morbidity and mortality.

INTRODUCTION

In the US, 306,000 hip fractures occurred in 2010.1 By 2040, it is estimated there will be 500,000 hip fractures per year.2 Most hip fractures occur among the elderly for whom complications are common and often life threatening. The morbidity and mortality associated with hip fractures is substantial, with reported mortality rates of 16% to 23% within 1 year after injury.3,5 Although the incidence of hip fractures may be on the decline, the cost associated with the treatment of hip fractures, which is among the most costly orthopedic procedures,6 continues to grow.7,8

The high morbidity, mortality, and cost associated2-6 with hip fractures emphasizes the need to monitor the outcomes of these patients, identify risk factors associated with adverse events, and evaluate the comparative effectiveness of techniques and implants for this high-risk population. These opportunities for care improvement can significantly reduce morbidity and mortality associated with these events and can reduce cost. Patient registries are one potential tool for monitoring outcomes in a real-world setting. In orthopedic surgery, arthroplasty registries introduced in the 1970s have led to a reduction in revision rates by providing feedback to surgeons on specific implants and techniques.9-12 National arthroplasty registries have also been critical in early identification of defective implants,11-13 including one of the most costly orthopedic recalls to date, the DePuy ASR hip system recall.14 Although the US does not yet have a fully functional national arthroplasty registry, institutional and regional registries have contributed to increased patient safety, quality improvement, identification of clinical best practices, and cost reduction.15,16

Hip fractures are captured by arthroplasty registries in some European countries,17-19 Australia,12 New Zealand,20 and Canada.21 In countries such as Norway,22 Sweden,23 and the United Kingdom (UK),24 dedicated hip fracture registries exist. These hip fracture registries monitor all procedures used to treat these events.22-24 In the US, single-institution studies and large-scale administrative databases have provided data for evaluation of hip fracture outcomes.25 Although these databases and claims data provide important information, some gaps in knowledge remain because these data sources contain limited detail, inaccurate codes, and unvalidated outcomes. To help fill this gap, Kaiser Permanente (KP), the largest US integrated health care system, developed the Hip Fracture Registry. The registry is intended to serve as a quality surveillance tool, and to monitor patients who undergo a surgical procedure because of a hip fracture.

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It includes information on patient characteristics, surgical procedures, morbidity and mortality, and characteristics of both the surgeon and the hospital. The purpose of this report is to provide an overview of the methods used by the KP Hip Fracture Registry and to describe the population and outcomes of patients registered during the first three years (2009-2011).

**METHODS**

**Setting and Population**

KP is an integrated health care system that covers more than 9.5 million individuals throughout 7 US geographic Regions. This integrated health care system provides medical services, owns hospitals, employs its clinicians, and provides patients with health insurance, ensuring a captured and stable population. Additionally, a comprehensive integrated electronic medical record (EMR) is used by the system (with full implementation in 2008), allowing monitoring of patients’ activities using unique identifiers. The KP membership has been shown to be mostly demographically and socioeconomically representative of the largest geographic areas it covers.

The registry’s target population is patients with fractures of the femoral neck, intertrochanteric region, or subtrochanteric region, which comprise nearly all operative, low-energy, fragility-type fractures in the elderly population. Pelvic, acetabular, distal femur, and shaft fractures are not included in the Hip Fracture Registry. This report describes patient information ascertained between January 2009 and December 2011.

**Data Collection Procedures**

The Hip Fracture Registry identifies relevant hip fracture cases using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), diagnostic and procedure codes recorded into KP’s EMR and administrative claims. All data are extracted electronically on a quarterly schedule and sent to a data repository for data management, validation, and reporting. The Hip Fracture Registry captures data collected from the 7 geographic Regions of the integrated health care system. The patients included in this report are from the 2 largest Regions covered by the Hip Fracture Registry—Northern and Southern California—with 33 Medical Centers and 474 participating surgeons.

**Variables Characterizing Patients, Surgeries, Surgeons, and Hospitals**

The Hip Fracture Registry has information related to the patient, procedure, surgeon, and hospital where the hip fracture was treated. Patient variables include age, sex, race, American Society of Anesthesiologists (ASA) score, comorbidities, and body mass index. Procedure variables include laterality and stipulate whether an open or closed reduction with internal fixation, internal fixation of bone without fracture reduction, hemiarthroplasty (partial hip replacement), or total hip arthroplasty was used to treat the hip fracture. Surgeon variables include information about total joint arthroplasty fellowship training as well as average annual volume of hip fracture surgical cases. Surgeons were classified as low volume if they performed fewer than 10 cases per year, medium volume if they performed 10 to 29 cases per year, and high volume if they performed 30 or more cases per year. The average annual hospital volume was also captured by the Hip Fracture Registry. Hospitals were considered low volume if they treated fewer than 60 cases per year, medium volume if 60 to 129 cases per year, and high volume if 130 or more cases per year.

**Outcomes**

The Hip Fracture Registry monitors 10 outcomes associated with hip fractures. These outcomes are length of stay (LOS), any readmissions within 30 and 90 days, pneumonia, pressure ulcers, dislocations, myocardial infarction, surgical site infections (deep and superficial), thromboembolic events (deep vein thrombosis [DVT] and pulmonary embolism [PE]), revisions, and mortality. Except for LOS and mortality, the outcomes were captured using ICD-9-CM diagnosis and procedure codes recorded into the EMR and administrative claims. The outcomes of revisions, surgical site infections, DVTs, and PEs were adjudicated by clinical content experts who reviewed the patient charts. The other outcomes were ascertained using only administrative and EMR data.

<table>
<thead>
<tr>
<th>Table 1. Characteristics of primary hip fracture cohort (N = 12,562)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Characteristic</strong></td>
</tr>
<tr>
<td>Age, years*</td>
</tr>
<tr>
<td>&lt; 65</td>
</tr>
<tr>
<td>65-74</td>
</tr>
<tr>
<td>75-84</td>
</tr>
<tr>
<td>≥ 85</td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td>ASA category</td>
</tr>
<tr>
<td>1 and 2</td>
</tr>
<tr>
<td>≥ 3</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td>Diabetes</td>
</tr>
<tr>
<td>Race/ethnicity*</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Hispanic</td>
</tr>
<tr>
<td>Asian</td>
</tr>
<tr>
<td>Black</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td>Multiracial</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Native American</td>
</tr>
<tr>
<td>Continuous variables</td>
</tr>
<tr>
<td>Median age, years</td>
</tr>
<tr>
<td>Median BMI*</td>
</tr>
</tbody>
</table>

*Missing data in < 0.1% (n = 1).
*Percentages total to more than 100% because of rounding.
*Missing data in 0.7% (n = 92).
ASA = American Society of Anesthesiologists; BMI = body mass index.
Revisions are defined as an operation that required any implant exchange after the primary hip fracture procedure. Revisions are tracked for the lifetime of the patient. Surgical site infections are adjudicated using the guidelines of the Centers for Disease Control and Prevention’s National Healthcare Safety Network; they include superficial infections that occur within 30 days and deep infections that occur within 1 year after an implant procedure. Death information was available for all patients (with possible delayed reporting) using data from the Social Security Administration updated with information recorded into the EMR.

Statistical Analysis

Descriptive statistics, including frequencies, proportions, means, standard deviations (SDs), medians, and interquartile ranges (IQRs), were computed using the software program SAS 9.2 (SAS Institute Inc, Cary, NC). Crude complication rates for all outcomes captured by the registry were provided as proportions of events, with the entire hip fracture population being included in the denominator. Revision density, which is the rate of revision per 100 years of observation, was also provided. Patients were considered lost to follow-up if they disenrolled from the integrated health care system or died during the study period.

RESULTS

Characteristics of Patients

Between 2009 and 2011, a total of 12,562 primary hip fractures were registered in the Hip Fracture Registry. The median age of the population was 82 (IQR = 73-87) years old, 68.6% were women, and 77.8% were white. See Table 1 for detailed population characteristics. Only 5.7% of the population had no comorbidities at the time of hip fracture, and most had multiple comorbidities (Table 2). The most common comorbidities were hypertension (70.8%), deficiency anemia (29.4%), renal failure (25.2%), fluid and electrolyte disorders (22.0%), chronic pulmonary disease (21.4%), and peripheral vascular disease (20.0%).

Table 3 presents the detailed fracture type and procedures for the population. The most prevalent fracture types were femoral neck fractures (43%) followed by closed intertrochanteric femoral neck fractures (36.0%). The most common procedures for hip fracture treatment were hemiarthroplasty (33.1%), open reduction of fracture with internal fixation (29.7%), and closed reduction of fracture with internal fixation (23.8%).

Outcomes after Hip Fractures

The median LOS at hospitals for patients with a hip fracture was 4 days (IQR = 3-6 days). Within 90 days of the primary hip fracture, 22.1% of patients were readmitted to the hospital and 12.3% died. The most common complications in this population was pneumonia (11.4%), followed by pressure ulcers (2.9%), and DVT (1.4%). Revisions occurred in 2.4% of patients (or 2.2 revisions/100 years of observation). The average follow-up duration for patients was 1.1 years (SD = 0.9), and 2.6% were lost to follow-up (Table 4).

Participating Hospitals and Surgeons

Of the 12,562 hip fractures, 13.7% were treated by surgeons with joint arthroplasty fellowship training. The median number of hip fracture cases a surgeon treated yearly was 18 (IQR = 13-24), and most surgeons were considered medium volume (10 to 29 cases per year; 68.4%; Table 5). The median number of cases per hospital treated yearly was 167 (IQR = 114-219), and most of the cases were treated in high-volume hospitals (63.0%; Table 5).

<table>
<thead>
<tr>
<th>Table 2. Comorbidity profile of primary hip fracture cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comorbidity parameter</td>
</tr>
<tr>
<td>------------------------</td>
</tr>
<tr>
<td>Total number in cohort</td>
</tr>
<tr>
<td>Comorbidities (at least 1)</td>
</tr>
<tr>
<td>Number of comorbidities*</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>≥ 5</td>
</tr>
<tr>
<td>Specific conditions*</td>
</tr>
<tr>
<td>AIDS</td>
</tr>
<tr>
<td>Alcohol abuse</td>
</tr>
<tr>
<td>Chronic blood loss anemia</td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
</tr>
<tr>
<td>Coagulopathy</td>
</tr>
<tr>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>Deficiency anemias</td>
</tr>
<tr>
<td>Depression</td>
</tr>
<tr>
<td>Drug abuse</td>
</tr>
<tr>
<td>Fluid and electrolyte disorders</td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Hypothyroidism</td>
</tr>
<tr>
<td>Liver disease</td>
</tr>
<tr>
<td>Lymphoma</td>
</tr>
<tr>
<td>Metastatic cancer</td>
</tr>
<tr>
<td>Other neurologic disorders</td>
</tr>
<tr>
<td>Paralysis</td>
</tr>
<tr>
<td>Peptic ulcer disease, bleeding</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
</tr>
<tr>
<td>Psychoses</td>
</tr>
<tr>
<td>Pulmonary circulation disease</td>
</tr>
<tr>
<td>Renal failure</td>
</tr>
<tr>
<td>Rheumatoid arthritis/collagen vascular disease</td>
</tr>
<tr>
<td>Solid tumor without metastasis</td>
</tr>
<tr>
<td>Valvular disease</td>
</tr>
<tr>
<td>Weight loss</td>
</tr>
</tbody>
</table>

*Missing data in 1.6% (n = 198).

a Elixhauser comorbidity measures. Diabetes and obesity are omitted from this list because they are obtained from different sources. Diabetes data are obtained from regional diabetic registries, and obesity data are obtained from body mass index measurements. Both comorbidities are included in Table 1.

AIDS = acquired immunodeficiency syndrome.
DISCUSSION

A Hip Fracture Registry was established to capture detailed information on hip fractures treated surgically in the KP integrated health care system. The current registered cohort was treated by 474 surgeons across 33 hospitals. The population identified by this registry is similar to the populations captured in other hip fracture registries, but some important differences were identified. Operative practices and outcomes associated with procedures differ in certain instances from those previously reported in the literature.

Patients included in the registry were mostly women, elderly, white, and had multiple comorbid conditions. Women constituted 68.6% of the population, which is similar to the 70% figure reported by other registries and agrees with other literature.

### Table 3. Patient-specific diagnosis and procedure type in primary hip fracture cohort

<table>
<thead>
<tr>
<th>Diagnostic codes</th>
<th>Total, No. (%)</th>
<th>Hemiarthroplasty (code 81.52), No. (%)</th>
<th>Internal fixation, with open reduction of fracture (code 79.35), No. (%)</th>
<th>Internal fixation, with closed reduction of fracture (code 79.15), No. (%)</th>
<th>Internal fixation, without fracture reduction (code 78.55), No. (%)</th>
<th>Total hip arthroplasty (code 81.51), No. (%)</th>
<th>Other, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>12,562 (100.0)</td>
<td>4163 (33.1)</td>
<td>3731 (29.7)</td>
<td>2989 (23.8)</td>
<td>1127 (9.0)</td>
<td>270 (2.1)</td>
<td>282 (2.2)</td>
</tr>
<tr>
<td>Fracture type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intracapsular</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(733.14, 820.00, 820.01, 820.02, 820.03, 820.09)</td>
<td>2603 (20.7)</td>
<td>1317 (31.6)</td>
<td>347 (9.3)</td>
<td>510 (17.1)</td>
<td>285 (25.3)</td>
<td>82 (30.4)</td>
<td>62 (22.0)</td>
</tr>
<tr>
<td>Extracapsular</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(820.20, 820.21, 820.22, 821.00)</td>
<td>5671 (45.2)</td>
<td>147 (3.5)</td>
<td>2995 (80.3)</td>
<td>1880 (62.9)</td>
<td>543 (48.2)</td>
<td>21 (7.8)</td>
<td>85 (30.1)</td>
</tr>
<tr>
<td>Other/cannot be determined</td>
<td>4288 (34.1)</td>
<td>2699 (64.8)</td>
<td>389 (10.4)</td>
<td>599 (20.0)</td>
<td>299 (26.5)</td>
<td>167 (61.9)</td>
<td>135 (47.9)</td>
</tr>
<tr>
<td>ICD-9 code specific</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>733.14: Pathologic fracture neck of femur</td>
<td>665 (5.3)</td>
<td>248 (6.0)</td>
<td>151 (4.1)</td>
<td>114 (3.8)</td>
<td>117 (10.4)</td>
<td>15 (5.6)</td>
<td>20 (7.1)</td>
</tr>
<tr>
<td>820.00: Fracture, femur neck; closed; intracapsular section, unspecified</td>
<td>78 (0.6)</td>
<td>50 (1.2)</td>
<td>3 (0.1)</td>
<td>16 (0.5)</td>
<td>4 (0.4)</td>
<td>2 (0.7)</td>
<td>3 (1.1)</td>
</tr>
<tr>
<td>820.01: Fracture, femur neck; closed; epiphysis (separation) (upper), transepiphyseal</td>
<td>50 (0.4)</td>
<td>0 (0.0)</td>
<td>4 (0.1)</td>
<td>1 (0.0)</td>
<td>21 (1.9)</td>
<td>0 (0.0)</td>
<td>24 (8.5)</td>
</tr>
<tr>
<td>820.02: Fracture, femur neck; closed; midcervical section, transcervical NOS</td>
<td>118 (0.9)</td>
<td>81 (2.0)</td>
<td>5 (0.1)</td>
<td>26 (0.9)</td>
<td>3 (0.3)</td>
<td>3 (1.1)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>820.03: Fracture, femur neck; closed; base of neck, cervicotrochanteric section</td>
<td>260 (2.1)</td>
<td>112 (2.7)</td>
<td>73 (2.0)</td>
<td>38 (1.3)</td>
<td>24 (2.1)</td>
<td>11 (4.1)</td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>820.09: Fracture, femur neck; closed; other, head of femur, subcapital</td>
<td>1432 (11.4)</td>
<td>826 (19.8)</td>
<td>111 (3.0)</td>
<td>315 (10.5)</td>
<td>116 (10.3)</td>
<td>51 (18.9)</td>
<td>13 (4.6)</td>
</tr>
<tr>
<td>820.20: Fracture, femur neck; pertrochanteric, closed; trochanteric section, unspecified, trochanter; NOS, greater; lesser</td>
<td>286 (2.3)</td>
<td>17 (0.4)</td>
<td>164 (4.4)</td>
<td>66 (2.2)</td>
<td>26 (2.3)</td>
<td>2 (0.7)</td>
<td>11 (3.9)</td>
</tr>
<tr>
<td>820.21: Fracture, femur neck; pertrochanteric, closed; intertrochanteric section</td>
<td>4517 (36.0)</td>
<td>123 (3.0)</td>
<td>2338 (62.7)</td>
<td>1602 (53.6)</td>
<td>411 (36.5)</td>
<td>16 (5.9)</td>
<td>27 (9.6)</td>
</tr>
<tr>
<td>820.22: Fracture, femur neck; pertrochanteric, closed; subtrochanteric section</td>
<td>706 (5.6)</td>
<td>6 (0.1)</td>
<td>414 (11.1)</td>
<td>205 (6.9)</td>
<td>68 (6.0)</td>
<td>2 (0.7)</td>
<td>11 (3.9)</td>
</tr>
<tr>
<td>820.8: Fracture; unspecified part of neck of femur, closed, hip NOS, neck of femur NOS</td>
<td>3964 (31.6)</td>
<td>2550 (61.3)</td>
<td>343 (9.2)</td>
<td>568 (19.0)</td>
<td>264 (23.4)</td>
<td>162 (60.0)</td>
<td>77 (27.3)</td>
</tr>
<tr>
<td>821.00: Fracture; closed; unspecified part of femur, thigh, upper leg</td>
<td>162 (1.3)</td>
<td>1 (0.0)</td>
<td>79 (2.1)</td>
<td>7 (0.2)</td>
<td>38 (3.4)</td>
<td>1 (0.4)</td>
<td>36 (12.8)</td>
</tr>
<tr>
<td>Other diagnosis</td>
<td>324 (2.6)</td>
<td>149 (3.6)</td>
<td>46 (1.2)</td>
<td>31 (1.0)</td>
<td>35 (3.1)</td>
<td>5 (1.9)</td>
<td>58 (20.6)</td>
</tr>
</tbody>
</table>

*a Some percentages may not total to 100 because of rounding.

ICD-9 = International Classification of Diseases, Ninth Revision; NOS = not otherwise specified.
with the higher incidence of hip fractures in women around the world. Of the registered patients, nearly 72% were age 75 years or older. This higher age is consistent with that of the population of hip fracture registries in Norway and the UK but is slightly younger than reported by arthroplasty registries. The Australian arthroplasty registry reported that in its bipolar hemiarthroplasty cohort at least 76% were age 75 years or older and 92% of its monoblock cohort was older than 75 years. This elderly population is consistent with the higher risk of hip fractures in older patients. Racial and ethnicity data, which are available in our patient population (21.7% of the population is nonwhite), were not available in other hip fracture registries and are most likely not captured data elements because of their countries' homogenous populations. This adds value to future findings from the presented registry, which can contribute information regarding minority groups.

Finally, 65.9% of the patients had an ASA score greater than 3, indicating substantial systemic disease, which is similar to the rate reported by the UK registry between 2011 and 2013 (approximately 60%). The proportion of patients with higher ASA score, however, was higher than reported by the Norwegian Hip Fracture Register (47%), which could be because of their inclusion of younger patients in their registry. We also found a high number of comorbid conditions in our patient population; 92.7% had at least 1 comorbid condition, and conditions such as hypertension, deficiency anemias, renal failure, and fluid and electrolyte disorders were common at the time of the hip fracture hospitalization. Other registries did not report on specific comorbid conditions, but a high prevalence of comorbid conditions has been reported by studies using administrative data in the US.

The most common type of fractures in our population was intertrochanteric femoral neck fracture (36%, ICD-9-CM 820.21) and unspecified femoral neck fractures (31.6%, ICD-9-CM 820.8). Because the registry relies on ICD-9-CM codes for identifying type of fracture, it cannot determine with certainty whether cases with unspecified location fracture codes are intracapsular vs extracapsular, or displaced vs undisplaced fractures. It can, however, determine the main treatment groups from the combination of ICD-9-CM procedure codes and diagnoses.

---

**Table 4. Postoperative outcomes of primary hip fracture cohort by procedure type**

<table>
<thead>
<tr>
<th>Postoperative outcome</th>
<th>Total, No. (%)</th>
<th>Hemiarthroplasty (code 81.52), No. (%)</th>
<th>Internal fixation, with open reduction of fracture (code 79.35), No. (%)</th>
<th>Internal fixation, with closed reduction of fracture (code 79.15), No. (%)</th>
<th>Internal fixation, without fracture reduction (code 78.55), No. (%)</th>
<th>Total hip arthroplasty (code 81.51), No. (%)</th>
<th>Other, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>12,562 (100.0)</td>
<td>4163 (33.1)</td>
<td>3731 (29.7)</td>
<td>2989 (23.8)</td>
<td>1127 (9.0)</td>
<td>270 (2.1)</td>
<td>282 (2.2)</td>
</tr>
<tr>
<td>Mortality, utilization, and outcomes identified with administrative/EMR data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death within 30 days</td>
<td>783 (6.2)</td>
<td>291 (7.0)</td>
<td>240 (6.4)</td>
<td>171 (5.7)</td>
<td>61 (5.4)</td>
<td>5 (1.9)</td>
<td>15 (5.3)</td>
</tr>
<tr>
<td>Death within 90 days</td>
<td>1546 (12.3)</td>
<td>563 (13.5)</td>
<td>481 (12.9)</td>
<td>340 (11.4)</td>
<td>127 (11.3)</td>
<td>13 (4.8)</td>
<td>22 (7.8)</td>
</tr>
<tr>
<td>Death (ever)</td>
<td>3278 (26.1)</td>
<td>1160 (27.9)</td>
<td>1002 (26.9)</td>
<td>744 (24.9)</td>
<td>293 (26.0)</td>
<td>35 (13.0)</td>
<td>44 (15.6)</td>
</tr>
<tr>
<td>Readmission within 30 days</td>
<td>1532 (12.2)</td>
<td>568 (13.6)</td>
<td>459 (12.3)</td>
<td>328 (11.0)</td>
<td>145 (12.9)</td>
<td>18 (6.7)</td>
<td>14 (5.0)</td>
</tr>
<tr>
<td>Readmission within 90 days</td>
<td>2775 (22.1)</td>
<td>978 (23.5)</td>
<td>840 (22.5)</td>
<td>630 (21.1)</td>
<td>261 (23.2)</td>
<td>43 (15.9)</td>
<td>23 (8.2)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>1427 (11.4)</td>
<td>496 (11.9)</td>
<td>441 (11.8)</td>
<td>333 (11.1)</td>
<td>117 (10.4)</td>
<td>24 (8.9)</td>
<td>16 (5.7)</td>
</tr>
<tr>
<td>Pressure ulcers</td>
<td>365 (2.9)</td>
<td>141 (3.4)</td>
<td>117 (3.1)</td>
<td>67 (2.2)</td>
<td>25 (2.2)</td>
<td>9 (3.3)</td>
<td>6 (2.1)</td>
</tr>
<tr>
<td>Dislocation</td>
<td>114 (0.9)</td>
<td>89 (2.1)</td>
<td>3 (0.1)</td>
<td>1 (0.0)</td>
<td>5 (0.4)</td>
<td>9 (3.3)</td>
<td>7 (2.5)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>110 (0.9)</td>
<td>27 (0.7)</td>
<td>29 (0.8)</td>
<td>35 (1.2)</td>
<td>16 (1.4)</td>
<td>3 (1.1)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Median length of stay, days (IQR)</td>
<td>4 (3-6)</td>
<td>4 (4-6)</td>
<td>4 (3-6)</td>
<td>4 (3-5)</td>
<td>4 (3-6)</td>
<td>3 (1-5)</td>
<td></td>
</tr>
<tr>
<td>Validated outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revision (all cause)</td>
<td>305 (2.4)</td>
<td>102 (2.5)</td>
<td>81 (2.2)</td>
<td>78 (2.6)</td>
<td>29 (2.6)</td>
<td>7 (2.6)</td>
<td>8 (2.8)</td>
</tr>
<tr>
<td>Septic revision</td>
<td>32 (0.3)</td>
<td>23 (0.6)</td>
<td>3 (0.1)</td>
<td>1 (0.0)</td>
<td>1 (0.1)</td>
<td>1 (0.4)</td>
<td>3 (1.1)</td>
</tr>
<tr>
<td>Revision rate per 100 years of observation</td>
<td>1342 (2.2)</td>
<td>4506 (2.3)</td>
<td>4713 (1.9)</td>
<td>3216 (2.4)</td>
<td>1208 (2.4)</td>
<td>288 (2.4)</td>
<td>360 (2.2)</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>173 (1.4)</td>
<td>65 (1.6)</td>
<td>57 (1.5)</td>
<td>25 (0.8)</td>
<td>12 (1.1)</td>
<td>8 (3.0)</td>
<td>6 (2.1)</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>156 (1.2)</td>
<td>59 (1.4)</td>
<td>43 (1.2)</td>
<td>33 (1.1)</td>
<td>13 (1.2)</td>
<td>5 (1.9)</td>
<td>3 (1.1)</td>
</tr>
<tr>
<td>Surgical site infection (any)</td>
<td>136 (1.1)</td>
<td>77 (1.9)</td>
<td>27 (0.7)</td>
<td>15 (0.5)</td>
<td>6 (0.5)</td>
<td>5 (1.9)</td>
<td>6 (2.1)</td>
</tr>
<tr>
<td>Surgical site infection (deep)</td>
<td>75 (0.6)</td>
<td>47 (1.1)</td>
<td>12 (0.3)</td>
<td>7 (0.2)</td>
<td>1 (0.1)</td>
<td>3 (1.1)</td>
<td>5 (1.8)</td>
</tr>
<tr>
<td>Surgical site infection (superficial)</td>
<td>61 (0.5)</td>
<td>30 (0.7)</td>
<td>15 (0.4)</td>
<td>8 (0.3)</td>
<td>5 (0.4)</td>
<td>2 (0.7)</td>
<td>1 (0.4)</td>
</tr>
</tbody>
</table>

* Some percentages do not total to 100 because of rounding. Codes are from the International Classification of Diseases, Ninth Revision, Clinical Modification.
* Missing data in 1.3% (n = 164).
* Only crude estimates of incidence are presented. No adjustments for confounders, loss to follow-up, or follow-up time are included (with the exception of the revision rate per 100 years of observation).
* EMR = electronic medical record; IQR = interquartile range.
By our estimates, at least 43% (n = 5315) of our registered fractures are intracapsular fractures (2603 from diagnostic codes only and 2712 from the procedures and diagnoses combined), making this the most common type of fracture in our registry, which is in agreement with other registries where a traditional fracture classification is used. In Sweden, the UK, and Norway the reported prevalence of intracapsular fractures is 54%, 58%, and 63%, respectively.

The most common procedures used to treat fractures were internal fixation and hemiarthroplasty, in agreement with other registries’ populations. Overall, 33.1% of the cases in our population were treated with hemiarthroplasty, which is slightly higher than the overall numbers of 25% reported by Sweden and 21% by Norway (no overall numbers available for the UK). Hemiarthroplasty is the most common procedure used for treatment of intracapsular fractures in our population (93% had a hemiarthroplasty), and it is also the most commonly used procedure to address intracapsular fractures in other registries, although only for displaced intracapsular fractures (53% Norway, 63% Sweden, and 77.5% UK). For the second most common fracture in our population, intertrochanteric femur neck fractures (36%), 96% were treated with internal fixation: 9% without fracture reduction, 35% with closed reduction, and 52% with open reduction. This again agrees with the reported internal fixation rate for these types of fracture in the UK, Sweden, and Norway (all > 95%). Finally, the use of total hip arthroplasty for addressing hip fractures is infrequent (2.1%), and this rate agrees with the small proportions seen by other registries (range = 1.1%-5%).

Medium- and high-volume surgeons (89.7%) and hospitals (98.3%) treat the majority of the hip fractures in our population. This information is not available in the reports of other dedicated hip fracture registries. The proportion of patients treated in high volume (63%) hospitals is, however, similar to those reported by studies using Medicare data (approximately 60% consistently from 1991 to 2008). Previous studies evaluating the outcomes of hip fracture treatment by hospital and surgeon volume suggest surgeon volume is an important factor when evaluating hip fracture outcomes, but hospital volume may not be as important.

Ten postoperative outcomes were available in the KP Hip Fracture Registry. Mortality, LOS, pressure ulcers, and repeated operations (“reoperations”) are the common outcomes monitored by the dedicated fracture registries. The incidence of mortality in our population within 30 days was 6.2%; this is comparable to mortality in the Norwegian registry (only a 4-month estimate is available and is 14%) and is slightly lower than in the UK registry (8%). This is also consistent with contemporary estimates from the US Medicare population of 5% to 6%. The LOS in our cohort was much shorter (median = 4 days) than that reported by other registries (range = 11-16 days) but was similar to the LOS in the US Medicare hip fracture cohort. Differences in LOS are probably because of the overall health care system structure and hip fracture care practices in the various countries. Pressure ulcers occurred in 2.9% of our population, which is comparable to the 3.7% reported by the UK hip fracture registry. Finally, the only reoperations monitored by our registry are subsequent revision procedures (defined as a surgery where one component is either removed and/or replaced for any reason) of the original hip fracture components, which we found occur at a rate of 2.2/100 years of observation (2.4% crude overall revision incidence). This rate is significantly lower than the 18% reoperation rate reported by the Norwegian Hip Fracture Register, probably because they track all subsequent reoperations and not just revisions. Complications related to the hip fractures such as pneumonia, myocardial infarction, DVT, PE, dislocations, and surgical site infections also are monitored by this registry but not by others. These complications, except for pneumonia, were infrequent (< 1.4%), an incidence that is mostly consistent with reports from other large hip fracture cohorts. Pneumonia was the most common complication in our population (11.4%) and was higher than the 5% reported by a meta-analysis of clinical trials by Lawrence et al. This higher incidence in our cohort could be caused by our use of administrative data to ascertain the cases without validating them with other records, which was probably done by the clinical trials included in the meta-analysis study.

This report’s main limitation is the reliance of its data source, the KP Hip Fracture Registry, on ICD-9-CM diagnostic and procedure codes to determine fracture location and procedures performed to address these fractures. Information on whether the fractures were displaced or nondisplaced was not available. Additionally, confirmation of whether they were located in the intracapsular or extracapsular area was not possible in all cases. The Hip Fracture Registry leverages the existing system’s EMR and administrative data sources to capture all hip fractures in the system. This is done instead of relying on the surgeon to report, which would not achieve full capture of this population. The tradeoff for full case capture means the Hip Fracture Registry has limited fracture location.
A Community-Based Hip Fracture Registry: Population, Methods, and Outcomes

Information. In addition, procedure codes do not offer information on specific types of hemiarthroplasty procedures (bipolar or unipolar) or internal fixation (whether screws only, screws and plates, or intramedullary rods were used). However, this limitation is currently being addressed by the Hip Fracture Registry by implementing procedure classification on the basis of the collected implant information from the procedure. This work is under development, but we hope to include it in future reports on the registry’s cohort.

Other limitations were a lack of certain comorbidity information, such as osteoporosis and intestinal disorders, which were not captured by the validated comorbidity algorithm used by the registry. Additionally, this report was descriptive and did not evaluate relationships between specific variables and outcomes associated with hip fracture procedures. No inferences can be made regarding the outcomes and specific treatments presented in this report.

Our report strengths include the description of a fully captured hip fracture population in a large and diverse integrated health care system in the US. Using unique identifiers and the EMR, the Hip Fracture Registry captured the full spectrum of care delivered to these patients after surgery and prospectively monitored several outcomes associated with these events in addition to the traditional outcomes tracked by other studies and registries. Some of the outcomes monitored (ie, surgical site infection, DVT, PE, reoperation, and revision surgery) are also adjudicated using additional sources, which guarantees a high internal validity for these data elements. Additionally, because data for the Hip Fracture Registry are captured electronically, possible response bias introduced by relying on clinicians to report events and complete the required registry information was nonexistent. Finally, the population captured included cases from a large number of hospitals and surgeons with a wide variety of surgical experience, which is representative of the larger orthopedic community.

CONCLUSION
A community-based registry of hip fractures was used to identify a contemporaneous cohort of patients with hip fractures who were mostly women, elderly, and white, with substantial multimorbidity. The KP Hip Fracture Registry population was treated predominantly with internal fixations or hemiarthroplasty procedures, which were performed primarily in high-volume hospitals by medium-volume surgeons. The incidence of 30-day mortality, readmission, and pneumonia was high in this patient population, and the incidence of other monitored complications was relatively low.

Using a hip fracture registry to understand patients and procedures performed to treat hip fractures, as well as the possible complications and outcomes associated with these events, can give orthopedic clinicians a major advantage in planning for the care of these patients.

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

Acknowledgment
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References
A Community-Based Hip Fracture Registry: Population, Methods, and Outcomes

k6B2C%3d&tabid=96&mid=523.


Fixation

I assert that a fractured thigh, if treated by extension only, would be accompanied with vastly more muscular irritability than if the same case was placed in a modern appliance, in which the limb was immovable in the strict meaning of the term fixation.

— Disease of the Hip, Knee and Ankle Joints, Hugh Owens Thomas, MD, 1834-1891, Welsh surgeon who is considered to be the father of orthopaedic surgery in Britain
Utility of the Multinational Association for Supportive Care in Cancer (MASCC) Risk Index Score as a Criterion for Nonadmission in Febrile Neutropenic Patients with Solid Tumors

Roger A Bitar, MD, MPH

ABSTRACT

Objectives: This retrospective study was initiated in febrile neutropenic inpatients with solid tumors in 4 community hospitals, to discover how the Multinational Association for Supportive Care in Cancer (MASCC) risk index score (RIS) of 21 or greater correlated with complications occurring in 198 episodes: whether it could help determine which patients not to admit, the savings of not admitting patients without complications, and whether an algorithm could facilitate management of those not admitted.

Methods: Febrile neutropenic episodes in patients with solid tumors were identified electronically between October 1, 2008, and November 15, 2010. Electronic charts were reviewed manually for inclusion criteria and data extraction. Episodes were stratified by an MASCC RIS below 21 or 21 or greater. Complications were correlated with the index.

Results: Inclusion criteria were met in 198 episodes. Sensitivity, specificity, and positive and negative predictive values of the MASCC RIS vs complications were 94%, 29.6%, 57.7%, and 84.9%, respectively. In episodes with an RIS 21 or greater, 42.3% had complications, misclassifying to low risk 69 episodes with complications. “Unable to eat” correlated with complications in 84% of episodes. In 3 patients stratified to no complication, a complication developed 24 hours after admission.

Conclusions: An MASCC RIS of 21 or greater could not be used as a criterion for “no complication/do not admit.” Inability to eat should be an admission criterion. Savings of approximately $1 million per 100 uncomplicated admissions could be realized if appropriate criteria for nonadmission could be devised. An algorithm to facilitate outpatient management is suggested.

INTRODUCTION

Treatment of malignancies is routine in community hospitals. Chemotherapy, one of the common forms of treatment, frequently results in neutropenic fever. Guidelines for the management of febrile neutropenia include antimicrobial therapy and, for patients with solid tumors, antecedent granulocyte colony-stimulating factor.1,2 Before these guidelines, virtually all febrile neutropenic patients were hospitalized. However, the depth and duration of neutropenia in patients receiving chemotherapy for hematologic and lymphoproliferative neoplasms is more profound than that occurring following chemotherapy for patients with solid tumors; thus, complications following chemotherapy for solid tumors are less frequent. Some investigators postulated that patients not experiencing complications would not need hospitalization, and thus, they have striven to identify these noncomplicated cases prospectively and manage them on an outpatient basis, resulting in substantial savings.

To this end, a stratification tool, the Multinational Association for Supportive Care in Cancer (MASCC) risk index score (RIS) was developed to predict the risk of serious complications. These risk criteria are listed in the Sidebar: Klastersky Criteria.3

There are 2 important features to note. First, only 2 of the 10 Klastersky criteria are objective, which introduces a problem in the methods. There is no objective definition of these criteria: confusion or altered mental state, such as the Glasgow Coma Scale; congestive heart failure requiring treatment, such as pulmonary edema with a PaO2 below 60 mmHg; bleeding severe enough to require transfusion, such as a hemoglobin level below 7 g/dL; arrhythmia or electrocardiographic changes requiring treatment, such as systolic blood pressure (BP) below 90 mmHg; or renal failure requiring treatment, such as a creatinine level above 4 mg/dL. Furthermore, the last criterion is completely subjective: “other complications judged serious and clinically significant by the investigator.” Second, an exclusion to this criterion was included as a footnote: “Viral or fungal, microbiologically documented primary infection during the febrile episode, without any described complication and resolving under therapy, was considered a part of the infectious process and was not considered a serious complication.”4

Table 1 lists the components of the MASCC RIS.3 (Note that only 4 of the 7 criteria are objective. Burden of illness, chronic obstructive pulmonary disease (COPD), and “no dehydration” are not objective criteria.) An MASCC RIS of 21 or above equals a low risk of complications; an MASCC RIS below 21 equals a high risk of complications.

Using an MASCC RIS of 21 or greater as low risk, only 6% of a validation group (n = 551) experienced serious complications compared with 39% who had a score below 21. Validation of this index.

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References

has been declared in publications from academic (university) medical centers. However, the definitions in all these studies (eg, burden of illness, COPD, or dehydration) were not consistently provided, and the mix of patients with solid vs hematologic and lymphoprolif erative neoplasms was not the same, raising the question of whether the results are comparable.

The current retrospective study of inpatients from 4 community hospitals was devised to answer the following questions.

1. How many times were the named items in the Klastersky criteria used as reasons for admission to the hospital by the general internists admitting patients? (As noted earlier, when a febrile neutropenic patient with an infection makes initial contact with a health care practitioner for that febrile episode, the Klastersky criteria do not consider that infection a complication, and, in addition, there are unnamed complications in the Klastersky criteria.)

2. Are there additional complications, not listed by name in the Klastersky criteria, that a physician might consider important in the nonadmission decision?

3. Would the course of patients stratified to the low-risk category (MASCC RIS ≥ 21) be without serious complications and, thus, be able to be managed as outpatients (ie, stratified to “Do not admit”)?

4. If inpatients with an MASCC RIS of 21 or higher did experience complications, what were they and on what day of hospitalization did they occur?

5. If the patients with an MASCC RIS of 21 or above were not admitted and experienced complications, what management algorithm could be proposed to identify these complications early?

6. What savings would be realized if all the patients without serious complications were not admitted to the hospital?

### METHODS

#### Patient Selection

Management of febrile neutropenic patients, at the time of this study and at the medical centers listed, was admission to the hospital, evaluation in the usual manner with appropriate laboratory tests and imaging studies, administration of granulocyte colony-stimulating factor (89%), and antimicrobial agents. All but 10 patients received acceptable antimicrobial regimens. Charts were retrospectively reviewed for the following inclusion criteria: adult inpatients with solid tumors who became neutropenic (absolute neutrophil count < 500/μL, except for 2 that were 600/μL) after chemotherapy, who were given an admission or discharge diagnosis of neutropenic fever, who had documented fever by self-report or on admission, and who received antimicrobial therapy for neutropenic fever. Patients younger than 18 years and those whose admissions lasted less than 24 hours were excluded. All inpatient electronic medical records of patients admitted to 4 Kaiser Permanente (KP) hospitals in California were searched for drug-induced neutropenia (International Classification of Diseases, Ninth Revision, code 288.0) and fever-presentation conditions classified elsewhere (code 780.61). The hospitals were San Diego Medical Center (admissions from October 1, 2008, to November 15, 2010); Irvine Medical Center and Anaheim Medical Center (Orange County; admissions from October 1, 2008, to April 30, 2010); and Woodland Hills Medical Center (admissions from October 1, 2008, to April 30, 2010). The charts of these patient episodes were sequentially and manually screened for inclusion criteria and reviewed in detail. If inclusion criteria were met, data were extracted.

Data included: age, sex, admission date, discharge date, death date, the type of solid tumor, whether it was metastatic beyond local nodes, admitting physician’s reason for admission, length of stay (LOS), reason for extended hospital stay, intensive care unit care, comfort care, other diagnoses in the problem list which might be considered immunocompromising.

### Table 1. Components of the Multinational Association for Supportive Care in Cancer Index

| Clinical characteristic | Score
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Burden of illness (1 of the 3 options only):</td>
<td></td>
</tr>
<tr>
<td>No or mild symptoms</td>
<td>5</td>
</tr>
<tr>
<td>Moderate symptoms</td>
<td>3</td>
</tr>
<tr>
<td>Severe symptoms</td>
<td>0</td>
</tr>
<tr>
<td>No hypotension (systolic BP &gt; 90 mmHg)</td>
<td>5</td>
</tr>
<tr>
<td>No chronic obstructive pulmonary disease</td>
<td>4</td>
</tr>
<tr>
<td>Solid tumor or no prior fungal infection in patient with hematologic neoplasm</td>
<td>4</td>
</tr>
<tr>
<td>No dehydration (hydration with IV fluids not required)</td>
<td>3</td>
</tr>
<tr>
<td>Outpatient at onset of fever</td>
<td>3</td>
</tr>
<tr>
<td>Age ≤ 60 years</td>
<td>2</td>
</tr>
</tbody>
</table>

* Burden of illness, no chronic obstructive pulmonary disease, and no dehydration are not objective criteria.

* Maximum score: 26 (5 + 5 + 4 + 4 + 3 + 3 + 2). Low risk for complication = score 21; high risk for complication = score < 21.

BP = blood pressure; IV = intravenous.
smoking status, diagnosis of COPD, occurrence of fever associated with neutropenia, days to temperature ≤ 37.5 and ≤ 38°C, an ANC < 500 cells/µL, return of ANC to greater than 500 cells/µL, duration of neutropenia, death, reception of filgrastim before and subsequently after admission, gastrointestinal symptoms (nausea, vomiting, diarrhea, abdominal pain, "unable to eat"), serum biochemical tests (creatinine > 2 mg/dL, potassium < 3 mEq/L, sodium of < 130 mEq/L, phosphorus of < 2.7 mg/dL), density/intensity of chemotherapy, types of infections, positive bacterial cultures, microorganisms isolated, antimicrobial agents prescribed when outpatient and inpatient, results of pertinent imaging studies, MASCC RIS components, and medical complications listed in the Klustersky criteria.

All febrile neutropenic patient episodes meeting inclusion criteria were divided into 2 groups on the basis of complications: Group 1, no complication (equivalent to “do not admit”), or Group 2, complication (equivalent to “admit”). Group 1 (n = 100) had only fever and neutropenia, had none of the medical complications (Table 2) on admission or within 24 hours of admission, and were able to eat. Group 2 (n = 98) had 1 or more of the complications listed in Table 2 at admission or within 24 hours of admission. There were 3 patients in Group 1 in whom complications developed 24 hours after admission, which if they had been present on presentation would have classified each patient into Group 2 initially. Each patient episode was assigned to an MASCC RIS of 21 or greater or below 21, and these scores were correlated with the no complication and complication groups (Figure 1). The KP Southern California institutional review board approved the study.

Medical Centers

In 2012, beds and discharges per month were as follows: San Diego, 392 beds and 32,491 discharges; Orange County, 350 beds (2 hospitals), 28,564 discharges; and Woodland Hills, 262 beds and 13,741 discharges. All 4 hospitals fall into the tertiary care category, providing a full range of basic and sophisticated diagnostic and treatment services, including many specialized services.

Statistical Analysis

A sample size of 200 episodes was chosen as the basis for another study, not yet published, from which this analysis was done. Two episodes did not meet criteria, leaving 198 episodes. Standard methods of calculating sensitivity, specificity, positive predictive value, and negative predictive value were used. The Wilcoxon rank sum test was used to compare for those who were unable to eat and for those who were able to eat.

**RESULTS**

Patient characteristics are shown in Table 3.

Klustersky Criteria versus Complications

Table 2 lists the components of the Klustersky criteria; complications, which includes the reasons for admission and subsequent complications; the MASCC RIS; and LOS. There are 69 patients in Table 2 who had an MASCC RIS of 21 or above and had reasons for admission and/or complications. Only 20 patients of the 69 had complications named in the Klustersky criteria as a reason for admission. If the Klustersky criteria were to be applied, the other 49 reasons for admission would have to be assumed to fall into the last Klustersky category, “other complications judged serious or clinically significant by the investigator.” Thirty-eight patients were unable to eat, 22 had identified infections, 21 could be considered to have mucositis, and 5 were found to have typhlitis.

**Risk Index Score versus Complications**

The sensitivity of the MASCC RIS was 94% (94 of 100 episodes) with a 95% confidence interval (CI) of 87.4% to 97.8%, and specificity was 29.6% (29/98; 95% CI = 20.8% to 39.7%). The positive predictive value was 57.67% (29/51; 95% CI = 49.7% to 65.4%), and the negative predictive value was 82.9% (29/35; 95% CI = 66.34% to 93.4%).

![Figure 1. Assignment of episodes of febrile neutropenia to Multinational Association for Supportive Care in Cancer (MASCC) risk index score (RIS) and complications.]

Three complications occurred after admission to the hospital in patients stratified to “no complication” and would have occurred on an outpatient basis if the patients had not been admitted.
<table>
<thead>
<tr>
<th>Patient episode number</th>
<th>Klastersky criteria (named)</th>
<th>Klastersky criteria (Presumed to be in ‘Other complications judged serious and clinically significant by the investigator’)</th>
<th>Reason for admission</th>
<th>Complication after admission</th>
<th>MASCC RIS</th>
<th>Length of stay, days</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>None</td>
<td>None</td>
<td>Cellulitis</td>
<td>None</td>
<td>21</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>SBP &lt; 90 mmHg/need for vasoressors</td>
<td>Nausea, vomiting</td>
<td>SBP &lt; 98 mmHg in a 90 year old</td>
<td>None</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>None</td>
<td>Unable to eat</td>
<td>Unable to eat, mucositis</td>
<td>None</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>None</td>
<td>Unable to eat, K 2.9 mEq/L</td>
<td>Unable to eat, K 2.9 mEq/L</td>
<td>Day 3: K 3 mEq/L</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>None</td>
<td>Unable to eat, nausea, diarrhea, abdominal pain</td>
<td>Unable to eat, nausea, diarrhea, abdominal pain</td>
<td>None</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>None</td>
<td>Unable to eat, nausea, vomiting, abdominal pain</td>
<td>Unable to eat, nausea, vomiting, abdominal pain</td>
<td>None</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>SBP &lt; 90 mmHg/need for vasoressors</td>
<td>Diarrhea</td>
<td>Diarrhea/SBP &lt; 90 mmHg</td>
<td>None</td>
<td>21</td>
<td>6</td>
</tr>
<tr>
<td>8</td>
<td>Arrhythmia, ECG changes</td>
<td>Unable to eat, nausea, vomiting</td>
<td>Unable to eat, nausea, vomiting, atrial flutter</td>
<td>None</td>
<td>21</td>
<td>6</td>
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<tr>
<td>9</td>
<td>None</td>
<td>Unable to eat, difficulty swallowing</td>
<td>Unable to eat, difficulty swallowing</td>
<td>None</td>
<td>21</td>
<td>6</td>
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<tr>
<td>10</td>
<td>None</td>
<td>Nausea, vomiting</td>
<td>Nausea, vomiting, bacteraemia</td>
<td>None</td>
<td>21</td>
<td>7</td>
</tr>
<tr>
<td>11</td>
<td>None</td>
<td>Nausea, abdominal pain, K &lt; 3 mEq/L</td>
<td>Nausea, abdominal pain, Typhlitis, K &lt; 3 mEq/L</td>
<td>None</td>
<td>21</td>
<td>7</td>
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<tr>
<td>12</td>
<td>None</td>
<td>Unable to eat, diarrhea</td>
<td>Unable to eat, diarrhea</td>
<td>Stomatitis</td>
<td>21</td>
<td>7</td>
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<tr>
<td>13</td>
<td>None</td>
<td>Nausea, vomiting,</td>
<td>Nausea, Vomiting, positive blood culture</td>
<td>None</td>
<td>21</td>
<td>7</td>
</tr>
<tr>
<td>14</td>
<td>SBP &lt; 90 mmHg/need for vasoressors, arrhythmia, ECG changes</td>
<td>Nausea, vomiting</td>
<td>Nausea, vomiting, Low SBP within first 24 hours, SVT 3 days</td>
<td>None</td>
<td>21</td>
<td>8</td>
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<tr>
<td>15</td>
<td>SBP &lt; 90 mmHg/need for vasoressors, bleeding requiring transfusion</td>
<td>Penile bleeding</td>
<td>Penile bleeding</td>
<td>Day 3: Na 124 mEq/L, Day 4: SBP &lt; 90 mmHg, Day 7: fluid overload</td>
<td>21</td>
<td>9</td>
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<tr>
<td>16</td>
<td>Confusion, altered mental state</td>
<td>Unable to eat</td>
<td>Unable to eat, confusion, brain metastases</td>
<td>None</td>
<td>21</td>
<td>9</td>
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<tr>
<td>17</td>
<td>None</td>
<td>Unable to eat, nausea, diarrhea</td>
<td>Unable to eat, nausea, diarrhea, C diff</td>
<td>Day 2: K 2.6 mEq/L, Day 5: atrial fibrillation</td>
<td>21</td>
<td>11</td>
</tr>
<tr>
<td>18</td>
<td>None</td>
<td>Unable to eat, nausea, abdominal pain</td>
<td>Unable to eat, nausea, abdominal pain, mucositis</td>
<td>Day 5: K 2.3 mEq/L, required TPN, fever</td>
<td>21</td>
<td>13</td>
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<tr>
<td>19</td>
<td>None</td>
<td>Unable to eat, nausea, vomiting, diarrhea, lower GI bleeding, K 2.8 mEq/L, Mg 0.8 mEq/L</td>
<td>Unable to eat, nausea, vomiting, diarrhea, lower GI bleeding, K 2.8 mEq/L, Mg 0.8 mEq/L</td>
<td>None</td>
<td>21</td>
<td>15</td>
</tr>
<tr>
<td>20</td>
<td>SBP &lt; 90 mmHg/need for vasoressors, ICU admission</td>
<td>Unable to eat, diarrhea, K 2.2 mEq/L</td>
<td>Unable to eat, diarrhea, mucositis, K 2.2 mEq/L</td>
<td>Day 4: hypotension, ICU, pneumonia, C diff, MI</td>
<td>21</td>
<td>18</td>
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<tr>
<td>21</td>
<td>None</td>
<td>Unable to eat, nausea, vomiting, diarrhea, C diff</td>
<td>Unable to eat, nausea, vomiting, diarrhea, C diff</td>
<td>None</td>
<td>21</td>
<td>19</td>
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<tr>
<td>22</td>
<td>Renal failure</td>
<td>Nausea, vomiting, abdominal pain</td>
<td>Nausea, vomiting, abdominal pain, ARF, bilateral hydronephrosis</td>
<td>Day 10: K 2.9 mEq/L, Day 14: colostomy</td>
<td>21</td>
<td>20</td>
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<tr>
<td>23</td>
<td>Confusion, altered mental state</td>
<td>Unable to eat</td>
<td>Unable to eat, cellulitis, mucositis</td>
<td>Day 4: confusion, carcinomatous meningitis</td>
<td>21</td>
<td>29</td>
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<tr>
<td>24</td>
<td>None</td>
<td>Unable to eat, abdominal pain, inpatient chemotherapy required,</td>
<td>Unable to eat, abdominal pain, SBO</td>
<td>Inpatient chemotherapy required, neutropenia, fever, bacteraemia</td>
<td>21</td>
<td>31</td>
</tr>
<tr>
<td>25</td>
<td>None</td>
<td>Nausea, diarrhea, abdominal pain</td>
<td>Nausea, diarrhea, abdominal pain, typhlitis</td>
<td>None</td>
<td>22</td>
<td>4</td>
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<tr>
<td>26</td>
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<td>None</td>
<td>Pleural effusion</td>
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<td>6</td>
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<tr>
<td>27</td>
<td>None</td>
<td>K 2.2 mEq/L, Hb 6.6 g/dL</td>
<td>Bacteraemia, K 2.2 mEq/L, decubitus debridement</td>
<td>Day 2: Hb 6.6 g/dL</td>
<td>22</td>
<td>6</td>
</tr>
<tr>
<td>28</td>
<td>None</td>
<td>Nausea, K 2.6 mEq/L</td>
<td>Nausea, K 2.6 mEq/L</td>
<td>None</td>
<td>22</td>
<td>6</td>
</tr>
<tr>
<td>29</td>
<td>SBP &lt; 90 mmHg/need for vasoressors, confusion, altered mental state, or seizure</td>
<td>Nausea, vomiting, diarrhea, abdominal pain, K 2 mEq/L</td>
<td>Nausea, vomiting, diarrhea, abdominal pain, altered mental state</td>
<td>Day 2: K 2 mEq/L, Day 3 SBP &lt; 90 mmHg</td>
<td>22</td>
<td>8</td>
</tr>
<tr>
<td>30</td>
<td>SBP &lt; 90 mmHg/need for vasoressors, PaO2 &lt; 60 mmHg/need for ventilation</td>
<td>Impending hip fracture</td>
<td>Impending hip fracture</td>
<td>Day 3: hypotension, Day 5: hypoxia, ARDS</td>
<td>22</td>
<td>8</td>
</tr>
<tr>
<td>31</td>
<td>None</td>
<td>Unable to eat, difficulty swallowing, Day 4: K 5.6 mEq/L, Day 9: K 6.1 mEq/L</td>
<td>Unable to eat, difficulty swallowing, mucositis</td>
<td>Day 4: K 5.6 mEq/L, Day 9: K 6.1 mEq/L</td>
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<tr>
<td>32</td>
<td>PaO2 &lt; 60 mmHg/need for ventilation,</td>
<td>Nausea, diarrhea</td>
<td>Nausea, diabetes, dehydration, Cr 2.7 mg/dL</td>
<td>Day 3: hypoxia Day 4: Cr 5.3 mg/dL, Day 6: colitis, hemodialysis</td>
<td>22</td>
<td>11</td>
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<tr>
<td>33</td>
<td>None</td>
<td>Na 126 mEq/L</td>
<td>Pneumonia, Na 126 mEq/L</td>
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<td>23</td>
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<tr>
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<td>None</td>
<td>Nausea, diarrhea, abdominal pain, Na 118</td>
<td>Nausea, diabetes, abdominal pain, hypotension, Na 118 mEq/L</td>
<td>None</td>
<td>23</td>
<td>3</td>
</tr>
</tbody>
</table>

(Continued on next page.)
<table>
<thead>
<tr>
<th>Patient case number</th>
<th>Klastersky criteria (named)</th>
<th>Klastersky criteria (Presumed to be in “Other complications judged serious and clinically significant by the investigator”)</th>
<th>Reason for admission</th>
<th>Complication after admission</th>
<th>MASCC RIS</th>
<th>Length of stay, days</th>
</tr>
</thead>
<tbody>
<tr>
<td>35</td>
<td>None</td>
<td>Unable to eat, nausea, vomiting, diarrhea, difficulty swallowing, Hb 6.6 g/dL</td>
<td>Unable to eat, nausea, vomiting, diarrhea, difficulty swallowing</td>
<td>Day 2: Hb 6.6 g/dL</td>
<td>23</td>
<td>6</td>
</tr>
<tr>
<td>36</td>
<td>None</td>
<td>None</td>
<td>Pneumonia</td>
<td>None</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>37</td>
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<td>Unable to eat, nausea, vomiting, diarrhea</td>
<td>Unable to eat, nausea, vomiting, diarrhea, abdominal pain, mucositis, colitis</td>
<td>None</td>
<td>23</td>
<td>8</td>
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<tr>
<td>38</td>
<td>None</td>
<td>Unable to eat, nausea, vomiting, abdominal pain</td>
<td>Unable to eat, nausea, vomiting, abdominal pain, intestinal perforation</td>
<td>None</td>
<td>23</td>
<td>8</td>
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<tr>
<td>39</td>
<td>None</td>
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<td>Unable to eat, nausea, vomiting, abdominal pain SBO</td>
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<td>23</td>
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<tr>
<td>40</td>
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<td>Unable to eat, mucositis</td>
<td>None</td>
<td>24</td>
<td>3</td>
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<tr>
<td>41</td>
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<td>Cellulitis</td>
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<td>24</td>
<td>5</td>
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<tr>
<td>42</td>
<td>None</td>
<td>Unable to eat, nausea</td>
<td>Unable to eat, nausea, difficulty swallowing, mucositis</td>
<td>None</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td>43</td>
<td>None</td>
<td>Unable to eat</td>
<td>Unable to eat, mucositis</td>
<td>None</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td>44</td>
<td>None</td>
<td>Nausea, vomiting, diarrhea, abdominal pain</td>
<td>Nausea, vomiting, diarrhea, abdominal pain, typhilitis</td>
<td>None</td>
<td>24</td>
<td>6</td>
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<tr>
<td>45</td>
<td>None</td>
<td>Abscess</td>
<td>None</td>
<td>24</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>46</td>
<td>SBP &lt; 90 mmHg/need for vasopressors</td>
<td>None</td>
<td>Perirectal abscess</td>
<td>Day 1: hypotension</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>47</td>
<td>None</td>
<td>Unable to eat, nausea</td>
<td>Unable to eat, nausea, mucositis</td>
<td>None</td>
<td>24</td>
<td>6</td>
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<tr>
<td>48</td>
<td>SBP &lt; 90 mmHg/need for vasopressors</td>
<td>Unable to eat</td>
<td>Unable to eat, nausea</td>
<td>Day 3: hypotension</td>
<td>24</td>
<td>7</td>
</tr>
<tr>
<td>49</td>
<td>PaO2 &lt; 60 mmHg/need for ventilation, arrhythmia, ECG changes</td>
<td>None</td>
<td>Syncope, K 2.1 mEq/L</td>
<td>Day 2: SVT, hypoxia</td>
<td>24</td>
<td>8</td>
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<tr>
<td>50</td>
<td>None</td>
<td>Nausea, vomiting, abdominal pain</td>
<td>Nausea, vomiting, abdominal pain, colitis</td>
<td>None</td>
<td>24</td>
<td>8</td>
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<tr>
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<td>None</td>
<td>Unable to eat, diarrhea, K 2.5 mEq/L</td>
<td>Unable to eat, diarrhea, difficulty swallowing, mucositis, K 2.5 mEq/L</td>
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<tr>
<td>52</td>
<td>None</td>
<td>Unable to eat, nausea, vomiting, diarrhea, K 2.7 mEq/L</td>
<td>Unable to eat, nausea, vomiting, diarrhea, difficulty swallowing, K 2.7 mEq/L</td>
<td>None</td>
<td>24</td>
<td>8</td>
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<tr>
<td>53</td>
<td>None</td>
<td>None</td>
<td>Bacteremia</td>
<td>ARF</td>
<td>24</td>
<td>12</td>
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<td>54</td>
<td>None</td>
<td>None</td>
<td>Chest pain</td>
<td>None</td>
<td>24</td>
<td>13</td>
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<tr>
<td>55</td>
<td>None</td>
<td>Unable to eat, nausea, vomiting, intractable hiccups</td>
<td>Unable to eat, nausea, vomiting, esophagitis</td>
<td>Day 1: intractable hiccups</td>
<td>24</td>
<td>20</td>
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<tr>
<td>56</td>
<td>None</td>
<td>Unable to eat, nausea, vomiting</td>
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<td>None</td>
<td>26</td>
<td>3</td>
</tr>
<tr>
<td>57</td>
<td>None</td>
<td>None</td>
<td>Cellulitis</td>
<td>None</td>
<td>26</td>
<td>4</td>
</tr>
<tr>
<td>58</td>
<td>None</td>
<td>Nausea, vomiting, diarrhea, abdominal pain</td>
<td>Nausea, vomiting, diarrhea, abdominal pain, typhilitis</td>
<td>None</td>
<td>26</td>
<td>4</td>
</tr>
<tr>
<td>59</td>
<td>None</td>
<td>Nausea, vomiting, abdominal pain</td>
<td>Nausea, vomiting, abdominal pain, typhilitis</td>
<td>None</td>
<td>26</td>
<td>5</td>
</tr>
<tr>
<td>60</td>
<td>None</td>
<td>Unable to eat, abdominal pain</td>
<td>Unable to eat, abdominal pain, typhilitis</td>
<td>None</td>
<td>26</td>
<td>5</td>
</tr>
<tr>
<td>61</td>
<td>None</td>
<td>Unable to eat, nausea, vomiting</td>
<td>Unable to eat, nausea, vomiting</td>
<td>Day 1: perianal herpes simplex virus</td>
<td>26</td>
<td>5</td>
</tr>
<tr>
<td>62</td>
<td>None</td>
<td>Nausea, diarrhea, K 2.6 mEq/L</td>
<td>Nausea, diarrhea, K 2.6 mEq/L</td>
<td>Enterovaginal fistula</td>
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<tr>
<td>63</td>
<td>None</td>
<td>Unable to eat, vomiting, abdominal pain</td>
<td>Unable to eat, vomiting, abdominal pain, mucositis</td>
<td>None</td>
<td>26</td>
<td>7</td>
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<td>64</td>
<td>None</td>
<td>Unable to eat, nausea, vomiting, diarrhea, abdominal pain, hypokalemia</td>
<td>Unable to eat, nausea, vomiting, diarrhea, abdominal pain, enteritis</td>
<td>Low K</td>
<td>26</td>
<td>7</td>
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<td>None</td>
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<td>Unable to eat, nausea, vomiting, rectal pain</td>
<td>None</td>
<td>26</td>
<td>9</td>
</tr>
<tr>
<td>66</td>
<td>None</td>
<td>Hb &lt; 6 g/dL, unable to eat, abdominal pain</td>
<td>Unable to eat, abdominal pain, Hb 5.4 g/dL, K 2.9 mEq/L</td>
<td>None</td>
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<td>9</td>
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<tr>
<td>67</td>
<td>None</td>
<td>Unable to eat, nausea, difficulty swallowing</td>
<td>Unable to eat, nausea, mucositis, difficulty swelling</td>
<td>None</td>
<td>26</td>
<td>10</td>
</tr>
<tr>
<td>68</td>
<td>None</td>
<td>Unable to eat, nausea</td>
<td>Unable to eat, nausea, mucositis</td>
<td>Day 2: fever, Day 6: ARF</td>
<td>26</td>
<td>11</td>
</tr>
<tr>
<td>69</td>
<td>None</td>
<td>Unable to eat, nausea, vomiting, diarrhea, abdominal pain</td>
<td>Unable to eat, nausea, mucositis, colitis</td>
<td>Day 6: ARF</td>
<td>26</td>
<td>13</td>
</tr>
</tbody>
</table>

ARDS = acute respiratory distress syndrome; ARF = acute renal failure; C diff = Clostridium difficile; Cr = creatinine; ECG = electrocardiogram; GI = gastrointestinal tract; Hb = hemoglobin; ICU = intensive care unit admission; K = potassium; MASCC = Multinational Association for Supportive Care in Cancer; Mg = magnesium; MI = myocardial infarction; Na = sodium; PaO2 = partial pressure of oxygen; RIS = risk index score; SBO = small-bowel obstruction; SBP = systolic blood pressure; SVT = supraventricular tachycardia; TPN = total parenteral nutrition.
Utility of the Multinational Association for Supportive Care in Cancer (MASCC) Risk Index Score as a Criterion for Nonadmission in Febrile Neutropenic Patients with Solid Tumors

Table 3. Characteristics of 198 patient episodes of solid tumors,
a

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. of patients (%)</th>
<th>MASCC RIS score &lt; 21 (n = 35), no. (%)</th>
<th>MASCC RIS score ≥ 21 (n = 163), no. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Median</td>
<td>61</td>
<td>67.5</td>
<td>59</td>
</tr>
<tr>
<td>Range</td>
<td>18-86</td>
<td>35-81</td>
<td>18-86</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>57 (29)</td>
<td>17</td>
<td>40</td>
</tr>
<tr>
<td>Female</td>
<td>141 (71)</td>
<td>18</td>
<td>123</td>
</tr>
<tr>
<td>Neoplasms</td>
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<td></td>
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<tr>
<td>Breast</td>
<td>93 (47.0)</td>
<td>7 (20.0)</td>
<td>86 (52.8)</td>
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<tr>
<td>Gastrointestinal</td>
<td>39 (19.7)</td>
<td>6 (17.1)</td>
<td>33 (20.3)</td>
</tr>
<tr>
<td>Lung</td>
<td>18 (9.1)</td>
<td>7 (20.0)</td>
<td>11 (6.8)</td>
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<tr>
<td>Sarcoma</td>
<td>12 (6.1)</td>
<td>5 (14.3)</td>
<td>7 (4.3)</td>
</tr>
<tr>
<td>Head and neck</td>
<td>9 (4.5)</td>
<td>2 (5.7)</td>
<td>7 (4.3)</td>
</tr>
<tr>
<td>Ovary</td>
<td>8 (4.0)</td>
<td>3 (8.6)</td>
<td>5 (3.1)</td>
</tr>
<tr>
<td>Prostate</td>
<td>7 (3.5)</td>
<td>2 (5.7)</td>
<td>5 (3.1)</td>
</tr>
<tr>
<td>Bladder</td>
<td>4 (2.0)</td>
<td>2 (5.7)</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>Testis</td>
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<td>0 (0)</td>
<td>2 (1.2)</td>
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<tr>
<td>PNET</td>
<td>2 (1.0)</td>
<td>1 (2.9)</td>
<td>1 (0.6)</td>
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<td>Unknown</td>
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<td>2 (1.2)</td>
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<td>Melanoma</td>
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<td>0 (0)</td>
<td>1 (0.6)</td>
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<tr>
<td>Uterus</td>
<td>1 (0.5)</td>
<td>0 (0)</td>
<td>1 (0.6)</td>
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<tr>
<td>Total neoplasms</td>
<td>198 (100)</td>
<td>35 (100)</td>
<td>163 (100)</td>
</tr>
<tr>
<td>Comorbidities</td>
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<tr>
<td>Diabetes mellitus</td>
<td>16 (8.1)</td>
<td>4 (11.4)</td>
<td>15 (9.2)</td>
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<tr>
<td>CKD stage ≥ 3</td>
<td>18 (9.1)</td>
<td>6 (17.1)</td>
<td>12 (7.4)</td>
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<td>Cirrhosis</td>
<td>2 (1.0)</td>
<td>1 (2.9)</td>
<td>1 (0.6)</td>
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<td>Rheumatoid arthritis</td>
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<td>Transplant</td>
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<td>1 (0.6)</td>
</tr>
<tr>
<td>Anti-TNF</td>
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<td>0 (0)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Hepatitis B</td>
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<td>0 (0)</td>
<td>1 (0.6)</td>
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<td>Hepatitis C</td>
<td>5 (2.5)</td>
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<td>5 (3.1)</td>
</tr>
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<td>HIV infection</td>
<td>1 (0.5)</td>
<td>0 (0)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Hypogammaglobulinemia</td>
<td>2 (1.0)</td>
<td>0 (0)</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>Hemochromatosis</td>
<td>2 (1.0)</td>
<td>1 (2.9)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Ulcerative colitis</td>
<td>1 (0.5)</td>
<td>0 (0)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unable to eat</td>
<td>54 (27.3)</td>
<td>16 (45.7)</td>
<td>38 (23.3)</td>
</tr>
<tr>
<td>GCSF, inpatient after admission</td>
<td>177 (89.4)</td>
<td>31 (86.6)</td>
<td>146 (89.6)</td>
</tr>
<tr>
<td>GCSF, outpatient before admission</td>
<td>33 (16.7)</td>
<td>6 (17.1)</td>
<td>27 (16.6)</td>
</tr>
<tr>
<td>Chemotherapy density and intensity meeting GCSF criteria</td>
<td>51 (25.8)</td>
<td>5 (14.3)</td>
<td>46 (28.2)</td>
</tr>
<tr>
<td>Documented infection</td>
<td>38 (19.2)</td>
<td>12 (34.3)</td>
<td>26 (16)</td>
</tr>
<tr>
<td>Antimicrobials before admission</td>
<td>18 (9.1)</td>
<td>4 (11.4)</td>
<td>14 (8.6)</td>
</tr>
<tr>
<td>Adequate antimicrobial regimen on admission</td>
<td>167 (94.4)</td>
<td>34 (97.1)</td>
<td>153 (93.9)</td>
</tr>
</tbody>
</table>

*a Some percentages may not total to 100 because of rounding.

There were 163 inpatient episodes with an MASCC RIS of 21 or higher. Sixty-nine of these had complications and/or reasons for admission on presentation. Thirty-eight of the 69 were unable to eat; 32 of the 89 had reasons for admission and/or complications. The other 31 of the 69 patients, those who were able to eat, required admission for various other reasons. See Table 2 for the reasons for admission and subsequent complications of the 32 episodes.

There were 35 episodes with an MASCC RIS below 21 (high risk for complication). Six of these patient episodes were misclassified by the MASCC RIS because no complication occurred that required hospitalization. The mean LOS for these 6 patients was 4.7 days (5, 3, 5, 5, 4, and 6 days, the last with a urinary tract infection that could have been treated orally with ciprofloxacin) compared with a mean LOS of 4.6 days for Group 1 and 7.6 days for Group 2.

Inability to Eat

Inability to eat was considered a serious complication and reason for admission; thus, it placed a patient episode in Group 2: complication. There were 54 episodes of 198 in which patients were unable to eat, 38 of whom had an MASCC RIS of 21 or above and 16 of whom had a score below 21. These 38 patient episodes were a subset of the 69 discordant patient episodes with an MASCC RIS of 21 or greater and a complication (Table 2). Inability to eat was associated with other serious complications in 32 of 38 episodes (84%). The 38 patients who were unable to eat had a mean LOS of 9.66 days compared with the mean LOS of the 31 patients who could eat, 7.0 days (p = 0.08 by Wilcoxon rank sum test). The mean MASCC RIS of those unable to eat and those able to eat was 23.1 and 22.8, respectively.

Correlation of Index with Other Outcomes

There was no useful correlation between the MASCC RIS and either the days to a body temperature at or below 37.5°C or the LOS (data not shown). Table 4 shows a correlation with deaths and the potential cost savings of preventing hospital admission (Table 5).
DISCUSSION

If patients with identified infections; intractable vomiting and diarrhea, either of the latter caused by mucositis or another complication; and inability to eat are included in the patients to whom the MASCC RIS is applied, the sensitivity of an MASCC RIS of 21 or greater to identify patients as a criterion for nonadmission was high (94%), but the positive predictive value was only 57.7% and the specificity only 29.6%. The range of the specificity of the MASCC RIS in some published studies (Table 6) varied from 40% to 95% (mean = 67.5%) in prospective studies and from 52% to 63.7% (mean = 60.9%) in retrospective studies. The variance in the specificity in these studies and the present study has not been explained, and a detailed analysis is beyond the scope of this article; however, a more detailed analysis is available in the guideline from the American Society of Clinical Oncology (ASCO).3 In most of these publications, it is not clear if patients, presenting with identifiable infections; intractable vomiting and diarrhea, either of the latter caused by mucositis or another complication; and the inability to eat and swallow medications were excluded before the calculation of the MASCC RIS because these clinical features were considered aspects of the febrile neutropenic syndrome and not complications. Thus, study design is a possible factor accounting for the variance. Another factor might be that the median age of the patients in the studies listed in the references was about 51 years compared with 61 years in the present study. In the MASCC RIS, 2 points are awarded for age younger than 60 years, indicating that those patients aged 60 years or older are at increased risk of complications. As noted earlier, in 69 of 163 inpatient episodes with an MASCC RIS of 21 or more, admission was necessary because of complications present on admission or which occurred during hospitalization (Table 2). The patients with these 69 misclassified inpatient episodes would not have been admitted if an MASCC RIS of 21 or greater was used as the criterion for nonadmission. If these patients were not admitted, the complications that occurred during hospitalization would have occurred outside the hospital, resulting in either reevaluation in a health care setting or death.

There were also 3 inpatient episodes with an MASCC RIS of 21 or above (Group 1), in which a complication occurred 24 hours after admission, a complication that would have been

<table>
<thead>
<tr>
<th>Table 4. Patient deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MASCC RIS</strong></td>
</tr>
<tr>
<td>13</td>
</tr>
<tr>
<td>19</td>
</tr>
<tr>
<td>19</td>
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<tr>
<td>19</td>
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<tr>
<td>24</td>
</tr>
<tr>
<td>24</td>
</tr>
<tr>
<td>24</td>
</tr>
</tbody>
</table>

*No = died in hospital.
AMI = acute myocardial infarction; ARDS = acute respiratory distress syndrome; ARF = acute renal failure; BP = blood pressure; HAP = hospital-acquired pneumonia; ICU = intensive care unit admission; MASCC = Multinational Association for Supportive Care in Cancer; RIS = risk index score; SBO = small-bowel obstruction; SVT = supraventricular tachycardia; TPN = total parenteral nutrition.
If the MASCC index were to be used to determine “do not admit,” it would have to be employed after determining whether a person was or was not able to eat or swallow...

best managed in the hospital. If the patients had not been admitted, or had been admitted and discharged after 24 hours of observation, they would have experienced these complications as outpatients. Those complications were hypokalemia (serum potassium concentration of 2.9 mEq/L) on Day 2, hypophosphatemia (phosphorus level of 2.2 mg/dL) on Day 3, and recurrent fever on Day 4. An additional 52-year-old woman, not identified as feeling or appearing sick or being dehydrated, had a temperature of 38.7°C, a BP of 81/54 mmHg, and a pulse of 130/min (3 criteria for systemic inflammatory response syndrome) in urgent care. She was referred to the Emergency Department, where she was hydrated and placed on an intravenous antimicrobial regimen. She was intermittently hypotensive until the BP finally stabilized 25 hours and 37 minutes later. Her MASCC RIS was 21 at the time of admission, but the RIS would have been different depending on when, in the course of this patient episode, it was calculated.

Because many complications, such as hypokalemia, hypophosphatemia, and recurrent fever, cannot be predicted with an MASCC RIS of 21 or higher, use of a protocol, algorithm, or guideline seems appropriate to help clinicians decide on the proper management. One is the ASCO guideline from 2012,9 and another is the National Comprehensive Cancer Network (NCCN) guideline.11 The recommended initial observation period in the ASCO guideline is 4 hours, and in the NCCN guideline it is 2 to 12 hours. The hypotensive patient described could have been considered stable at 2 to 4 hours and possibly discharged to home. However, the physician, simply using clinical judgment, decided this patient needed admission. This decision was consistent with the ASCO guideline, which clearly states that a patient with criteria for systemic inflammatory response syndrome should be admitted. Therefore, following the ASCO guideline would have ensured admission for this last patient, but using an MASCC RIS of 21 or higher would not. The limitation of the MASCC RIS is evident by consulting Table 4 of the ASCO guideline (available at: http://jco.ascopubs.org/content/31/6/794/T4.expansion.html).9 The table lists 41 exclusions (42 if the footnote regarding systemic inflammatory response syndrome is included) to using an MASCC RIS of 21 or greater as a criterion for treating a febrile neutropenic patient as an outpatient.9 Furthermore, neither the NCCN guideline for the management of nonadmitted patients nor the ASCO guideline specify frequency of laboratory testing for these potential outpatients. Rubenstein et al12 suggested obtaining a complete blood count every other day and biochemical panels on Day 7 or the last day of observation. If the biochemical panels for the patients with hypokalemia and hypophosphatemia had been drawn on Day 7, a delay in detection would have occurred. The protocol for patients discharged from the hospital on a regimen of oral antimicrobial therapy in the article by Klastersky et al13 included temperature recorded every 6 hours, laboratory tests every other day for 5 days, and phone contact with the patient every other day. The ASCO guideline recommends daily telephone contact and “frequent evaluation for at least 3 days in clinic or at home.”

Data in the present study support the ASCO guideline for management of these patients. Although the ASCO guideline recognizes the lack of data supporting multiple aspects of outpatient management, modifications to the guideline, following discharge to an outpatient setting, could include recording the patient’s vital signs approximately every 6 to 8 hours, establishing phone contact with the patient or caregiver within 8 to 12 hours following discharge, and serum biochemical tests (electrolytes, creatinine, calcium, phosphorus, and magnesium) daily or every other day for 3 times, or until results are normal.

Importance of Inability to Eat

This study chose inability to eat, as an admission criterion, vs inability to swallow oral medications because “unable to eat” was recorded in the progress notes. In my view, neither is adequate or objective because outpatients need both adequate nutrition and appropriate medications. Some patients who are unable to eat can swallow oral medications, and some patients who are unable (or unwilling) to swallow oral medications are able and willing to swallow nutritional liquid drinks. Inability to swallow oral medications is considered by the ASCO guideline to be an exclusion for outpatient management. It is not named as one of the complications in the Klastersky criteria. In the study by Klastersky et al,13 which identified patients who were stable and ready for discharge from the hospital after 24 hours of observation, the equivalent of “unable to eat”—“able to swallow”—was employed after stratification by the MASCC index and was not incorporated into the MASCC index. Those unable to swallow were excluded from early discharge despite an MASCC RIS of 21 or higher. If the MASCC RIS were to be used to determine “do not admit,” it would have to be employed after determining whether a person was or was not able to eat or swallow—as noted earlier, inability to eat was associated with other serious complications, and all physicians admitting patients in this study considered it a criterion for admission. However, because
there are 42 exclusions in the ASCO guideline for managing a patient as an outpatient, as mentioned earlier, there is questionable utility to modifying the MASCC RIS to include “unable to eat/unable to swallow oral medications.” That inability to eat is important has been highlighted in a study by Escalante et al, who noted that 80% of patients with Grade 3 or higher mucositis required admission. The NCCN guideline also includes Grades 3 to 4 mucositis as a criterion for high risk. Until patients who are unable to eat or to swallow oral medications, yet who have no other complications, can be managed as outpatients, they will require admission.

Limitations of Klastersky Criteria and Index

The Klastersky criteria are inadequate as nonadmission criteria for these reasons: 1) only 2 of the 10 complications are objective; 2) the majority, 49 of the 69, of the complications experienced by the patients in this study with an MASCC RIS of 21 or higher were not among the named complications; and 3) inability to eat and inability to swallow are not named.

The MASCC RIS of 21 or above is inadequate for the nonadmission decision for these reasons: 1) only 4 of the 7 components of the MASCC RIS are objective; 2) it misclassified to low risk 42.3% of patient episodes with complications; 3) it has to be checked against 42 other exclusions based on the ASCO guideline; and 4) “unable to eat/unable to swallow” are not incorporated.

Alternative to Index

The alternative to the MASCC RIS is clinical judgment or a more reliable index. Although the MASCC RIS has been incorporated into both Infectious Diseases Society of America and ASCO guidelines, I believe a fair question is: Is this index really superior to clinical judgment? Furthermore, I believe it would be beneficial to conduct a study in which a physician assigns an MASCC RIS at the point of entry to health care and again at the point when an admitting physician, blinded to the MASCC RIS, evaluates the patient regarding admission. The admitting physician would decide, on the basis of clinical acumen and the ASCO guideline, whether the patient should be admitted. The patient would be observed in the hospital for 24 hours. Complications would be correlated with the MASCC RIS and the clinical decision.

Savings

The cost of intensive outpatient management would probably be less than the cost of inpatient management.

<p>| Table 6. Sensitivity and specificity of the MASCC RIS in various studies |
|--------------------------------------------------|--|---|---|---|---|---|</p>
<table>
<thead>
<tr>
<th>Source, year</th>
<th>Type of study</th>
<th>Total</th>
<th>Sensitivity, %</th>
<th>Specificity, %</th>
<th>Deaths, %</th>
</tr>
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<tbody>
<tr>
<td>Uys, 2004</td>
<td>Prospective</td>
<td>70</td>
<td>&gt; 21</td>
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<td>&lt; 21</td>
<td>3</td>
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<tr>
<td>Total</td>
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<td>Baskaran, 2008</td>
<td>Retrospective</td>
<td>34.5</td>
<td>&gt; 21</td>
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<td>169</td>
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<td>4.9</td>
<td>11.4</td>
<td></td>
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</tbody>
</table>

* Results of the current study.

MASCC = Multinational Association for Supportive Care in Cancer; NA = not available; RIS = risk index score; SS/SSh = severe sepsis or septic shock.
(approximately $10,000 per uncomplicated admission). In 1993, Rubenstein and colleagues estimated the medication cost of outpatient management as $2302 for oral therapy and $7336 for intravenous therapy, but the total cost of managing the patients was not provided. Elting et al calculated the costs of outpatient vs inpatient management in 2008 and found the total cost of inpatient management to be about twice that of outpatients.

**Study Limitations**

There are some limitations to this study. First, as noted earlier, the MASCC RIS lists only 4 actual objective criteria. The burden of illness category is purely subjective, dependent on the recorder. This study accepted designations such as COPD, dehydration, and other terms such as vomiting, diarrhea, unable to eat, and so on, without requiring an objective definition. (The ASCO guideline, Table 2, Figure 2. Proposed outpatient management algorithm.*

* Modified from the American Society of Clinical Oncology (ASCO) guideline, to include the following:
  - Patient agrees to outpatient treatment while neutropenic, including potential frequent visits to clinic/hospital.
  - Residence ≤ 1 hour or ≤ 30 miles (48 km) from clinic or hospital, even in inclement weather.
  - Patient's primary care physician or infectious disease physician, or oncologist agrees to outpatient management.
  - Attendant or attendants who agree to outpatient treatment and are competent at observation and communication, and at home 24 hours a day until neutropenia and other clinical problems resolve.
  - Telephone and transportation available 24 hours a day.
  - Either an oncology or infectious disease nurse practitioner or physician's assistant or a clinically trained home infusion pharmacist or clinically trained oncology nurse or infectious disease nurse able to communicate with patient daily.

1. **High risk**
   - (Usual criteria for admission/ASCO guideline)
   - Includes all patients unable to eat
   - Admit
   - Observation for 36 hours
   - VS q8 h first 48 h
   - Telephone contact 8-12 h
   - Postdischarge and daily
   - Daily CBC w diff, electrolytes, Cr, Ca, Mg, phosphate for 2 days, then electrolytes, Cr, Ca, Mg, phosphate every other day twice

2. **Low risk**
   - (Absence of usual clinical criteria for admission/ASCO guideline)
   - Support for management as outpatient
   - Yes
   - Stable at time of entry to health care
   - Yes

3. **CONCLUSIONS**

This study answered the 6 questions presented in the Introduction. First, of 69 misclassified patients with complications and an MASCC RIS of 21 or greater, only 20 had serious complications named in the Klastersky criteria, meaning that the other 49 patients had complications not named and which had to be assumed to be included in the last component, “other complications judged serious and clinically significant by the investigator.”

Second, there were additional complications, not named in the Klastersky criteria, which were important in the nonadmission decision, such as inability to eat (Table 2).

Third, the MASCC RIS of 21 or greater could not be used to make the nonadmission decision for a febrile neutropenic patient with a solid tumor because, in this study, a score of 21 or higher misclassified 42.3% of patients with complications to low risk.

Fourth, 3 patients with an MASCC RIS of 21 or greater experienced complications 24 hours after admission; the...
complication and the day of occurrence were noted. Because 2 of the 3 complications that occurred were biochemical and the additional one was recurrent fever, the index is unlikely to be able to predict their occurrence.

Fifth, therefore, an algorithm or protocol for the management of outpatients is advisable. An algorithm has been constructed from the implications of the data in this study and the ASCO guideline (Figure 2).

Sixth, substantial savings could be realized if uncomplicated patients could be managed as outpatients (approximately $1 million per 100 uncomplicated admissions in 2012 dollars).

The possibility of creating an MASCC-like RIS from truly objective data, which could be used to predict complications and the safety of not admitting a febrile neutropenic patient, requires further investigation.

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

Acknowledgment
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References

State of Mind
A cancer is not only a physical disease, it is a state of mind.

— Michael Baden, MD, b 1934, physician and forensic pathologist
ABSTRACT

Background: Lack of physical activity is prevalent in youths. Pediatricians seek referrals to reliably increase outputs, especially in their overweight and underactive patients.

Objective: Within a randomized controlled trial, we contrasted 2 physical activity/nutrition treatments on the basis of social cognitive and self-efficacy theory, and a comparison condition, on time in moderate-to-vigorous physical activity (MVPA) during the 45-min/day physical activity segment of elementary afterschool care.

Methods: In youths ranging in age from 9 to 12 years (9.7 ± 0.8 years, overall), the Original Youth Fit For Life treatment (Original YFFL; n = 49), the Revised Youth Fit 4 Life treatment (Revised YF4L, n = 43), and a comparison condition of typical care (Comparison, n = 46) were contrasted using a 3 (groups) × 2 (sexes) analysis of variance incorporating means of 3 accelerometer measurements over 12 weeks.

Results: There was a significantly greater amount of time in MVPA in the Revised YF4L group than either the Original YFFL or Comparison groups (F2, 132 = 281.20, p < 0.001). Boys completed significantly more time in MVPA than girls (F2, 132 = 16.43, p < 0.001); however, there was not a significant group × sex interaction. Supplementary analyses indicated sedentary time was significantly less by 29% in the Revised YF4L when contrasted with the Comparison group.

Conclusion: The Revised YF4L protocol that sought to maximize participants’ cardiovascular physical activity appeared to improve upon the Original YFFL treatment on time in MVPA. Thus, pediatricians might have confidence in referring their patients to such evidence-based approaches. Future research should also evaluate the effects of YF4L on psychosocial predictors of physical activity and change in body mass index.

INTRODUCTION

In the US, more than one-third of youths are presently overweight or obese.1 Comorbidities include increased risk for type 2 diabetes, heart disease, orthopedic injuries, cardiorespiratory problems, and self-esteem issues.2,3 Physical activity among children of all ages has decreased,4 and this decrease is associated with an inappropriately high weight.5 The Centers for Disease Control and Prevention’s recommendation for physical activity in children is at least 60 minutes per day of moderate-to-vigorous physical activity (MVPA).6 However, a recent population-based study using accelerometry found that only 42% of US children ages 9-11 years attained this volume.7 Consistent with other research,8 the percentage of boys attaining the recommended amount of physical activity (49%) was considerably greater than that of girls (35%). Notably, the percentages fall to an even more dismal 8% completing the recommended minimum starting at age 12 (3% for girls).7 Because physical activity is the strongest predictor of controlling weight as one ages,9 these patterns of low activity suggest a continuation of the obesity epidemic unless substantial changes occur.

Pediatricians take seriously the need for children to obtain enough physical activity to prevent or improve inappropriately high weight, as well as for promoting cardiovascular fitness. Because pediatricians are not likely to be in a position to directly provide physical activity to patients, they often seek community-based resources as referrals. However, the effectiveness of these resources may vary greatly. For example, although local sports and recreation programs are widely available, overweight, deconditioned, and nonathletic children might feel threatened around more fit and athletic peers. This might lead to even less desire for physical activity for them in the future. Also, many popular sports (eg, baseball, softball, bowling) might not provide much MVPA.

Although physical education (PE) class during the school day provides an obvious venue for physical activity in elementary school students, recent research found that only 27% of a typical class period of 45 minutes (-12 min) is spent in MVPA.10 This is consistent with earlier findings,11-13 and falls significantly short of the Centers for Disease Control and Prevention’s recommendations of at least 50% of the PE class period being in MVPA.14 Fewer than 4% of elementary schools provide daily PE, and walking or bicycling to school and recess time have decreased.4 Although physical activity is associated with favorable academic performance,15 school administrators have been unwilling to increase or improve PE. Thus, the highly utilized after-school care setting has been suggested as important for facilitating physical activity.16

Although the provision of dedicated time and space for physical activity during-after school care is common,
Evidence-Based Referral: Effects of the Revised “Youth Fit 4 Life” Protocol on Physical Activity Outputs

Self-regulation skills more palatable, and better supporting consistent nutrition themes. Ages 9–12 were selected for this investigation because there was a somewhat different YF4L curriculum for ages 5–8 and 9–12 (suggesting the need for separate study). It was expected that the Revised YF4L treatment would be associated with a significantly greater duration of time in MVPA, and significantly less time in sedentary and light physical activities, than both the Original YFFL treatment and typical after-school care processes. Boys were expected to demonstrate greater time in MVPA, regardless of group. It was hoped that this initial validation study would inform revisions of the YF4L treatment in regard to its effects on physical activity outputs. Also, results might provide data for pediatricians to assess the usefulness of YF4L for referral of their patients.

METHODS

Participants

Participants included youths, ages 9–12 years, enrolled in randomly selected elementary after-school care programs operated by YMCA facilities in the greater Atlanta, GA, area. Parents/legal guardians signed written consent forms, and participants provided verbal assent to study staff. Institutional review board approval was received, and procedures conformed to the provisions of the Declaration of Helsinki. An inclusion requirement was attendance in at least 2 of the 3 monthly measurement sessions. Data were excluded if a youth arrived late or left early, demonstrated inappropriate behavior, or reported an injury. Thus, the final sample sizes for the 1) typical after-school care processes (Comparison, n = 46), 2) Original YFFL protocol (n = 49), and 3) Revised YF4L protocol (n = 43) reflected those adjustments.

The sample size adjustments did not significantly differ by group ($\chi^2(df = 2) = 1.09, p = 0.579$), with a mean removal of 26.9% of youths, overall, caused by the above conditions. There was also no significant group difference in age ($F_{2,105} = 0.90, p = 0.410$; overall mean ± SD = 9.7 ± 0.8 years), sex ($\chi^2(df = 2) = 2.37, p = 0.305$; 51.4% girls, overall), or ethnic grouping ($\chi^2(df = 8) = 14.10, p = 0.079$; 31.9% white, 43.5% African American, 14.5% Hispanic, 6.5% Asian, and 3.6% of other ethnicities, overall). On the basis of postal zip codes of participants’ residences, almost all were in the middle class.

Measures

Physical activity intensity category and time were quantified using the Actigraph GT3X accelerometer (Actigraph, Pensacola, FL). Consistent with previous research,29 the monitor was attached at the left side of the waist with a belt, over participants’ clothing. A 30-s sampling interval (epoch) was used to best capture activity patterns found in youths of ages 9 to 12 years.30 The accelerometer recorded 45 minutes (± 1 min) of physical activity during each of the 3 monthly measurements. No measurements were made in the initial week of after-school care because the learning of new physical activity tasks associated with the present protocols might have affected outputs most during this time. The ActiGraph ActiLife data analysis software, version 5.10.0 (ActiGraph, Pensacola, FL), converted accelerometer counts into time in sedentary, light, moderate, and vigorous physical activity on the basis of cut points established by Evenson,30 which were subsequently determined to be the most accurate estimations available for ages 5 to 15 years.31 MVPA was derived by summing the times in moderate and vigorous physical activity.

Several previous studies reported strong interinstrument reliability of the Actigraph accelerometer ($r = 0.84-0.92$).32-34 There were also significant correspondences between scores derived from the ActiGraph accelerometer and VO2 treadmill testing ($r = 0.82-0.87$)34 and doubly labeled water measurements ($r = 0.39-0.54$)35 in children within the age range of this research. It was suggested that the Actigraph accelerometer had the largest body of research supporting its use.36

Procedure

YMCA-based after-school care was administered in the same elementary school that participants attended during
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Competition with oneself, rather than with other participants, was emphasized.

The school day by the existing after-school care counselors. Regardless of group, the school gymnasium was used for the standard session of 45 min/day reserved for physical activity. Study staff secured the accelerometers to each participant’s waist. Although it was obvious that the accelerometer assessed physical activity, there was no coaching given to participants or counselors by study staff to either maximize or minimize intensities. As far as possible, all were kept blind to the purposes of the study. After-school care counselors were generally unfamiliar with PE instruction methods before the training provided on the present protocols. No counselor was involved with more than 1 group. The number of participants per group ranged from 10 to 18, although not all youths present were included in this research (owing mostly to an inability of study staff to secure written consent from parents/guardians).

For the Comparison group, there was no training provided to after-school care counselors beyond information needed for supervision of physical activity in a safe environment. This was provided during the job orientation. For this study, counselors were asked to administer the physical activity component of after-school care in the manner that was typical for them. Some participants ran, some played skill-games in small groupings, and some engaged in primarily sedentary pursuits. It was also an option for participants to use the sport or physical activity equipment (eg, balls and jump ropes) that were stored in the gymnasium.

For the Original YFFL group, after-school care counselors were provided 5 hours of training in the protocol’s 4 components: cardiovascular exercise, strength exercise (via rubber resistance bands), behavioral skills, and nutrition. This was supported by an instructor manual and participant workbook that guided program processes and the required apparatus (eg, balls, bean bags, resistance bands). In addition to the behavioral skills (eg, short- and long-term goal setting, obtaining progress feedback, thought stopping and use of productive self-talk, recruiting social supports) and nutrition-education components, 30 to 35 minutes was to be dedicated to physical activity via noncompetitive games or tasks that were designated as either high or moderate intensity. Every attempt was to be made to keep participants 1) active, 2) challenging themselves, and 3) fostering feelings of mastery and self-efficacy regarding their fitness and physical abilities. The treatment was intended for ages 5 to 12 years.

For the Revised YF4L group, after-school care counselors were provided a newly designed training of approximately 5 hours, a supporting manual, and apparatus similar to the Original YFFL. There was a separate training manual for ages 5 to 8 years; however, only the 9- to 12-year-old version applied here. Although application of behavioral skills training and nutrition education remained in the Revised YF4L (in an enhanced form), the separate strength training component was omitted. Rather, participants’ own body weight now replaced use of the resistance bands in an effort to minimize time being nearly stationary. Also, both behavior and nutrition topics were reinforced through the use of a new array of cardiovascular activities (ie, “content reinforcement activities”), and new moderate- and high-intensity tasks were incorporated. Competition with oneself, rather than with other participants, was emphasized. On the basis of earlier research on the Original YF4L,21,22 behavioral skills and their associated graphics (eg, posters, hand-outs) were intended to better improve participants’ physical self-concept, fitness goal progress, and self-efficacy. As with the Original YFFL, 30 to 35 min/session was to be dedicated to physical activities, and a goal of attaining a mean of 25 to 30 minutes in MVPA was set.

Although the physical activity component of after-school care was five days/week, and the Original YFFL and Revised YF4L protocols met three days/week and four days/week, respectively, analyses were based on single sessions to facilitate statistical contrasts. All personal identifiers were removed before data analyses. Fidelity checks for physical activity programming were completed once every two weeks by YMCA wellness staff using a structured observation form. Any problems were quickly resolved in association with the after-school counselor’s supervisor.

Data Analyses
To detect the moderate effect size found in related analyses and pilot research39 at the statistical power of 0.80, an overall minimum sample size of 117 was required.40 The significance level was set at $\alpha = 0.05$ (2-tailed). It was previously suggested that 3 accelerometer measurements foster accuracy in assessing physical activity outputs in youth.41 Thus, after using the expectation-maximization algorithm for imputation of missing data of no more than 1 of the 3 monthly measurements,42 the mean number of minutes in each physical activity category (ie, sedentary, light, moderate, and vigorous) was calculated. There was no significant difference in scores based on date of measurement for any of the physical activity categories.

For the primary analysis, a 2-way between-subjects analysis of variance3 (groups) x (sexes) was used to contrast the Comparison, Original YFFL, and Revised YF4L groups; boys and girls; and their interaction on mean number of minutes in MVPA. Post hoc follow-up tests using the Least Significant Difference method were incorporated for pairwise contrasts. Supplementary analyses were also completed on each of the 4 separately measured physical activity intensity categories (ie, sedentary, light, moderate, and vigorous) in the same manner. Effect sizes were expressed as partial eta-square ($\eta^2_p$) where 0.01, 0.06, and 0.14 denote small, moderate, and large effects, respectively.

RESULTS
Primary Analysis
For MVPA, the main effect for treatment group was significant ($F_{2, 132} = 281.20, p < 0.001, \eta^2_p = 0.71$). The main effect for sex was also significant ($F_{1, 132} = 16.43, p < 0.001, \eta^2_p = 0.11$). There was not a significant group x sex interaction ($F_{2, 132} = 0.54, p = 0.582, \eta^2_p = 0.01$). Descriptive statistics and
results of all pairwise post hoc analyses are given in Table 1.

**Supplementary Analyses**

For sedentary time, the main effect for treatment group was not significant \(F_{2, 132} = 5.57, p = 0.005, \eta_p^2 = 0.08\). The main effect for sex was not significant \(F_{1, 132} = 1.91, p = 0.169, \eta_p^2 = 0.01\). There was not a significant group × sex interaction \(F_{2, 132} = 0.21, p = 0.813, \eta_p^2 = 0.003\).

For light physical activity, the main effect for treatment group was not significant \(F_{2, 132} = 2.08, p = 0.130, \eta_p^2 = 0.03\). The main effect for sex was significant \(F_{1, 132} = 4.81, p = 0.030, \eta_p^2 = 0.04\). There was not a significant group × sex interaction \(F_{2, 132} = 1.05, p = 0.354, \eta_p^2 = 0.02\).

For vigorous physical activity, the main effect for treatment group was significant \(F_{2, 132} = 12.01, p = 0.001, \eta_p^2 = 0.08\). There was not a significant group × sex interaction \(F_{2, 132} = 1.05, p = 0.354, \eta_p^2 = 0.02\).

For moderate-to-vigorous physical activity, the main effect for treatment group was not significant \(F_{2, 132} = 2.52, p = 0.085, \eta_p^2 = 0.04\). The main effect for sex was significant \(F_{1, 132} = 10.04, p = 0.002, \eta_p^2 = 0.07\). There was not a significant group × sex interaction \(F_{2, 132} = 0.37, p = 0.692, \eta_p^2 = 0.01\).

### Table 1. Minutes in physical activity intensity categories, by group and participants’ sex

<table>
<thead>
<tr>
<th>Group</th>
<th>Boys</th>
<th>Girls</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD (n)</td>
<td>Mean ± SD (n)</td>
<td>Mean ± SD (n)</td>
</tr>
<tr>
<td>Moderate-to-vigorous physical activity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comparison</td>
<td>13.51 ± 5.57</td>
<td>11.19 ± 6.30</td>
<td>11.19 ± 6.30</td>
</tr>
<tr>
<td>Original YFFL</td>
<td>14.70 ± 3.46</td>
<td>13.30 ± 3.88</td>
<td></td>
</tr>
<tr>
<td>Revised YF4L</td>
<td>17.48 ± 4.76</td>
<td>16.20 ± 4.14</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>15.07 ± 4.67</td>
<td>13.50 ± 5.26</td>
<td></td>
</tr>
<tr>
<td>Sedentary time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comparison</td>
<td>11.23 ± 8.69</td>
<td>12.19 ± 6.68</td>
<td></td>
</tr>
<tr>
<td>Original YFFL</td>
<td>10.12 ± 5.19</td>
<td>10.32 ± 4.76</td>
<td></td>
</tr>
<tr>
<td>Revised YF4L</td>
<td>7.80 ± 3.05</td>
<td>8.61 ± 2.90</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>9.84 ± 5.36</td>
<td>10.41 ± 5.22</td>
<td></td>
</tr>
<tr>
<td>Light physical activity</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Comparison</td>
<td>20.26 ± 6.66</td>
<td>21.47 ± 5.22</td>
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</tr>
<tr>
<td>Original YFFL</td>
<td>21.01 ± 2.84</td>
<td>21.83 ± 3.73</td>
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<tr>
<td>Revised YF4L</td>
<td>19.67 ± 4.95</td>
<td>20.18 ± 4.34</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>20.42 ± 4.83</td>
<td>21.19 ± 4.48</td>
<td></td>
</tr>
<tr>
<td>Moderate physical activity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comparison</td>
<td>9.54 ± 4.23</td>
<td>7.91 ± 4.61</td>
<td></td>
</tr>
<tr>
<td>Original YFFL</td>
<td>8.76 ± 2.00</td>
<td>8.15 ± 2.40</td>
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</tr>
<tr>
<td>Revised YF4L</td>
<td>9.99 ± 2.68</td>
<td>9.26 ± 2.38</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>9.33 ± 3.03</td>
<td>8.42 ± 3.33</td>
<td></td>
</tr>
<tr>
<td>Vigorous physical activity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comparison</td>
<td>3.97 ± 2.33</td>
<td>3.28 ± 2.22</td>
<td></td>
</tr>
<tr>
<td>Original YFFL</td>
<td>5.94 ± 2.42</td>
<td>5.15 ± 2.37</td>
<td></td>
</tr>
<tr>
<td>Revised YF4L</td>
<td>7.50 ± 3.17</td>
<td>6.94 ± 3.03</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>7.54 ± 2.91</td>
<td>5.09 ± 2.93</td>
<td></td>
</tr>
</tbody>
</table>

A different letter superscript adjacent to the mean score (a, b, or c) within the same measure denotes a statistically significant difference within the post hoc test among the 3 groups (Comparison, Original YFFL, Revised YFFL). For example, in the moderate-to-vigorous physical activity measure, the Comparison and Original YFFL groups did not significantly differ from each other, but the Revised YF4L group did significantly differ from both.

An asterisk (*) within the same measure denotes a significantly greater score, by sex.

### Discussion

The Revised YF4L treatment was associated with a significantly greater duration of time in accelerometer-measured MVPA when contrasted with typical after-school care and the Original YFFL protocol. This is an important finding because numerous studies suggested the positive effects of the original theory-based protocol on various health behaviors and their psychosocial predictors. Replication should also be completed on the YF4L version for ages 5 to 8 years. Although limitations included a lack of data on 1) psychosocial mediators of MVPA; 2) effects on BMI, nutrition, and changes in MVPA outside of the programs, and 3) expectation effects (eg, Hawthorne effect;...
Rosenthal effect), these initial findings on the Revised YF4L protocol in elementary after-school care were informative. Additional validation research is now required to evaluate effects of YF4L on BMI and psychosocial factors. Also, because resistance training was omitted in the new YF4L curriculum (except for some body weight resistance incorporated within the increased cardiovascular exercise time), favorable benefits related to muscle mass and muscular strength gains might have been reduced.

**CONCLUSION**

It is hoped that, ultimately, widespread dissemination of evidence- and theory-based protocols such as YF4L will allow pediatricians to have confidence in referring patients in need of programs for increasing their MVPA and, possibly, normalizing their BMI. Involvement from physicians in matters of health behavior change is increasingly warranted and could have immense pay-offs for the future health of the nation.

**Disclosure Statement**

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

**Acknowledgments**

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**References**


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Exercise

Nothing is to be found that can substitute for exercise in any way … . Exercise will expel the harm done by most of the bad regimens that most men follow. Not all motion is exercise. Exercise is powerful or rapid motion or a combination of both, vigorous motion which alters breathing and increases its rate.

— Moses Maimonides, 1138-1204, medieval Sephardic Jewish philosopher, astronomer, Torah scholar, and physician
Relationship between Participation in Patient- and Family-Centered Care Training and Communication Adaptability among Medical Students: Changing Hearts, Changing Minds

Lisa Rossignol, MA

ABSTRACT
Background: Patient- and family-centered care (PFCC) training is an important component of many medical school curricula in the US.

Purpose: To determine if an existing quantitative measure of communication adaptability can be used to determine skills acquired by medical students after PFCC training.

Methods: A census was conducted of 43 third-year medical students at the University of New Mexico School of Medicine, Albuquerque, NM. Students participated in the Families as Faculty program of Parents Reaching Out during their pediatric rotation. A pretest and posttest of Duran’s 1983 Communicative Adaptability Scale was performed.

Results: A one-way analysis of variance was conducted and revealed that there was statistical significance for the factor called appropriate disclosure (p = 0.04). When mean plot was conducted, there was a positive correlation between pretest and posttests in social experience, wit, and social confirmation. There was a negative correlation for articulation and social composure, which was not significant.

Conclusion: The Communicative Adaptability Scale was an effective way to evaluate communication skills that students acquire from PFCC training. An increase in appropriate disclosure is an important gain because it means students have become more sensitive to the level of intimacy that the other person is seeking and the student is willing to offer more information. Information sharing is one of the core concepts of PFCC. Finally, the negative correlation for articulation and social composure indicate that Families as Faculty may increase anxiety for medical students, so this is an area of the education that may need to be revisited.

INTRODUCTION
This study seeks to determine if a standardized measurement of communicative adaptability can be used to evaluate skills taught to medical students after patient- and family-centered care (PFCC) training. PFCC care ensures the health and well-being of children and their families through a respectful professional-family partnership. It honors the strengths, cultures, traditions, and expertise that everyone brings to this relationship. According to the US Maternal and Child Health Bureau Division of Services for Children with Special Health Needs, family-centered care is the standard of practice that results in high-quality services.¹

The University of New Mexico in Albuquerque, NM, uses the services of these two programs: Families as Faculty (FAF), which is a division of Parents Reaching Out, a statewide nonprofit interested in advocacy for individuals with disabilities, and the New Mexico Leadership Education in Neurodevelopmental and Related Disabilities, located at the university’s Center for Development and Disability. Families that have a child with a disability welcome a medical student from the University of New Mexico into their home for an informal visit, in which the family members talk openly about their collective experience with various practitioners and medical systems. The goal is that medical students gain insight into how families function and how they feel about health care, which leads to the acquisition of communication skills that deliver greater expressions of respect and dignity, information sharing, participation, and collaboration.²

Despite several attempts by other universities to study PFCC training, there has been little success in articulating what students are learning or how they are being professionally transformed. Because PFCC training is delivered through the mode of verbal and nonverbal communication from health care workers, PFCC education would influence how students communicate. This study seeks to determine if an existing construct, the Communicative Adaptability Scale (CAS), is an effective tool to evaluate whether students acquire the ability to communicate more effectively because of PFCC training.

LITERATURE REVIEW
The purpose of this literature review is to build the theoretical groundwork for evaluating what effect PFCC education has on the communication adaptability that medical students use with patients when they become physicians. This study is an effort to corroborate the expectations of these programs or to produce recommended modifications to the programs or future studies. As knowledge of the concepts of PFCC grow in popularity among hospital administrators, there continues to be very little study about the effectiveness of educational programs on this topic. There has been limited success in capturing any data about PFCC education and the impact it
Relationship between Participation in Patient- and Family-Centered Care Training and Communication Adaptability among Medical Students: Changing Hearts, Changing Minds

has on professional-family communication. Cegala and Brox\(^3\) posit that of the physician training research that has been conducted, “Less than 30\% of the studies … had a design adequate for assessing the effects of training interventions … .” If PFCC training is not working in the manner that is expected, it may be necessary to modify education programs or to abandon initiatives altogether.

In exploring this question, it is important to look at a study that has examined the population of college students for relationships between communication adaptability and intercultural apprehension. Duran\(^4\) defines communication adaptability as “the ability to perceive socio-interpersonal relationships and adapt one’s interaction goals and behaviors accordingly.” Intercultural apprehension is defined as follows: “One’s level of fear or anxiety associated with interacting with people of different cultures and ethnic and/or racial groups.”\(^5\)

Long and Anarbaeva\(^6\) used the CAS, which has a high inter-item reliability (\(\alpha = 0.948\)), and the Personal Report of Intercultural Communication Apprehension, which also has a high inter-item reliability (Cronbach \(\alpha = 0.941\)).\(^7\) The questionnaire was completed by 124 graduate and undergraduate students between the ages of 18 and 45 years. A strong relationship between the 2 variables was revealed. Long and Anarbaeva concluded: “As communicative adaptability increased, intercultural communication apprehension decreased.” This study showed that a clear relationship exists between communication adaptability and intercultural apprehension.

Next, intercultural communication must be linked to physician-patient relationships. Manderson and Allo
tey\(^8\) defined intercultural or cross-cultural communication as the “conveying of information and the response to the information in an interaction between members from different cultures.” They proposed that “In the clinical interaction, this occurs between individuals from a culture of health professionals and individuals who fall into the category of ‘patient’ or ‘sick client.’” Manderson and Allo
tey suggested that the greatest deficit of the prevailing participatory decision-making model\(^8,9\) is that it lacks an education component for the physician. The participatory decision-making model supposes that the clinician might employ variations of education for the patient but does not factor the demand for a physician to be educated by a patient with a different cultural background and belief system.

“These influences affect the development of a sense of the other’s competence, the practitioner’s sense of the patient’s ability to comply with treatment, and the practitioner’s ability to deliver effective treatment.”\(^9\)

In a study designed to monitor the long-term reproductive health issues of African and Middle Eastern refugees in Australia, researchers studied 150 women by using quantitative instruments, focus groups, and interviews. They wrote, “Twenty percent specifically raised issues of communication difficulties with the health services, which included the lack of availability of interpreters, the practitioner giving them information that they perceived to be inappropriate, and an inability of doctors to ‘hear what they were being told.’”\(^10\) Despite the women being from diverse ethnic, economic, and religious backgrounds, there was a “strong perception of discrimination, miscommunication and poor quality service provision within health and welfare agencies.”

Hamilton\(^11\) continued the evaluation of the participatory decision-making model of physician-patient interaction. This model is taught in most Western universities and assumes that patients “both linguistically and culturally are equipped to engage in a discussion with their doctor about diagnosis and treatment, working together to develop a treatment management plan.” As was discussed by Manderson and Allo
tey, patients represent their own culture, which might not benefit from this traditional model.\(^3\) Hamilton proposed that effective communication by practitioners would require “… multiple models to accommodate cultural and other differences in their patients.”\(^11\)

Franck and Callery\(^12\) conducted an extensive, critical literature review of all PFCC literature in an attempt to find operational definitions, themes, constructs, and empirical indicators. The authors found inconsistency in definition of terms and in the practical application of PFCC throughout various systems. The largest deficit cited was that “health professionals’ judgments about the credibility of mothers’ reports sometimes led them to dismiss important assessments.”\(^12\) Franck and Callery were unable to find any evidence that education in PFCC concepts has led to any acquisition of skills and suggested that the construct of partnership “should lead to the concept of shared decision-making and subconcept of participation in decision-making.”

Another study looked at cultural competency, intercultural communication, and family-centered care even more specifically by examining the experience of professionals working with children with special health care needs and their parents.\(^13\) The professionals studied were participants in the Virginia Leadership Education in Neurodevelopment and Related Disabilities program. Participants completed the program between 1996 and 2006 and had been working in their discipline for at least 1 year. The Measure of Processes of Care for Service Providers was used.\(^14\) The device contained 27 questions on a Likert-style scale that represented 4 factors of family-centered care: 1) showing interpersonal sensitivity, 2) providing general information, 3) communicating specific information about the child, and 4) treating people respectfully. Researchers also included a qualitative question: “What have been the greatest barriers to family-centered care in your occupation?”

Thirty-three graduates of the Virginia Leadership Education in Neurodevelopment and Related Disabilities program replied to the survey, resulting in the identification of five major qualitative themes: 1) institutional culture, 2) absence of a care coordinator, 3) insufficient training in intercultural/interpersonal communication skills, 4) policy factors, and 5) family factors. Quantitative results showed that “interdisciplinary professionals were providing care consistent with the principles of PFCC in the areas of treating people respectfully, communicating specific information to families, and showing interpersonal sensitivity.” The study recognized the very small population of respondents and suggested that only those who were actively engaged in PFCC practices responded. Lotze
et al.\(^3\) also recognized that no data from practitioners existed before they attended in-depth PFCC training.

Finally, Johnson et al.\(^3\) addressed the effectiveness of family-centered care education of medical students at the University of Vermont College of Medicine, Burlington, VT. That program was the template for the FAF program, which Parents Reaching Out and the University of New Mexico School of Medicine have used since 1997. When the University of Vermont medical students completed a visit with their family faculty, they were asked to complete and submit a paper on “how they learned from the family and how that might influence their practice in the future.” Three reviewers completed a pilot study that consisted of 45 papers collected from July 2001 to June 2002 in order to establish a set of themes. Then, a fourth, independent reviewer was given the task of reviewing 58 papers that were completed between July 2002 and June 2003 using the categories provided by the pilot study. An early theme that was found concerned the issues the families had with physicians; this theme was broken into 14 categories—all consisting of communication failures. The top 2 most frequent themes were collaboration with families and listening. The authors proposed that an evaluation of the application of communication skills resulting from this program would be an interesting study.

Collectively these studies indicate a need for establishing measurements for the skill acquisitions that may result from PFCC training. Although the CAS has been used in very limited studies, the strong relationship it showed to intercultural apprehension makes it a desirable device for evaluating PFCC training.

The hypothesis of the current research is that PFCC training will result in increased communicative adaptability by medical students.

**METHODS**

After an extensive literature review, I concluded that there was a need to establish measurements for the skill acquisitions that may result from PFCC training for medical students. The CAS has been used in very limited studies, but it has a high reliability and has been used in university students by Long and Anarbaeva,\(^7\) making it a strong device for measuring PFCC education programs. Although there are several newer, valid instruments for physicians who practice medicine, there has been little work looking directly at medical school education in PFCC or communication training and skills.

A census was conducted of 71 medical students in their third year at the University of New Mexico School of Medicine beginning in August 2011 through August 2012. There was a 100% voluntary participation rate. Students participated in Parents Reaching Out’s FAF program during their pediatric rotation. A pretest was administered, in paper form, to medical students during their orientation into the FAF training at the University of New Mexico Hospital, Albuquerque, NM. The pretest used the CAS, which has a high interitem reliability (\(\alpha = 0.948\)). The participants were asked to rate themselves with 30 Likert-style statements, with answers from 1 to 5, with 1 being “least likely” and 5 being “most likely.” The numbers were then entered into a chart that sorted the scores into 6 categories: social experience (the ability to take skills learned from previous encounters to improve future social exchanges and enjoy new and challenging social interactions); wit (skillful, intellectual humor); social composure (a speaker who appears to be calm and composed); articulation (an ability to speak clearly and choose words appropriately); social confirmation (the ability to appropriately gauge what another person needs from an interaction); and appropriate disclosure (an ability to divulge or withhold appropriate amounts of personal information). Students were not provided with a space for any identifying information or demographic information for this study.

After completion of the FAF seminar, the medical students were given the same survey. The posttest was administered, in paper form, at the end of the debriefing session at Parents Reaching Out. Again, subjects were not provided space for any demographic information such as sex, race, or age.

**RESULTS**

A one-way between-groups analysis of variance was conducted to explore the impact of PFCC training on medical students as measured by the CAS. Questionnaires were divided into pretest and posttests, and means were compared on the 6 factors: social experience, wit, social composure, articulation, social confirmation, and appropriate disclosure. There was statistical significance at the \(p < 0.04\) for appropriate disclosure shown in Table 1.

A mean plot was conducted on each of the six factors, which revealed a positive correlation between pretest and posttests for each factor except for social composure and articulation, which illustrated negative slopes (not significant).

**DISCUSSION**

The CAS questionnaire is a moderately effective way to evaluate communication skills that students acquire from PFCC training. An increase in appropriate disclosure is an important gain because it means students have likely become more sensitive to the level of intimacy that the other person is seeking and the student is willing to offer more information. Information sharing is one of the core concepts of PFCC, so gains in this factor are important.

<table>
<thead>
<tr>
<th>Factor</th>
<th>df</th>
<th>F ratio</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social experience</td>
<td>1, 84</td>
<td>1.60</td>
<td>0.21</td>
</tr>
<tr>
<td>Wit</td>
<td>1, 84</td>
<td>1.48</td>
<td>0.23</td>
</tr>
<tr>
<td>Social composure</td>
<td>1, 84</td>
<td>0.01</td>
<td>0.91</td>
</tr>
<tr>
<td>Articulation</td>
<td>1, 84</td>
<td>0</td>
<td>0.96</td>
</tr>
<tr>
<td>Social confirmation</td>
<td>1, 84</td>
<td>1.89</td>
<td>0.84</td>
</tr>
<tr>
<td>Appropriate disclosure</td>
<td>1, 84</td>
<td>4.39</td>
<td>0.04</td>
</tr>
</tbody>
</table>

* One-way between-groups analysis of variance, with significance \(< 0.05\). df = degrees of freedom.
One possibility is that students learn the importance of articulating their own values about patients and families aloud. During the FAF presentation, the facilitator displayed a value statement that said, “We believe all families care deeply about their children” and continued to discuss the importance of articulating, to families, that physicians share these values. The values expressed by PFCC seem to be commonsense, but patients and families may not believe that physicians hold these ideas.

Conversely, FAF may increase anxiety for medical students. Although not statistically significant, the mean plots did show a negative shift of skills relating to comfort with communicating and the ability to express ideas clearly. This area of the education may need to be revisited. One possible explanation for the rise in anxiety levels about communicating could stem from a new understanding that, to be successful, the students will have to become more intimate with some patients who desire interactions that are more intimate. The medical school curriculum does not necessarily provide instruction on ways to communicate with diverse populations of patients and families.

Study Limitations

The population size of this study was very small because the University of New Mexico only admits 60 to 75 students per year to the School of Medicine, so there is very little opportunity to increase the study population unless other universities that use FAF programs participate. At such a small size, it is difficult to assess outcomes of FAF training, on 6 factors, accurately. It is possible that a larger study could reveal more statistical significance between the pretest and posttest. Also, because this is a census of all medical students at the University of New Mexico’s School of Medicine in their third year and pediatric rotation, this information cannot be generalized to any other population. However, as a stepping-stone to more robust, substantial studies into medical school education, this study provides an important contribution to the medical literature.

The construction of this specific PFCC training may also be a factor in the outcome of this study. Although the speakers at the one-hour FAF orientation were almost always the same, the host families where students went were diverse in socioeconomic, racial, religious, and ethnic backgrounds. Future studies may need to conduct research into the type of messages that are being delivered via the host families. Perhaps the messages students are receiving are negative or hostile toward physicians, and that accounts for the negative tendencies of posttest scores on the articulation and social composite elements. Evaluating the messages of host families may allow future researchers to control and test different styles of messaging or content during family visits to determine whether family stories have an impact on student experience.

Possible confounding that may have occurred is additional PFCC training that students received from attending physicians and other residents during their pediatric rotation. Further study would be beneficial into the other types of PFCC training the students are receiving during this rotation or other rotations.

It is possible that students are receiving negative guidance from other staff that suggests communicating with families is not a high priority and that they will be penalized for spending too much time chatting with patients. Despite the possibility of contrary messages, this study documents that students are experiencing alterations in the way they perceive and adapt to what the other person needs from a communication interaction, which is a strong showing for a training program that is designed to improve how physicians and patients work together.

CONCLUSION

Future studies may seek to link CAS scores with other measures, such as patient satisfaction scores or safety data. It is important to understand that this study was not intended to study physicians who are already practicing, but it may prove useful to link CAS scores with future performance of physicians once they have set up their own practices.

Finally, the ultimate goal of this study was to link existing, highly reliable communication research measures to health care research. In the past few decades, physicians have begun to see the benefit of employing communication scholars in research that involves interaction and messaging. This notion is not to say that physicians are not capable of successful research involving communication, but that their work can only be strengthened by interdisciplinary collaboration with scholars who have the ability to provide new insight into interactions and relational dynamics.

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

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

References


The Move to Touch

A practitioner of experience does not seize the patient’s forearm with his hand as soon as he comes, but first sits down and with a cheerful countenance asks how the patient finds himself; and if the patient has any fear, he calms him with entertaining talk, and only after that moves his hand to touch the patient.

— De Medicina, Aulus Aurelius Cornelius Celsus, c 25 BC – c 50 AD, Roman encyclopaedist
A Ten-Year Case-Control Study of Passive Smoke Exposure as a Risk Factor for Pertussis in Children

Mark A Schmidt, PhD, MPH; Samantha K Kurosky, MS; John P Mullooly, PhD; Colleen Chun, MD; Sheila Weinmann, PhD

ABSTRACT

Context: Passive exposure to cigarette smoke in the household as a risk factor for pertussis disease has not been well characterized.

Objective: To determine whether pertussis was associated with household secondhand smoke in children.

Methods: We conducted a matched case-control study of laboratory-confirmed pertussis cases occurring from January 1, 1996, through December 31, 2005, in children up to 12 years of age who were members of a large managed care organization. Controls were matched one-to-one on age group and type of Health Plan account. Passive cigarette smoking was determined through a retrospective review of the medical records of cases, controls, and their respective household members.

Main Outcome Measures: Cases of pertussis infection were identified from a microbiology laboratory database and through diagnostic codes from the International Classification of Diseases, Ninth Revision, with the diagnosis confirmed by culture or polymerase chain reaction.

Results: Sixty-five laboratory-confirmed cases of pertussis were identified. Cases and controls were similar in sex (p = 0.73), race (p = 0.57), and receipt of pertussis antigen-containing vaccine (p = 0.24). Using multivariable conditional logistic regression analysis, we did not detect a statistically significant association between pertussis and household passive exposure to cigarette smoking (adjusted odds ratio = 1.2; 95% confidence interval = 0.5-2.9).

Conclusion: Although we did not detect an association in this analysis, the possible relationship between passive exposure to smoking and childhood pertussis remains an important research question and should be a priority for future studies.

INTRODUCTION

Pertussis, or whooping cough, is a respiratory tract infection and a major public health burden because of its high infectivity and severe manifestations among infants. Pertussis is caused by the bacterial species, Bordetella pertussis, which is transmitted from person to person via aerosolized droplets. Rates of childhood immunization against pertussis in the US are high, with more than 83% of children younger than age 3 years having received 4 doses of pertussis antigen-containing vaccine. However, children too young to be fully immunized, older underimmunized children, and immunized teenagers and adults with waned immunity are at risk of pertussis infection acquired from symptomatically infected individuals. Whereas adolescents and adults may have a relatively mild illness, pertussis in infants is particularly severe. According to the Centers for Disease Control and Prevention in 2011, infants younger than age 2 months who were too young to be immunized accounted for 57% of all infant hospitalizations and 85% of all infant deaths due to pertussis in the US.

Passive cigarette smoke exposure (PSE) in the household as a possible risk factor for pertussis infection among children has not been well characterized in the literature. Our prior work investigating the impact of PSE on pneumococcal infection prompted us to conduct a case-control study within the population of a large managed care organization to compare household smoking exposure histories recorded in the electronic medical record (EMR) of pediatric pertussis cases with those of matched controls.

METHODS

We conducted our study among the member population of the Kaiser Permanente Northwest (KPNW) Health Plan, using a similar protocol and the same control group described for our investigation of PSE as a risk factor for invasive pneumococcal disease. We selected pertussis cases occurring from January 1, 1996, through December 31, 2005, among KPNW members from birth through age 12 years. Potential cases were identified from either of the following: 1) a microbiology laboratory database as having pertussis confirmed by culture, direct fluorescent-antibody testing, or polymerase chain reaction or 2) the EMR as having a pertussis-related code from the International Classification of Diseases, Ninth Revision (ICD-9: 033, 033.0, 033.8, 033.9, and 484.3). When ICD-9 codes were used for case identification, we manually reviewed the EMR to exclude those without documented laboratory confirmation of pertussis infection.

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Where possible, we used our control population from the study of invasive pneumococcal disease. Among this group, we determined which potential controls were closest in age to our cases on their “reference date,” defined as the collection date of the pertussis-positive specimen from the case, and matched 1 control to each pertussis case, by age group (0-2, 3-5, and 6-12 years) and type of Health Plan account. We matched controls and cases on the basis of the reference date to avoid confounding the relationship between smoking exposure and pertussis occurrence by secular changes in pertussis incidence and capture of smoking history within the EMR. Because the study design involved collecting PSE information from the EMR of family members if available to us, we matched group members based on Health Plan account (child plus family members or child alone) to equalize our access to the family member’s EMR between cases and their matched controls. For 11 pertussis cases without a suitable control from this control population, we randomly selected 1 control for each case from the KPNW member population, using the same criteria.

We reviewed the health records of all cases and new controls, plus the records of their family members where available, to collect PSE history, using standardized data collection instruments. We categorized each case and control as definitely exposed, probably exposed, probably not exposed, definitely not exposed, or unknown (Table 1). For all cases and controls, we collected information about receipt of pertussis antigen-containing vaccines before the collection date of the pertussis-positive specimen (cases) or equivalent reference date (controls) through electronic abstraction of the Vaccine Safety Datalink vaccine dataset. We defined vaccine exposure as “vaccinated” if the subject had received at least one pertussis antigen-containing vaccine before the reference date or “unvaccinated” if they had not. We determined whether cases and controls were up to date with the receipt of pertussis antigen-containing vaccines, as appropriate for age, using Advisory Committee on Immunization Practices recommendations.

We constructed conditional logistic regression models to investigate the relationship between PSE and pertussis. Our main model included only the matched case-control pairs for whom PSE history was categorized for both members of the pair. Because of the small number of study participants, we considered participants to be “exposed” if they were categorized as “definitely exposed” or “probably exposed.” We considered participants to be “unexposed” if they were categorized as “definitely not exposed” or “probably not exposed.” Variables evaluated for confounding in multivariable models included sex, race, history of being breastfed, daycare attendance, and receipt of pertussis antigen-containing vaccine before the reference date. The latter was retained in the final multivariable model.

To account for any possible selection bias related to the exclusion of case-control pairs in which at least one of the members had an unknown PSE history, we conducted a sensitivity analysis, including all case-control pairs in two separate models. For Model 1, we compared the combination of unexposed and unknown pairs with exposed pairs; for Model 2, we compared the combination of unexposed pairs with exposed and unknown pairs. We included vaccine history in both models to adjust for potential confounding.

This protocol was reviewed and approved by the KPNW institutional review board.

**RESULTS**

We identified 65 laboratory-confirmed pertussis cases meeting our criteria, 33 of which occurred in infants younger than 1 year of age. Positive test results for pertussis included 53 cases confirmed by culture, 5 by direct fluorescent-antibody testing, 4 by

<p>| Table 1. Categorization of passive household smoking exposure for pertussis cases and matched controls |</p>
<table>
<thead>
<tr>
<th>Category of exposure</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definitely exposed</strong></td>
<td>One or more persons in the household (including babysitter) smokes, recorded within two years of the reference date (RD). No conflicting information from family members’ charts. No mention in the child’s record that adults smoke outside.</td>
</tr>
<tr>
<td><strong>Probably exposed</strong></td>
<td>Conflicting information on smoking in the household, but at least one record that someone in the household smokes, or Meets criteria for “definitely exposed” but the child’s record mentions that adults smoke outside. Evidence must show that all adults in the household smoke outside for the child to be classified as “probably exposed” rather than “definitely exposed,” or Meets criteria for “definitely exposed” except that the only available information is recorded more than two years before RD.</td>
</tr>
<tr>
<td><strong>Probably not exposed</strong></td>
<td>One parent is a nonsmoker. No information on smoking status of the other parent, or One or more adults quit smoking but either quit within the last five years or quit at some unknown date, and the child’s record says household is nonsmoking, or Any notation in any family member’s record that no one in the household smokes, or Both parents are documented nonsmokers or former smokers but information on at least one parent is more than two years old.</td>
</tr>
<tr>
<td><strong>Definitely not exposed</strong></td>
<td>Unequivocal information from a child’s record within two years of RD that no one in the household smokes, or Information present within two years before RD that both parents are nonsmokers. Former smoker parents quit more than five years before RD.</td>
</tr>
<tr>
<td><strong>Unknown</strong></td>
<td>No smoking-related information found in any family member’s medical record.</td>
</tr>
</tbody>
</table>
A Ten-Year Case-Control Study of Passive Smoke Exposure as a Risk Factor for Pertussis in Children

culture and direct fluorescent-antibody testing, and 3 by polymerase chain reaction. Table 2 describes demographic and exposure information of pertussis cases and matched controls. Cases and controls were similar with respect to sex (p = 0.73) and white vs nonwhite race (p = 0.57). A similar proportion of cases (68%; n = 44) and controls (78%; n = 51) had received a pertussis antigen-containing vaccine (p = 0.24). Among those vaccinated, a similar proportion of cases (77%; n = 34) and controls (40; 78%) were up to date with pertussis vaccination for their age (p = 0.89). Because cases and controls were similar by up-to-date vaccination status and because our small sample size would potentially limit our ability to consider additional variables in our main model, we decided to consider only whether our subjects were vaccinated or unvaccinated for the remainder of the analysis. A higher proportion of cases than controls was categorized as exposed to PSE (37% vs 27%), but the control group had a higher proportion of subjects with missing data on PSE (18% in controls vs 8% in cases).

For 15 (23%) of the case-control pairs, 1 or both members had unknown PSE, and these pairs were excluded from our main-effects analysis. Among the remaining 50 case-control pairs, 28 (56%) had concordant case-control exposure histories (7 in which both members were exposed and 21 in which both members were unexposed). In our conditional logistic regression model, which calculated the odds ratio (OR) using data from the 22 discordant pairs, we found no statistically significant relationship between pertussis and PSE in the household (OR = 1.2; 95% confidence interval [CI] = 0.5-2.8; Table 3). Our results remained similar after adjusting for receipt of pertussis antigen-containing vaccine (adjusted OR = 1.2; 95% CI = 0.5-2.9). We included the 15 case-control pairs with at least 1 member with unknown PSE in our sensitivity analyses. In Model 1, we placed those with missing PSE data in the unexposed category; in Model 2, we placed them in the exposed category. Thus, the range of ORs that could have resulted from this study if there had been no missing data was 1.1 to 1.7.

**DISCUSSION**

We did not detect an association between laboratory-confirmed pertussis and PSE in the household in this analysis; however, this remains an important

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**Table 2. Demographic and exposure characterization of 65 pertussis cases and matched controls**

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Cases, no. (%)</th>
<th>Controls, no. (%)</th>
<th>Chi squared p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (male)</td>
<td>33 (51)</td>
<td>36 (56)</td>
<td>0.73</td>
</tr>
<tr>
<td>Race (white)</td>
<td>18/20 (90)</td>
<td>25/26 (96)</td>
<td>0.57</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1 year</td>
<td>33 (51)</td>
<td>23 (35)</td>
<td></td>
</tr>
<tr>
<td>1-2 years</td>
<td>7 (11)</td>
<td>17 (26)</td>
<td></td>
</tr>
<tr>
<td>3-5 years</td>
<td>7 (11)</td>
<td>7 (11)</td>
<td></td>
</tr>
<tr>
<td>6-12 years</td>
<td>18 (28)</td>
<td>18 (28)</td>
<td></td>
</tr>
<tr>
<td>Exposure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccinated against pertussis</td>
<td>44 (68)</td>
<td>51 (78)</td>
<td>0.24</td>
</tr>
<tr>
<td>Up-to-date vaccination for age</td>
<td>34/44 (77)</td>
<td>40/51 (78)</td>
<td>0.89</td>
</tr>
<tr>
<td>&lt; 1 year</td>
<td>19/21 (90)</td>
<td>11/12 (92)</td>
<td></td>
</tr>
<tr>
<td>1-2 years</td>
<td>2/3 (67)</td>
<td>2/3 (67)</td>
<td></td>
</tr>
<tr>
<td>3-5 years</td>
<td>1/3 (33)</td>
<td>1/3 (33)</td>
<td></td>
</tr>
<tr>
<td>6-12 years</td>
<td>2/3 (67)</td>
<td>2/3 (67)</td>
<td></td>
</tr>
<tr>
<td>Passive smoker</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposed</td>
<td>24 (37)</td>
<td>18 (27)</td>
<td>0.69</td>
</tr>
<tr>
<td>Unexposed</td>
<td>36 (55)</td>
<td>35 (54)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>5 (8)</td>
<td>12 (18)</td>
<td></td>
</tr>
</tbody>
</table>

---

**Table 3. Adjusted odds ratios of conditional logistic models assessing the relationship between passive smoke exposure and pertussis, adjusting for receipt of pertussis vaccine**

<table>
<thead>
<tr>
<th>Variable†</th>
<th>Odds ratio (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main analysis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexposed</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Exposed</td>
<td>1.2 (0.5-2.9)</td>
<td>0.67</td>
</tr>
<tr>
<td>Vaccinated</td>
<td>0.9 (0.5-2.3)</td>
<td>0.75</td>
</tr>
<tr>
<td><strong>Sensitivity analysis, Model 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexposed + unknown</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Exposed</td>
<td>1.7 (0.8-3.8)</td>
<td>0.19</td>
</tr>
<tr>
<td>Vaccinated</td>
<td>0.5 (0.2-1.2)</td>
<td>0.11</td>
</tr>
<tr>
<td><strong>Sensitivity analysis, Model 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexposed</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Exposed + unknown</td>
<td>1.1 (0.5-2.3)</td>
<td>0.87</td>
</tr>
<tr>
<td>Vaccinated</td>
<td>0.5 (0.2-1.3)</td>
<td>0.15</td>
</tr>
</tbody>
</table>

† Exposed includes participants categorized as “definitely exposed” or “probably exposed.” Unexposed includes participants categorized as “definitely not exposed” or “probably not exposed.”

§ Conditional adjusted odds ratio for main model included 50 pairs with known passive smoke exposure. 22 of which were discordant. Conditional adjusted odds ratio for sensitivity analysis models included 65 pairs, 35 of which were discordant.

CI = confidence interval.
research question to study. In an in vitro model, cigarette smoke exposure was associated with an increased number of *B. pertussis* organisms binding to buccal epithelial cells from nonsmokers compared with unexposed cells. Among cigarette smokers, studies have described decreased mucociliary clearance, decreased levels of circulating immunoglobulins, decreased natural killer cell activity, depressed neutrophil chemotaxis and phagocytic activity, and decreased release of pro-inflammatory cytokines. Cigarette smoking also is associated with increased permeability of the respiratory epithelium. Further research is needed to investigate whether similar immune alterations occur in children exposed to cigarette smoke. Among children, PSE has been associated with an increased risk of invasive bacterial infections from *Streptococcus pneumoniae*, *Neisseria meningitidis*, *Haemophilus influenzae* type b, *Mycobacterium tuberculosis* infection, and viral infections, including respiratory syncytial virus. In addition, smokers with pertussis infection are more infectious than non-smokers because of greater severity and duration of cough. This is especially important, as household members are the estimated source for 60% to 83% of infant cases of pertussis, and adults have been responsible for introducing pertussis into the household in 26% of household outbreaks and for 42% of all household secondary cases.

Our main study strengths were the use of information from EMR and laboratory records, reducing exposure misclassification and outcome misclassification, and a study period that extended over 10 years. Our main limitation was the small sample size of the study population because of a low incidence of pertussis during the study period. Our sample size was further restricted by incomplete household PSE history for some study participants, although we accounted for this through our sensitivity analysis and this limitation did not alter our findings.

**CONCLUSION**

Pertussis is now considered a resurgence disease; its incidence has increased overall during the past 3 decades, with more notable increases and multiple outbreaks since the mid- to late 2000s. In 2012, Oregon had an outbreak of pertussis and recorded more than 900 cases (23.3 cases per 100,000)—its highest occurrence since 1953. The incidence rate was highest among infants (253/100,000 persons), followed by children aged 10 to 14 years (104/100,000), aged 1 to 4 years (81/100,000), and aged 5 to 9 years (67/100,000). Twenty-six infants had severe disease requiring hospitalization. If PSE is linked to increased risk or severity of pertussis in childhood, this would allow targeted education for parents about eliminating household PSE and would assist clinicians in assessing the child’s risk for pertussis infection. Improved documentation of PSE in the EMR would assist future studies of the relationship between PSE and pertussis risk in children.

**Disclosure Statement**

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

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**References**


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**A Ten-Year Case-Control Study of Passive Smoke Exposure as a Risk Factor for Pertussis in Children**
Pertussis

Fevers attacked boys of four months, of ten months and a little older, countless numbers of whom died. Principally that common cough, which is usually called Quinta or Quintana . . . Serious are the symptoms of this . . . For they are without this troublesome coughing for . . . four or five hours . . . then this paroxysm of coughing returns, now so severe that blood is expelled with force through the nose and through the mouth.

— Guillaume de Baillou (Ballonius), 1538-1616, French physician and considered founder of modern epidemiology
ABSTRACT

The 2014 Kaiser Permanente Care Management Institute National Hypertension Guideline was developed to assist primary care physicians and other health care professionals in the outpatient treatment of uncomplicated hypertension in adult men and nonpregnant women aged 18 years and older. The new guideline reflects general acceptance, with minor modifications, of the “Evidence-Based Guideline” report by the panel members appointed to the National Heart, Lung, and Blood Institute 8th Joint National Committee. A major practice change is the recommendation for goal systolic blood pressure less than 150 mmHg in patients aged 60 years and older who are treated for hypertension in the absence of diabetes or chronic kidney disease. This article describes the reasons for, evidence for, and consequences of the change, and is followed by the National Guidelines handout.

INTRODUCTION

The 2014 Kaiser Permanente (KP) Care Management Institute National Hypertension Guideline was developed to assist primary care physicians and other health care professionals in the outpatient treatment of uncomplicated hypertension in adult men and nonpregnant women aged 18 years and older. The new guideline reflects general acceptance of the “Evidence-Based Guideline” report by the panel members appointed to the National Heart, Lung, and Blood Institute (NHLBI) 8th Joint National Committee (JNC 8). A major practice change is the recommendation for goal systolic blood pressure less than 150 mmHg in patients aged 60 years and older who are treated for hypertension in the absence of diabetes or chronic kidney disease (CKD) compared with the previous standard less than 140 mmHg. This change has major consequences for the routine primary care management of patients with hypertension.

How Large Is the Affected Population and How Strong Is the New Recommendation?

Using the results of the National Health and Nutrition Examination Survey between 2005 and 2010, it has been estimated that the US treatment-eligible adult hypertension population would decrease from 20.3% to 19.2% compared with that of the 7th Joint National Committee guideline, and the population with treatment-eligible hypertension who are aged 60 years and older would decline from 68.9% to 61.2%. As of October 2014, with an 85% hypertension control rate less than 140/90 mmHg, there are 18,690 patients aged 60 years and older without diabetes or CKD in the KP Southern California hypertension registry who have systolic blood pressures of 140 to 149 mmHg and are affected by the new recommendation. These patients represent 2.5% of the total KP Southern California adult hypertension registry of 740,003 individuals.

Evidentiary support for this recommendation was strong, according to the Care Management Institute Grading of Recommendations Assessment, Development and Evaluation (GRADE) standard for grading the quality of evidence scale, and it received a strong rating using principles evaluating the strength of the body of evidence and degree of certainty developed by the NHLBI before it convened the first JNC 8 panel meeting in August 2008. This recommendation was a segue from the relevant Evidence Statements, which evaluated randomized clinical trials passing scrutiny from a 14-category evidence assessment scale used by a trained and independent methodology team collaborating with those experts appointed to the JNC 8 panel. These Evidence Statements are available in the full online Evidence-Based Guideline report.

What is the Basis of the Supportive Evidence?

The age 60 years threshold for the systolic blood pressure target was decided on the basis of the Systolic Hypertension in the Elderly Program (SHEP) trial findings and the Systolic Hypertension in Europe (Syst-Eur) trial results. In these highly rated randomized controlled trials, stroke, the primary endpoint, was reduced by 36% and 42%, respectively, and major cardiovascular events were reduced by 32% and 31%, respectively. These two large trials containing representative population samples fulfilled the NHLBI strong evidence requirement for multiple supportive randomized controlled trials. The JNC 8 Evidence Statements 1 to 3 for Clinical Question 2 describe the evidence, and a strong recommendation is the logical result.

There is no evidence from a randomized controlled clinical trial to support the opinion that a systolic blood pressure goal less than 140 mmHg in the elderly hypertensive population is superior to a systolic goal less than 150 mmHg. The absence
of evidence for a lower blood pressure target does not equal benefit. One opinion properly criticizes the strength of the Japanese Trial to Assess Optimal Systolic Blood Pressure in Elderly Hypertensive Patients' and Valsartan in Elderly Isolated Hypertension Study\(^6\) results demonstrating equivalency of goal systolic pressure less than 140 mmHg compared with goal systolic pressures less than 150 mmHg and less than 160 mmHg, because these were short-term trials.\(^7\) However, that critique does not offer additional information to the previously published Evidence-Based Guideline Clinical Question 2: Evidence Statement 6, which attached low-quality evidence to these trials.\(^{p84-5}\)

**PROBLEMS WITH USE OF ACHIEVED BLOOD PRESSURE TRIALS**

Achieved blood pressure trials are those in which the intervention is to introduce antihypertensive medication to examine the effect of medication on cardiovascular risk reduction rather than to examine outcomes achieving a prespecified goal blood pressure. These trial results should not be used to inform blood pressure targets because they ask a different question. Retrospective analyses correlating achieved blood pressures to outcome measures are inherently biased.

The NHLBI process followed by the panel appointed to JNC 8 is in agreement with The Cochrane Collaboration methodologists who independently decided the following:

The cohort of patients with low blood pressure as identified by achieved blood pressure selects for patients who did not have sustained elevated blood pressure in the first place . . . , for patients in whom the blood pressure is most easily reduced with low doses of antihypertensive drugs, for patients with the lowest baseline blood pressure, and for patients who are most compliant with drug and non-drug therapy to lower blood pressure . . . . All of these factors are also most likely associated with a lower risk of having an adverse cardiovascular event. The approach is thus heavily biased for finding [fewer] cardiovascular events in the patients with low blood pressure, and thus must not be encouraged.\(^8\)

These limitations of analyses based on post hoc achieved blood pressures were confirmed in an analysis of the African American Study of Kidney Disease and Hypertension, which concluded that the retrospective use of achieved blood pressures would have erroneously led to the opposite conclusion of the intention-to-treat goal blood pressure analysis in this landmark study.\(^9\)

The Felodipine Event Reduction study,\(^10\) the Perindopril Protection against Recurrent Stroke trial,\(^11\) and Blood Pressure Trialsists’ Collaboration reports\(^12\)-\(^14\) purport to show that additional blood pressure lowering is beneficial. These are examples of clinical trials and meta-analyses representing on-treatment achieved blood pressure results rather than intention-to-treat goal blood pressure outcomes and were rejected by the NHLBI methodology team because of bias. Notably, reference to mean achieved systolic blood pressures in the SHEP and Syst-Eur trials of 142 mmHg and 144 mmHg, respectively, fails to mention the mean achieved systolic blood pressure in Syst-Eur, which was 151 mmHg.\(^6\)

The argument to use “totality of evidence” does not constitute sufficient rationale for inclusion of clinical trials and meta-analyses containing inherent bias.

**Where Does the Lower-is-Better Blood Pressure Hypothesis Originate, and Has It been Validated?**

Much of the “lower is better” paradigm is based on strong prospective observational data of more than 1 million patients in 61 prospective studies\(^15\) as well as on many retrospective analyses of achieved blood pressures in the clinical trials. However, the retrospective findings are mixed. A more recent population-based retrospective cohort study revealed no difference between systolic intensification thresholds of 130 mmHg to 150 mmHg across a broad spectrum of baseline cardiovascular risk.\(^16\) Analyses of large numbers of hypertensive KP patients with hypertension, as well as US military veterans with hypertension and CKD, suggest increased mortality and end-stage kidney disease associated with lower attained blood pressures.\(^17,18\)

Does the treatment of blood pressure to lower blood pressure targets, as opposed to higher blood pressure targets, reverse cardiovascular risk? Seven randomized clinical trials have investigated this hypothesis in high-risk patients with CKD, diabetes, older age, and a personal history of stroke. None has shown significant benefit for meeting the primary endpoint with more intense antihypertensive therapy that seeks a lower blood pressure goal.\(^19,20\)

**WHAT IS THE RISK OF REVERSING POPULATION GAINS IN CARDIOVASCULAR BENEFIT?**

How can we be sure that a higher systolic goal will not reverse gains already made in stroke and cardiovascular disease reduction? Gains in cardiovascular disease reduction have been associated with hypertension control, widespread use of high-potency statins, and improved secondary prevention in patients with known coronary artery disease and stroke.\(^21,22\) Because patients are receiving better overall care, power calculations for recent hypertension treatment trials on the basis of adverse rates of cardiovascular events for historic cohorts often fall short of forecasts, leading to underpowering.\(^19,20\) Given the success of population care strategies achieving very high rates of blood pressure control and eliminating racial performance gaps in large diverse populations,\(^23-29\) we need to ensure that we use the highest evidence base to define blood pressure targets. Implementation difficulties and problems with clinical inertia are independent issues and should not be used to justify inappropriately low blood pressure goals.

**What are the Risks of Overtreatment?**

Overtreatment needs to be a concern. In the KP Southern California adult hypertension registry in which nearly 90% of patients attained blood pressure control less than 140/90 mmHg, the mean systolic pressure is 127 mmHg, and almost 10% of patients receiving antihypertensive therapy have a most recent systolic pressure less than 110 mmHg. The
disadvantages of overtreatment include: 1) exposure to side effects of unnecessary medications and excessive medication doses; 2) polypharmacy in the elderly; 3) reduced medication adherence associated with a large number of medications; 4) a possible increase in falls with serious injury; and 5) possibly a J- or U-curve increase in cardiovascular risk; and 6) unnecessary use of limited health care resources, including office visits, population care outreach, medication prescriptions, and laboratory testing. A general review of 16 treatment trials indicated the potential for harm with more aggressive antihypertensive therapy in the absence of benefit.

Is There a Risk of Changing Goal Blood Pressure in the Presence of Uncertainty?

How can we be certain that the systolic blood pressure target less than 150 mmHg for patients with hypertension aged 60 years and older is accurate? The purpose of guideline development is to gather evidence with the least chance of bias, and this sort of evidence is best obtained from higher-quality randomized controlled clinical trials. All the panelists appointed to JNC 8 concurred with the NHLBI evidence review process, and, following several straw votes during more than one year, the final recorded vote at a face-to-face meeting conducted in Bethesda, MD, at the National Institutes of Health on February 27-28, 2013, on Recommendation 1 was 15 in favor and 2 against. The final recorded vote on the 3 evidence statements supporting Recommendation 1 was unanimously in favor. The SHEP and Syst-Eur trial results provide strong evidence to support the Evidence-Based Guideline's recommended goal blood pressure in elderly patients. In contrast, there are no known clinical trials that address goal blood pressure that have examined the 18- to 59-year age stratum, and therefore recommendation for less than 140/90 mmHg for this population is based on expert opinion.

There is a need for additional clinical trials examining the question of goal blood pressure for various populations of hypertensive individuals. Those trials should include examination of important health outcomes at a goal systolic pressure less than 150 mmHg compared with less than 130 mmHg in elderly patients with diabetes and CKD. There is good evidence to justify such a randomized clinical trial in patients with diabetes, including Evidence Statement 18 for Clinical Question 2 in James et al. If the ongoing Systolic Blood Pressure Intervention Trial does not find a significant outcome difference treating to goal systolic pressure less than 140 mmHg compared with less than 120 mmHg in patients with CKD, a future trial comparing less than 150 mmHg with less than 130 mmHg would be justified in this population as well.

Is the Evidence-Based Guideline Recommendation for Goal Systolic Pressure Less than 150 mmHg for Age 60 and Older an Outlier Compared with Other Guidelines?

Recommendations from the 2013 European Society of Hypertension/European College of Cardiology for blood pressure goals in the treatment of hypertension in elderly patients include a few “may consider,” “if treatment is well tolerated” recommendations along with a top “solid evidence” recommendation. That single, solid-evidence recommendation targets a goal systolic blood pressure 140 mmHg to 150 mmHg “in the elderly.” In the SHEP and Syst-Eur trials, “elderly” enrollment began at age 60 years. In an e-mail from Giuseppe Mancia, MD, co-chair of the European Society of Hypertension/European College of Cardiology guideline, which was circulated to panel members appointed to JNC 8, elderly was defined as beginning at age 65 years (G Mancia, MD; personal communication, 2013 Dec). In a letter to the European Society of Hypertension/European College of Cardiology guideline authors in the December 2013 issue of the Journal of Hypertension, a writer expressed concern regarding the new blood pressure goal stating that it was “rational” but worried about the impact on clinical inertia. In their letter of reply, Mancia et al stated, “Clinical inertia has to be fought … by other means than by recommending inappropriately low [blood pressure] targets.”

Therefore, there is fair concordance in the age group targeted for a systolic blood pressure goal target less than 150 mmHg in hypertension guidelines submitted by hypertension experts on both sides of the Atlantic.

Why Not Make the Threshold for the less than 150 mmHg Goal Recommendation Age 80 Rather than Age 60?

Given the findings of the SHEP and Syst-Eur trials, there is greater certainty defining the age group 60 years and older, rather than age 80 years and older, for goal systolic pressure less than 150 mmHg. Only a single trial, the Hypertension in the Very Elderly Trial, has established goal systolic blood pressure in the age 80 years and older population less than 150 mmHg, a population described as the “very elderly.”

A single randomized clinical trial does not constitute sufficient evidence to merit a strong recommendation at this age level in the presence of multiple randomized clinical trials in support of the age 60 threshold.

Does the less than 150 mmHg Goal Recommendation Include Higher Risk Groups?

Epidemiologic data have defined higher cardiovascular risk strata in the general population, but randomized controlled clinical trials demonstrating statistically significant reversal of risk with lower blood pressure goals in higher-risk groups have been notably absent. SHEP and Syst-Eur enrolled patient populations that were representative of a broad spectrum of cardiovascular risk. Increasing age alone is a dominant cardiovascular disease risk factor. Additionally, the SHEP trial population included 14% African-American patients compared with 12.6% in the US population. Both SHEP and Syst-Eur also included patients with a history of myocardial infarction and stroke.

Sixty-one percent of patients in SHEP had a baseline electrocardiographic abnormality. Thirty percent of patients in Syst-Eur had a prior “cardiovascular complication.” The
Hypertension in the Very Elderly Trial included patients with myocardial infarction, stroke, and heart failure.26,36

Attention has been drawn to the Secondary Prevention of Small Subcortical Strokes trial comparing goal systolic pressure less than 150 mmHg to less than 130 mmHg in patients with a personal history of lacunar stroke.20 Although the primary endpoint of recurrent stroke was non-significant (p = 0.08), confidence in tervals (0.64 to 1.03) did not preclude benefit of the lower goal. Furthermore, the subgroup of intracerebral hemorrhage was significantly reduced (p = 0.03).6 However, “there was no heterogeneity in treatment effect on the primary outcome in any of the demographic or clinical subgroups,” the annual primary stroke rate in the control group was only 2.77% vs 7% predicted, and intracerebral hemorrhage comprised fewer than 10% of total strokes.20 The nonstatistically significant separation of total stroke in the more intensively treated group compared with the less intensively treated group in the Secondary Prevention of Small Subcortical Strokes trial was only 0.5% events per year. Therefore, the evidence favoring a goal systolic pressure other than lower than 150 mmHg in hypertensive individuals aged 60 years and older with a personal history of stroke is speculative.

ENDORSEMENTS OF THE EVIDENCE-BASED GUIDELINE

The American Academy of Family Physicians, representing more than 100,000 primary care physicians, has endorsed the Evidence-Based Guideline. That approval is important because nearly all hypertensive patients receive hypertension care from primary care physicians. Additionally, the National Quality Committee for Quality Assurance has adopted the new reform, and goal systolic blood pressure less than 150 mmHg in the absence of diabetes is a 2014 performance measure for the Healthcare Effectiveness Data and Information Set. The Veteran’s Administration and Department of Defense patient care systems have adopted goal systolic blood pressure less than 150 mmHg for general population hypertension patients age 60 and over.36

It will be difficult to reproduce the methodologic rigor and independent sponsorship of the Evidence-Based Guideline now that the NHLBI has unfortunately decided to remove itself from stewardship of future hypertension guidelines, and will not approve any guideline. The level of evidence-based medicine used to develop this hypertension guideline, on the basis of Institute of Medicine principles, is unsurpassed. An essential point is that blood pressure goals for patients with hypertension must be based on a high degree of evidence, and bias is best removed by reliance on the randomized controlled clinical trials to make this determination. A common rationale for recommending blood pressure goals lower than those that are evidence based is to combat clinical inertia. However, implementation is a separate issue, and high-performing systems of health care have addressed clinical inertia successfully.26-29,36

Disclosure Statement

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

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* Cochair, European Society of Hypertension/European College of Cardiology guideline committee, Milano, Italy.


Normal

If we possessed instruments delicate enough we might be able to determine what the normal arterial pressure of a given individual was, and to note any variation from it . . . . We are . . . driven to depend upon the most treacherous of all methods, the impressions conveyed to our minds through the sensory nerves of the fingers . . . . By constant practice and study, each physician makes for himself a standard of atrial pressure which he recognizes as normal.

— The Study of the Pulse, Sir James Mackenzie, MD, 1853-1925, Scottish cardiologist and pioneer in the study of cardiac arrhythmias
TOOL 1. Key Points

- Hypertension is an important and modifiable risk factor for atherosclerotic cardiovascular disease (ASCVD).
- For all adults, encourage a heart-healthy lifestyle to reduce the risk of ASCVD. This includes regular physical activity, weight reduction and maintenance, smoking cessation, and controlling blood pressure, cholesterol, and diabetes.
- For adults aged 60 and older without diabetes or chronic kidney disease (CKD), treat to a goal systolic blood pressure (SBP) <150 mmHg and goal diastolic blood pressure (DBP) <90 mmHg.
- For all adults aged under 60, and those aged 60 and older with diabetes or chronic kidney disease (CKD), treat to a goal SBP <140 mmHg and goal DBP <90 mmHg.

Introduction

This Clinician Guide is based on the 2014 KP National Hypertension Guideline. It was developed to assist primary care physicians and other health care professionals in the outpatient treatment of hypertension in nonpregnant adults aged 18 and older. The drug treatment algorithm excludes patients with known stage 4-5 chronic kidney disease, coronary artery disease, and heart failure. The KP National Hypertension Guideline has adopted the new recommendations from the 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8) with minor modifications. It is not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by practitioners.

Definitions

The KP National Hypertension Guideline Team uses the JNC 7 classification of hypertension, which is based on the mean of two or more properly measured seated BP readings on each of two or more office visits.

TOOL 2. Definition of Hypertension (JNC 7)

<table>
<thead>
<tr>
<th>The JNC 7 Report defines blood pressure (BP) as:</th>
<th>Systolic Blood Pressure (SBP) mmHg</th>
<th>Diastolic Blood Pressure (DBP) mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;120</td>
<td>&lt;80</td>
</tr>
<tr>
<td>Prehypertension</td>
<td>120 – 139</td>
<td>80 – 89</td>
</tr>
<tr>
<td>Stage I Hypertension</td>
<td>140 – 159</td>
<td>90 – 99</td>
</tr>
<tr>
<td>Stage II Hypertension</td>
<td>≥160</td>
<td>≥100</td>
</tr>
</tbody>
</table>

Screening for Hypertension

- Screen all adults aged 18 and older for hypertension.
- Screen adults with normal blood pressure (<120/<80) every two years.
- Screen adults with pre-hypertension or cardiovascular risk factors annually.

Treatment Initiation and BP Targets

In addition to lifestyle interventions, the following are recommendations for the general population without diabetes or chronic kidney disease (CKD):

TOOL 3. Treatment Initiation

Lifestyle modifications:
- Consume a diet that is moderately low-sodium, low-fat with a high intake of fruits and vegetables (DASH diet)
- Weight reduction - for patients with a BMI ≥25 kg/m²
- Limit alcohol consumption
- Exercise - at a moderate pace to achieve 150 min/week (i.e., 30 min/5 days/week)
- Stop smoking or use of tobacco products
- Assist patients to achieve medication and lifestyle adherence by means of a vigorous step-care approach to therapy and an organized system of regular medical follow-up and review
- Prescribe once-daily medication and combination therapy, whenever possible
- Address depression/anxiety issues in order to maximize patient adherence
- Use patient education in conjunction with other strategies, particularly in the context of team care utilizing nurses and pharmacists
- Educate patients about their goal blood pressure

Footnotes

§ Because elderly patients are at higher risk of side effects of treatment, including risk of postural hypotension, check standing blood pressures to guide treatment decisions.

* When weighing the risks and benefits of a lower BP goal for people aged 70 years or older with estimated GFR less than 60 ml/min/1.73 m², antihypertensive treatment should be individualized, taking into consideration factors such as frailty, comorbidities, albuminuria, and estimation of non-age-related eGFR decline (e.g., if eGFR + 1/2 age is <85).
GENERAL POPULATION

- Aged ≥60 years without diabetes or chronic kidney disease (CKD):
  - Initiate pharmacologic treatment to lower blood pressure (BP) if systolic blood pressure (SBP) ≥150 mmHg or diastolic blood pressure (DBP) ≥90 mmHg.
  - Treat to a goal SBP <150 mmHg and goal DBP <90 mmHg.
  - If pharmacologic treatment for high BP results in lower achieved SBP (e.g., <140 mmHg) and treatment is well-tolerated and without adverse effects on health or quality of life, treatment does not need to be adjusted.

- Aged <60 years and those aged > 60 with diabetes or chronic kidney disease (CKD):
  - Initiate pharmacologic treatment to lower BP when SBP ≥140 or DBP ≥90 mmHg.
  - Treat to a goal SBP <140 mmHg and goal DBP <90 mmHg.

CHRONIC KIDNEY DISEASE (CKD)

- When weighing the risks and benefits of a lower BP goal for people aged 70 years or older with estimated GFR ≤60 mL/min/1.73 m², antihypertensive treatment should be individualized, taking into consideration factors such as frailty, comorbidities, albuminuria, and estimation of non-age-related eGFR decline (e.g., if eGFR + ½ age is <85).

- If goal BP cannot be reached using only the drugs listed for first-line treatment due to a contraindication or need to use more than 3 drugs to reach goal BP, use antihypertensive drugs from other classes.

- Consider referral to a hypertension specialist for patients in whom goal BP cannot be attained using the above strategy or for the management of complicated patients for whom additional clinical consultation is needed.

RISK OF POSTURAL HYPOTENSION IN THE ELDERLY

- Because elderly patients are at higher risk of side effects of treatment, including risk of postural hypotension, check standing blood pressures to guide treatment decisions.

First-Line Drug Treatment for Hypertension*

- In the general nonblack population, including those with diabetes, initial antihypertensive treatment includes a thiazide-type diuretic, calcium channel blocker (CCB), angiotensin-converting enzyme inhibitor (ACEI), or angiotensin receptor blocker (ARB).
- In the general black population, including those with diabetes, initial antihypertensive treatment includes a thiazide-type diuretic or CCB.
- In the population aged ≥18 years with CKD, initial (or add-on) antihypertensive treatment includes an ACEI or ARB to improve kidney outcomes. This applies to all CKD patients with hypertension, regardless of race or diabetes status.
- Medication up-titrations are recommended at intervals of 2-4 weeks (for most patients) until control is achieved. Consider follow-up labs when up-titrating or adding lisinopril, lisinopril/HCTZ, chlorothalidone, HCTZ, or spironolactone.

Lifestyle Modifications

- Supplement treatment of uncomplicated hypertension with lifestyle modifications:
  - Consume a diet that is moderately low-sodium, low-fat with a high intake of fruits and vegetables (DASH diet).
  - Sodium restriction (≤2.4 gm sodium daily)
  - Weight reduction for patients with a BMI ≥25 kg/m²

INITIAL COMBINATION TREATMENT OF HYPERTENSION

- The main objective of hypertension treatment is to attain and maintain goal BP.
- If goal BP is not reached within 4 weeks of treatment, increase the dose of the initial drug or add a second drug from one of the classes listed for first-line treatment (thiazide-type diuretic, CCB, ACEI, or ARB).

- Continue to assess BP and adjust the treatment regimen until goal BP is reached. If goal BP cannot be reached with 2 drugs, add and titrate a third drug from the list provided. Do not use an ACEI and ARB together in the same patient.
- If goal BP cannot be reached using only the drugs listed for first-line treatment due to a contraindication or need to use more than 3 drugs to reach goal BP, use antihypertensive drugs from other classes.
- Consider referral to a hypertension specialist for patients in whom goal BP cannot be attained using the above strategy or for the management of complicated patients for whom additional clinical consultation is needed.

STEP-CARE THERAPY

Because most people with hypertension will need more than one drug to control their hypertension effectively:

- Initial single-pill combination therapy with lisinopril-hydrochlorothiazide is preferred.
- For three drugs: If blood pressure is not controlled on a thiazide-type diuretic + ACEI, then use a thiazide-type diuretic plus ACEI plus dihydropyridine calcium channel blocker.
- For four drugs: If blood pressure is not controlled on a thiazide-type diuretic plus ACEI plus dihydropyridine calcium channel blocker, then use thiazide-type diuretic plus ACEI plus dihydropyridine calcium channel blocker plus spironolactone or beta-blocker.

BMI Calculator

- Calculate BMI using the formula:
  - BMI = weight (kg) / height squared (m²)
  - BMI = weight (pounds) x 703 / height squared (inches²)

- Limit alcohol consumption: no more than one alcoholic drink (for women) or two alcoholic drinks (for men) daily
- Exercise: at a moderate pace to achieve 150 min/week (i.e., 30 min/5 days/week)
- Stop smoking or use of tobacco products
- Encourage adherence to medications and lifestyle modifications:
  - Assist patients to achieve medication and lifestyle adherence by means of a vigorous step-care approach to therapy and an organized system of regular medical follow-up and review.
  - Prescribe once-daily medication and combination therapy, whenever possible.
  - Address depression and anxiety issues in order to maximize patient adherence. See KP National Depression Guideline at: http://cl.kp.org/pkc/national/cmi/programs/depression/guideline/index.html
  - Use patient education in conjunction with other strategies, particularly in the context of team care utilizing nurses and pharmacists.
  - Educate patients about their goal blood pressure, because patients who are knowledgeable about their goal BP are more likely to achieve it.
• Consider medication non-adherence.
• Consider interfering agents (e.g., NSAIDs, excess alcohol).
• Consider white coat effect. Consider BP checks by medical assistant (e.g., two checks with 2 readings each, 1 week apart).
• Consider discontinuing lisinopril/HCTZ and changing to chlorthalidone 25 mg plus lisinopril 40 mg daily. Consider additional agents (hydralazine, terazosin, minoxidil).
• Consider stopping atenolol and adding diltiazem to amlodipine, keeping heart rate >55.
• Avoid using clonidine, verapamil, or diltiazem together with a beta-blocker. These heart rate-slowing drug combinations may cause symptomatic bradycardia over time.
• Consider secondary etiologies.
• Consider consultation with a hypertension specialist.

1. CKD is defined as albuminuria (>30 mg of albumin/g of creatinine) at any age and any level of GFR, or an estimated GFR or measured GFR <60 mL/min/1.73 m² in people aged <70 years. When weighing the risks and benefits of a lower BP goal for people aged 70 years or older with estimated GFR < 60 mL/min/1.73 m², antihypertensive treatment should be individualized, taking into consideration factors such as frailty, comorbidities, albuminuria, and estimation of non-age-related eGFR decline (e.g., if eGFR + ½ age is <85).
2. ACE-inhibitors and ARBs are contraindicated in pregnancy and not recommended in most women of childbearing age. calcium channel blockers and spironolactone (Pregnancy Risk Category C), and beta-blockers (Pregnancy Risk Category D) should only be used in pregnancy when clearly needed and the benefits outweigh the potential hazard to the fetus. In the general black population, including those with diabetes, initial antihypertensive treatment includes a thiazide-type diuretic or CCB.
3. For patients with CKD, age 18-75 and intolerant to ACEI with cough and lacking pregnancy potential, losartan should be started prior to adding thiazide.
Special Considerations

HYPERTENSION TREATMENT FOR WOMEN OF CHILDBEARING POTENTIAL

- Because half of all pregnancies are unplanned, unless there is a compelling indication, do not prescribe medications contraindicated in pregnancy, such as ACEIs/ARBs, to women of childbearing potential.
- For women of childbearing potential taking medications contraindicated in pregnancy, such as ACEIs/ARBs:
  - Discuss the potential risks to the fetus should they become pregnant.
  - Discuss practicing contraceptive measures with extremely low failure rates (sterilization, implant, or IUD).
- Advise women using ACEIs/ARBs to stop these medications and contact their OB/GYN provider immediately if they become pregnant.
- Advise women using ACEIs/ARBs for heart failure or cardiomyopathy and become pregnant to contact their obstetrician immediately. Their obstetrician, in consultation with cardiology, will substitute a suitable alternative to avoid decompensation.

LIPID THERAPY IN PATIENTS TAKING HYPERTENSION MEDICATIONS

- Evaluate patients with hypertension for dyslipidemia and initiate or continue statin treatment according to their total cardiovascular risk profile.
- Determine the need to initiate or continue lipid-lowering therapy based on ASCVD risk assessment using the AHA/ACC Pooled Cohort Equations: http://tools.cardiosource.org/ASCVD-Risk-Estimator

TOOL 7. Dosage Range for Selected Antihypertensive Medications*

<table>
<thead>
<tr>
<th>SELECTED ANTIHYPERTENSIVE MEDICATION</th>
<th>USUAL DOSAGE RANGE</th>
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</thead>
<tbody>
<tr>
<td>Thiazide-type Diuretics</td>
<td></td>
</tr>
<tr>
<td>Chlorthalidone (Hygroton)</td>
<td>12.5 – 25 mg daily</td>
</tr>
<tr>
<td>Hydrochlorothiazide (HCTZ) (Esidrix)</td>
<td>25 – 50 mg daily</td>
</tr>
<tr>
<td>Thiazide-type Diuretics Single Pill</td>
<td></td>
</tr>
<tr>
<td>HCTZ/lisinopril (Prinicity)</td>
<td>10/12.5 mg - 20/25 mg BID</td>
</tr>
<tr>
<td>Spironolactone/HCTZ (Aldactazide)</td>
<td>25/25 mg daily</td>
</tr>
<tr>
<td>ACE Inhibitors (ACEI)</td>
<td></td>
</tr>
<tr>
<td>Lisinopril (Zestril, Prinivil)</td>
<td>10 – 40 mg daily</td>
</tr>
<tr>
<td>Captopril (Capoten)</td>
<td>12.5 – 50 mg BID</td>
</tr>
<tr>
<td>Long-Acting Dihydropyridine Calcium</td>
<td></td>
</tr>
<tr>
<td>Channel Blockers (CCB)</td>
<td></td>
</tr>
<tr>
<td>Amlodipine (Norvasc)</td>
<td>2.5 – 10 mg daily</td>
</tr>
<tr>
<td>Felodipine ER (Plendil)</td>
<td>2.5 – 20 mg daily</td>
</tr>
<tr>
<td>Nifedipine ER (Procadia XL)</td>
<td>30 – 90 mg daily</td>
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<tr>
<td>Angiotensin II Receptor Blockers (ARB)</td>
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</tr>
<tr>
<td>Losartan (Cozaar)</td>
<td>25 – 100 mg daily</td>
</tr>
<tr>
<td>Aldosterone Receptor Blocker</td>
<td></td>
</tr>
<tr>
<td>Spironolactone (Aldactone)</td>
<td>12.5 – 25 mg daily</td>
</tr>
<tr>
<td>Beta-Blockers (BB)</td>
<td></td>
</tr>
<tr>
<td>Atenolol (Tenormin)</td>
<td>25 – 100 mg total, daily or BID</td>
</tr>
<tr>
<td>Bisoprolol (Zebeta)</td>
<td>5 – 10 mg daily</td>
</tr>
<tr>
<td>Carvedilol (Coreg)</td>
<td>3.125 – 37.5 mg BID</td>
</tr>
<tr>
<td>Metoprolol (Lopressor)</td>
<td>25 – 100 mg BID</td>
</tr>
<tr>
<td>Metoprolol ER (Toprol XL)</td>
<td>25 – 200 mg daily</td>
</tr>
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</table>

*Availability of medications may vary depending on regional formularies.

TOOL Overview

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DISCLAIMER

Kaiser Permanente Clinical Practice Guidelines, Clinician Guides, and Clinical Tools/Resources have been developed to assist clinicians by providing an analytical framework for the evaluation and treatment of selected common problems encountered in patients. They are not intended to establish a protocol for all patients with a particular condition. While the guidelines provide one approach to evaluating a problem, clinical conditions may vary significantly from individual to individual. Therefore, the clinician must exercise independent judgment and make decisions based upon the situation presented. While great care has been taken to assure the accuracy of the information presented, the reader is advised that KP cannot be responsible for continued currency of the information, for any errors or omissions in this guideline, or for any consequences arising from its use. These recommendations are not used to make utilization management determinations regarding the medical necessity of a member's care.
This photograph was taken at sunrise from a hot air balloon above the town of Gōreme in the Cappadocia region of Turkey. Cappadocia is known for its natural pillar-like rock formations, which ancient peoples carved into houses, churches, and monasteries.

Ms Bourgon is a Physician Assistant in Urgent Care at Kaiser Permanente Orange County in Santa Ana, CA.
Beer Potomania—An Unusual Cause of Hyponatremia

Dean A Kujubu, MD; Ardeshir Khosraviani, MD

ABSTRACT

The first case of severe hyponatremia, since referred to as beer potomania, was reported in 1972. Electrolyte abnormalities are common findings in patients with a history of heavy alcohol use. Excessive consumption of beer, in particular, which has a low solute content (sodium concentration, 1.8 mEq/L and potassium concentration, 7.2 mEq/L), to the exclusion of other solute intake may result in severe hyponatremia. We report a case of severe hyponatremia that occurred in a patient who, owing to his underlying colon cancer, was drinking beer and ingesting little other food. His hyponatremia improved with increased solute intake and, upon correction of his serum sodium, he had no subsequent neurologic sequelae.

INTRODUCTION

The first case of severe hyponatremia in a heavy beer drinker patient was reported in 1972 by Gwinup et al. This condition has since been referred to as beer potomania. Electrolyte abnormalities are common findings in patients with a history of heavy alcohol use. In the study by Liamis et al, among hospitalized patients with history of chronic alcohol consumption, 17.3% had hyponatremia. The excessive consumption of beer in particular, which has a low solute content (sodium concentration, 1.8 mEq/L; potassium concentration, 7.2 mEq/L), to the exclusion of other solute intake may result in severe hyponatremia. We report a case of severe hyponatremia that occurred in a patient who, owing to his underlying colon cancer, was drinking beer and ingesting little other food. His hyponatremia improved with increased solute intake and, upon correction of his serum sodium, he had no subsequent neurologic sequelae.

CASE PRESENTATION

A Hispanic man, age 84 years, with history of chronic alcohol abuse and recently diagnosed stage IV sigmoid adenocarcinoma presented to the Emergency Department with abdominal pain, because of worsening abdominal pain, he was drinking his habitual quantities of beer but otherwise eating minimally. On physical examination, his temperature was 37.1°C, blood pressure 142/81 mmHg, pulse rate 78 beats/min, without orthostatic changes, respiratory rate 18 breaths/min, and oxygen saturation 97% on room air. He was in no acute distress and did not appear intravascularly volume depleted. His lungs were clear bilaterally, and his heart sounds were normal without murmurs. He had tenderness in the epigastric area without rebound tenderness, with normal bowel sounds and no organomegaly. He was oriented and coherent in conversation. His neurologic exam and deep tendon reflexes were normal. He had no tremors.

The patient’s laboratory data showed white blood cells 15.4 × 1000/mcL, hemoglobin 12.7 g/dL, platelets 347 × 1000/mcL, international normalized ratio 1.1, glucose 160 mg/dL, sodium 116 mEq/L, potassium 4.1 mEq/L, chloride 85 mEq/L, CO2 19 mEq/L, blood urea nitrogen 6 mg/dL, creatinine 0.58 mg/dL, serum osmolality 250 mOsm/kg, uric acid 3 mg/dL, phosphorus 2.8 mg/dL, calcium 8.3 mg/dL, magnesium 1.1 mg/dL, alanine transaminase 20 U/L, aspartate transaminase 27 U/L, total bilirubin 0.8 mg/dL, thyroid stimulating hormone 2.19 mcIU/ml, albumin 2.8 g/dL, and cortisol 23.8 mcg/dL. His urinalysis showed specific gravity 1.005, pH 6, negative leukocyte esterase, negative nitrate, white blood cells 0-2, red blood cells 0-3, urine sodium 35 mEq/L, urine chloride 37 mEq/L, urine potassium 11 mEq/L, urine creatinine 26 mg/dL, and urine osmolality 182 mOsm/kg. A computed tomography scan of his abdomen and pelvis with intravenous contrast revealed a new abscess adjacent to the previously seen sigmoid carcinoma with local lymphadenopathy and hepatic metastatic disease.

The patient received 1 L of 0.9% sodium chloride intravenously in the Emergency Department and was started on antibiotics for the sigmoid abscess. The surgical consultant did not recommend surgical intervention. He received intravenous thiamine and magnesium supplementation for his history of heavy alcohol drinking and hypomagnesemia. He was encouraged to increase his oral intake with a normal diet as tolerated. He subsequently underwent a brisk diuresis of approximately 1.8 L during the first 8 hours. His intravenous fluid was promptly discontinued and the patient’s serum sodium was checked every 2 to 3 hours to monitor for overly rapid correction. His serum sodium increased by 8 mEq/L, to the exclusion of other solute intake may result in severe hyponatremia. We report a case of severe hyponatremia that occurred in a patient who, owing to his underlying colon cancer, was drinking beer and ingesting little other food. His hyponatremia improved with increased solute intake and, upon correction of his serum sodium, he had no subsequent neurologic sequelae.

CASE PRESENTATION

A Hispanic man, age 84 years, with history of chronic alcohol abuse and recently diagnosed stage IV sigmoid adenocarcinoma presented to the Emergency Department with nausea, weakness, decreased appetite, and abdominal pain for the past 3 to 4 days. The patient had been ingesting approximately 12 cans of beer daily in addition to his usual diet for the preceding 50 years, but during the week before his presentation, because of worsening abdominal pain, he was drinking his habitual quantities of beer but otherwise eating minimally. On physical examination, his temperature was 37.1°C, blood pressure 142/81 mmHg, pulse rate 78 beats/min, without orthostatic changes, respiratory rate 18 breaths/min, and oxygen saturation 97% on room air. He was in no acute distress and did not appear intravascularly volume depleted. His lungs were clear bilaterally, and his heart sounds were normal without murmurs. He had tenderness in the epigastric area without rebound tenderness, with normal bowel sounds and no organomegaly. He was oriented and coherent in conversation. His neurologic exam and deep tendon reflexes were normal. He had no tremors.

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In the study by Liamis et al., the intake of fluid in excess of this amount will not result in a dilutional hyponatremia. Moreover, the ingestion of large volumes of fluid in these patients results in the washout of the medullary urea concentration gradient, reducing the kidneys’ ability to produce maximally dilute urine. When additional solute is provided, a brisk diuresis ensues, resulting in rapidly increasing serum sodium concentrations, necessitating careful, frequent monitoring as well as the administration of electrolyte-free fluids or even antidiuretic hormone analogues should the serum sodium rise by more than 8 mEq/24 hours to 10 mEq/24 hours.

Precipitating the osmotic demyelination syndrome (ODS) in chronically hyponatremic patients by infusing saline load is a real danger. Case reports of ODS with rapid sodium correction have been published. In a literature review done by Sanghvi et al.,6 of 22 patients with beer potomania, 4 (18%) had ODS. Although infusion of hypertonic saline classically has been associated with development of ODS, Karp and Laureno7 suggest that the rapid correction of hyponatremia may occur even with infusion of normal saline or with fluid restriction alone, resulting in ODS. On the basis of the underlying pathophysiology of beer potomania, Sanghvi et al.6 provided clinical recommendations for the management of these patients (see Sidebar: Management Recommendations for Hyponatremia Caused by Beer Potomania).

Because of the potential for overly rapid correction of serum sodium resulting in irreversible neurologic consequences in these patients with beer potomania, intensive care and frequent, serial measurements of serum electrolytes are recommended.

Our patient’s history, clinical euvoletic state, and prompt diuresis in response to 1 L of intravenous normal saline administered in the Emergency Department led us to suspect that he indeed had beer potomania. Our patient was consuming 12 cans (12 ounces each) of beer daily, which is approximately 4.3 L. According to the published content of beer, our patient’s solute intake was approximately 30 mEq potassium, 7 mEq sodium, 150 g carbohydrate, and 20 g protein per day. If the metabolism of every 10 g of protein results in the generation of 50 mmoles of urea, we estimate that our patient’s daily solute intake was in the range of 200 mOsM/day to 250 mOsM/day. Our patient was older so it was unlikely that he would be able to maximally dilute his urine to 50 mOsm/kg, because with aging the kidneys’ ability to produce dilute urine declines.8 The capacity is further limited by the washout of his medullary concentration gradient owing to excessive fluid intake. If the maximally dilute urine

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### Common Causes of Hyponatremia

- **Hyponatremia with high osmolality**
  - Hyperglycemia, mannitol infusion, advanced renal failure

- **Hyponatremia with normal osmolality**
  - Hyperlipidemia, paraproteinemia

- **Hyponatremia with low osmolality**
  - Hypovolemic hyponatremia
    - Volume depletion with sodium loss in excess of water
  - Hypervolemic hyponatremia
    - Heart failure, cirrhosis, nephrotic syndrome
  - Euvolemic hyponatremia
    - Syndrome of inappropriate antidiuretic hormone, reset osmostat
    - Hypothyroidism, glucocorticoid deficiency, renal failure
    - Primary polydipsia, beer potomania, low solute intake
    - Medications, including thiazide diuretics

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### Management Recommendations for Hyponatremia Caused by Beer Potomania

- Nothing by mouth except medications for 24 hours
- No intravenous fluids unless symptomatic
- Prescribe intravenous fluids in finite amounts if needed
- Intensive care status
- Check serum sodium every 2 hours
- Goals
  - Serum sodium increase < 10 mEq/L in first 24 hours
  - Serum sodium increase < 18 mEq/L in first 48 hours
- Reduce serum sodium levels if necessary
- Give any intravenous medications in sugar solution (5% dextrose in water)
- If caloric intake is needed, use intravenous sugar solution (5% dextrose in water)
our patient could produce was 75 mOsm/kg rather than 50 mOsm/L, with daily solute intake of 200 mOsm/day to 250 mOsm/day he would need to drink only in excess of 2.7 L to 3.3 L of fluid per day before he would become hyponatremic, which was well below the range of his intake. After the initial correction of his hyponatremia during the first 48 hours, his serum sodium remained in the range of 130 mEq/L to 133 mEq/L for the rest of his hospitalization. His persistent hyponatremia was most probably because of an underlying syndrome of inappropriate antidiuretic hormone secretion from metastatic cancer or a reset osmostat owing to his poor nutritional state, malignant tumor, or alcoholism.\(^9,10\) His underlying tendency toward hyponatremia prevented his serum sodium from overcorrecting while his solute intake increased and his water intoxication resolved.

**Disclosure Statement**

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

**Acknowledgment**

*Mary Corrado, ELS, provided editorial assistance.*

**References**


**Hard Drinking**

The effects of hard drinking are flatulence, loss of appetite, morning sickness, wasting of the flesh and strength, tremblings, pains of the stomach, cough, jaundice, dropsy, forgetfulness and inattention, giddiness, diarrhea, broken sleep.

—William Heberden, MD, 1710-1801, English physician
Leukocytoclastic vasculitis (LCV), also termed hypersensitivity vasculitis, is a small-vessel vasculitis with a reported incidence rate of about 30 cases per million people per year and is thought to affect men and women in equal numbers. The skin is the organ most commonly involved in LCV. Typical presentation is a painful, burning rash predominantly in the lower extremities (Figure 1), with up to one-third of patients presenting with trunk and upper extremity involvement. The skin manifestations of LCV include palpable purpura, maculopapular rash, bullae, papules, plaques, nodules, ulcers, and livedo reticularis. Patients with LCV may also present with arthralgias or arthritis involving the knees or ankles.

The differential diagnosis for LCV includes drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome, amyloidosis, antiphospholipid syndrome, Behcet disease, Churg-Strauss syndrome, granulomatosis with polyangiitis, Henoch-Schonlein Purpura, urticarial vasculitis, immune thrombocytopenic purpura, and meningococcemia. Multiple etiologic factors including drugs, infections, foods, autoimmune diseases, collagen vascular diseases, and malignancies have been associated with LCV.

In the evaluation of patients with LCV, laboratory tests including a complete blood count, erythrocyte sedimentation rate, biochemistry profile with liver and renal function, and urinalysis are useful in excluding other vasculitides, determining the presence of systemic disease, and identifying an associated disorder, which can provide prognostic information. Patients with suspected LCV presenting to the Emergency Department may require parenteral analgesics for pain control, and those patients not requiring hospitalization should be referred to a dermatologist upon discharge. Diagnosis of LCV is confirmed on histologic examination of a biopsy from the affected area that demonstrates perivascular and vascular leukocytic infiltrates along with fibrinoid necrosis. Mild, skin-limited LCV does not require treatment apart from rest, elevation of the legs, ice packs to the affected area, and removal or treatment of the inciting cause. Presence of arthralgia or arthritis requires use of nonsteroidal antiinflammatory drugs, or a short course of oral steroids (eg, prednisone or methylprednisolone) at a dose of 1 mg/kg/day for 4 weeks followed by a steroid taper. Most patients respond to such treatment. A single-pulse dose of intravenous corticosteroids (eg, methylprednisolone, 15 mg/kg) may be required, followed by oral corticosteroids in more severe cases. Colchicine has also reportedly been useful in patients with skin and joint symptoms, though success in a small, randomized controlled trial was limited. Colchicine should be used with caution in persons with kidney disease and in pregnant women. Most patients with cutaneous leukocytoclastic vasculitis are treated in an outpatient setting. Inpatient care is needed in patients who have severe systemic vasculitic syndromes and severe organ dysfunction. In the absence of internal involvement, the majority of cases of LCV resolve within weeks to months, with approximately 10% of patients experiencing chronic or recurrent disease.
References

Medicine

The critical sense and sceptical attitude of the Hippocratic school laid the foundations of modern medicine on broad lines, and we owe to it: first, the emancipation of medicine from the shackles of priestcraft and of caste; secondly, the conception of medicine as an art based on accurate observation, and as a science, an integral part of the science of man and of nature; thirdly, the high moral ideals, expressed in that most “memorable of human documents” (Gomperz), the Hippocratic oath; and fourthly, the conception and realization of medicine as the profession of a cultivated gentleman.

— Sir William Osler, MD, 1st Baronet, 1849-1919, Canadian physician and one of four founding professors of Johns Hopkins Hospital
After QT prolongation, hyperacute T waves are the earliest-described electrocardiographic sign of acute ischemia, preceding ST-segment elevation.¹ Hyperacute T waves are broad-based and symmetrical, usually with increased amplitude and often associated with a depressed ST take off.¹ Hyperacute T waves are most evident in the anterior chest leads and are more apparent when a previous electrocardiogram is available for comparison.² Hyperacute T waves are noted early after the onset of coronary occlusion and transmural infarction and tend to be a short-lived structure that evolves rapidly into ST-segment elevation.³ The electrocardiographic differential diagnosis of the hyperacute T wave includes both transmural acute myocardial infarction and hyperkalemia as well as early repolarization, left ventricular hypertrophy, and acute myopericarditis.⁴ The principle entity to exclude is hyperkalemia—this T-wave morphology may be confused with the hyperacute T wave of early transmural myocardial infarction. In contrast to hyperacute T waves associated with myocardial ischemia or infarction, hyperkalemic T waves tend to be narrow and peaked with a prominent or sharp apex.⁵ For patients presenting with hyperacute T waves in the setting of suspected myocardial ischemia or infarction, treatment includes symptomatic control with nitroglycerin or morphine, oral antiplatelet agents (aspirin), consideration of anticoagulation with unfractionated heparin, and obtaining frequent serial 12-lead electrocardiograms (every 5 to 10 minutes). Prompt consultation with a cardiologist is indicated in these cases.

References
So Much Sky
Colored pencils on paper
3" x 6"

Sharon Lee Hostler, MD

This image was sketched outside the Mabel Dodge Luhan House at the 2014 Taos Writing Workshop. The artist, who grew up in the Green Mountains of Vermont and practices medicine near the Blue Ridge Mountains of Virginia, saw the brilliant blue sky over Taos as dwarfing all, even the towering mountains of New Mexico.

Dr Hostler is the McLemore Birdsong Professor of Pediatrics at the University of Virginia School of Medicine and Vice Provost for Faculty Development at the University of Virginia in Charlottesville.
INTRODUCTION
Sugars are simple carbohydrates found naturally in fruit and milk. Although we do get some of the sugar we consume from these foods, much of our intake comes from sugars that are added to processed foods and beverages. Cane sugar, high-fructose corn syrup, agave, honey, evaporated cane juice, and other forms of sugar are added to products such as sodas, cakes, cookies, and candies. They are also added to many processed foods such as breakfast cereals, pasta sauce, yogurt, soymilk, barbeque sauce, and bottled teas. In fact, using their new online database, the Environmental Working Group has found that almost 60% of the 80,000 products evaluated contained added sugar.1,2 For examples of sugar content in commonly consumed foods, see Sidebar: Examples of the Amounts of Sugar Found in Processed and Restaurant Foods and Drinks.

Most people have a natural propensity for sweet foods and beverages. Data from the US Department of Agriculture reveals that in 2013, Americans consumed 22.3 teaspoons of added caloric sweeteners a day, which is significantly more than the American Heart Association’s recommendation. Artificial and alternative sweeteners have also been added to a plethora of foods. These sweeteners range from about 180 times sweeter to as much as 13,000 times sweeter than sugar. Consumption of both sugar and artificial sweeteners may be changing our palates or taste preferences over time, increasing our desire for sweet foods. Unfortunately, the data on this are lacking. In the summer of 2014, a group of 20 people from Kaiser Permanente facilities throughout California agreed to cut out all added sugars and artificial sweeteners for 2 weeks and then complete a survey to determine whether their taste preferences had changed. After the 2-week challenge, 95% of participants (18 out of 19 respondents) found that sweet foods and drinks tasted sweeter or too sweet, 75% (15 out of 20 respondents) found that other foods tasted sweeter, and 95% (19 out of 20 respondents) said moving forward they would use less or even no sugar. Additionally, 86.6% of participants (13 out of 15 respondents) stopped craving sugar after 6 days. Although this was a small survey, the results suggest that using a 2-week sugar challenge can help to reset taste preferences and make consuming less or no sugar easier. Physicians should consider recommending a sugar and artificial sweetener challenge to all their patients, especially those with obesity, diabetes, or cardiovascular disease.
New Recommendations for Sugar

In 2009, for the first time ever, the American Heart Association came out with recommendations for sugar consumption. For women, they recommend consuming no more than 6 teaspoons or 100 calories of added sugar each day. This is equivalent to about 24 g of sugar. For men, they recommend no more than 9 teaspoons or 150 calories of added sugar a day. This is equal to about 35 g of sugar. It is interesting to note that one 12-ounce can of cola has about 10 teaspoons of sugar, putting the drinker, whether a man or a woman, over the limit recommended by the American Heart Association with just one item.

The World Health Organization’s new draft guidelines say sugar consumption should be less than 10% of total energy intake per day, but a reduction to below 5% would have added benefits. Five percent of 2000 calories would be 100 calories (around 6 teaspoons or 24 g) of sugar per day. Recommendations for sugar consumption associated with the use of sugars and artificial sweeteners, their consumption may be changing our palates or taste preferences over time, increasing our desire for sweet foods. Unfortunately, the data on this are lacking.

I asked Marion Nestle, PhD, for her thoughts on the impact of sugar and artificial sweeteners on the palate. She told me, “Sugar is sweet and everyone loves it. Artificial sweeteners give the illusion of sweetness and not everyone loves them. People get used to a level of sweetness that tastes good to them. The more sugar we eat, the more it takes to reach that taste point. To people deprived of sugar (do any still exist?), even a little tastes delicious. At this point, just about everyone would be healthier eating less sugar and enjoying it more” (Marion Nestle, PhD, personal communication; 2014 Oct 24).3

An Altered Palate

I have seen for myself the impact that sugar can have on taste preferences. As a child I loved sugar. I was the one who ate 7 cupcakes at a birthday party and would eat all my Easter candy in a day. For a number of reasons, I decided to cut out sugar when I was in my late 20s. Two things happened pretty quickly: 1) I found out I did not crave sugar once I cut it out, and 2) other foods tasted sweeter to me, foods that had never tasted sweet before, such as Wheat Thins. I realized that my palate appeared to be changing in response to the lack of sugar in my diet, just as the palate can change when salt is limited. This idea was supported by what happened one day when I made a smoothie for several friends using only strawberries and bananas. The smoothie tasted great to me and was really sweet. However, to my surprise, every one of my friends said it was too sour and they wanted to add sugar.

I also noticed that people who consumed a lot of artificial sweeteners seemed to have altered a palate. A case in point is a friend who uses artificial sweeteners every day. One year at Thanksgiving she added several packets of an artificial sweetener to a dessert because it was not sweet enough for her. Although it was more than sweet enough for everyone else, her copious use of artificial sweeteners seemed to have altered her palate and made super-sweet foods normal for her.

Examples of the Amounts of Sugar Found in Processed and Restaurant Foods and Drinks

| 1 tsp sugar | 4 g |
| Kiwi Strawberry Vitamin Water, 20 oz bottle | 32 g |
| Yoplait Original Mountain Blueberry Yogurt, 6 oz | 26 g |
| Oscar Mayer Lunchables Ham and Cheddar Cracker Stackers (with fruit punch) | 31 g |
| Silk Very Vanilla Soy Milk, 1 cup | 15 g |
| Sweet Baby Rays Barbecue Sauce, 2 tbsp | 16 g |
| Kellogg’s Smart Start Strong Heart Antioxidants Cereal, 1 cup | 14 g |
| Starbucks Blueberry Scone | 20 g |
| Subway 6” BBQ Oven Roasted Chicken Melt | 17 g |
| Panda Express Orange Chicken (2 Entrée meal) with chow mein | 47 g |
| California Pizza Kitchen Thai Crunch Salad (full) | 48 g |

THE SUGAR CHALLENGE

Because there is a lack of data on the impact of sugar and artificial and alternative sweeteners on the palate, I decided to try a 2-week sugar and artificial sweetener challenge and then look at its impact on taste. In the summer of 2014, a group of 20 people from Kaiser Permanente facilities throughout California agreed to try the challenge (see Sidebar: Sugar and Artificial Sweetener Challenge Instructions).

After the two-week challenge, I asked the participants to fill out a survey to determine whether their palate had changed (see Sidebar: Survey Results of the Two-Week Challenge).

Some comments about the challenge were:
- “I think this challenge really helped me to reset my palate. Before the challenge I did not eat a lot of sugar, but would put stevia in my tea, oatmeal, and yogurt daily. Now I enjoy the flavor of it without the added sweetener.”
- “I enjoyed the challenge; it opened my eyes to how many processed products add sugar. Thank you for helping me move on to a healthier lifestyle.”
- “I rediscovered that I like my morning espresso unsweetened—used to drink it that way before getting hooked on sweetener. Will not go back. Also found that adding raisins to oatmeal eliminated need to use a couple packets of Splenda.”
- “I realized I was emotionally dependent on these evening snacks and they were not contributing to my goals around weight loss/maintenance. It was a good exercise.”

Many of us eat and drink too much sugar and would benefit from consuming less of it. Although this was a small survey, the results suggest that we can make consuming less or no sugar easier by cutting out sugar and artificial sweeteners for two weeks. We can also let our patients know that cravings seem to go away for most people after just 6 days and that food and desserts will taste sweeter for most people after the challenge. Finding processed foods with less added sugar, eating more real foods instead of processed foods, choosing fruit for dessert, and having some tasty dessert recipes that do not add sugar, can also help patients move forward with a low- or no-sugar diet. Two of the best recipes from a Kaiser Permanente healthy dessert contest (banana cream pie and watermelon and berry skewers) follow this article and are worth trying.

CONCLUSION

Eating fewer processed foods and choosing more real, whole, and plant-based foods make it easy to consume less sugar. These changes will also improve the overall quality of our diet, which is important for optimal health.

In a very real sense, we are being set up to desire and consume more and more sugar. Using a two-week challenge to reset our palates can help our patients—and us—more easily transition to a healthier diet with less sugar and alternative and artificial sweeteners. Physicians should consider recommending a sugar

### Sugar and Artificial Sweetener Challenge Instructions

For two weeks, cut out all added sugars and artificial sweeteners.

1. Do not add any form of sugar (see list below) or any alternative sweeteners to foods or drinks! Avoid artificial and alternative sweeteners including Sweet ‘N Low, Equal, Splenda, monk fruit, neotame, stevia, and xylitol, etc. No added sweeteners!
2. Avoid all sweetened sodas, bottled teas, sports drinks, energy drinks, fruit drinks and juice (even 100% juice), specialty coffee drinks, and any other liquid with added sweeteners.
3. Cut out any foods that have a lot of added sugar or any artificial sweeteners such as cookies, cake, candy, yogurt, soy or almond milk, breakfast cereals, energy bars, or other foods. Read labels! Aim for food with 5 g or less of added sugar. Look at the ingredient lists of foods you eat for other names for sugar such as the following:

<table>
<thead>
<tr>
<th>Added Sugar</th>
<th>Alternative Sweeteners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>High-fructose corn syrup</td>
</tr>
<tr>
<td>Corn syrup</td>
<td>Maple syrup</td>
</tr>
<tr>
<td>Agave</td>
<td>Evaporated cane juice</td>
</tr>
<tr>
<td>Dextrose</td>
<td>Coconut palm sugar</td>
</tr>
<tr>
<td>Grape sugar</td>
<td>Turbinado sugar</td>
</tr>
<tr>
<td>Brown sugar</td>
<td>Powdered sugar</td>
</tr>
<tr>
<td>Date sugar</td>
<td>Brown rice syrup</td>
</tr>
</tbody>
</table>

Note: Plain unsweetened milk and yogurt and fruit contain natural sugar, which is fine because it is not added sugar. Limit dried fruits to 2 servings per day and fresh fruits to 4 to 5 servings per day.

### Survey Results of the Two-Week Challenge

Participants craved sugar after cutting it out, but cravings went away for
- 53.3% of participants after 3 days (8 out of 15 people responding)
- 86.6% of participants after 6 days (13 out of 15 people responding)

After the 2-week challenge:
- 95% of participants found that sweet foods and drinks tasted sweeter or too sweet (18 out of 19 people responding)
- 75% found that other foods, such as baby carrots, apples, or crackers, tasted sweeter (15 out of 20 people responding)
- 95% said moving forward, they would use less or even no sugar (19 out of 20 people responding)
- 35% said they lost weight (7 out of 20 people responding)

Eating out and social events were identified as problematic, so creating a plan of action to deal with these situations, including bringing a healthy dessert such as fresh fruit, was recommended.

Because many of the foods participants regularly ate contained more sugar than they anticipated, taking a look at food items such as breakfast cereals, alternative milk drinks, sauces, and drinks and finding lower- or no-sugar options before the challenge was also recommended.
Banana Cream Pie (adapted with permission from Living on Live Food by Alissa Cohen)
Submitted by Ed Hernandez, Kaiser Permanente, Senior PC/IAN Analyst, Regional Offices, Pasadena, CA

Ingredients

Crust
1 cup raw almonds
1 cup dates (soaked)
1 cup shredded coconut

Filling
6 small ripe bananas
1 cup shredded coconut
½ peeled apple
1 teaspoon pure vanilla
½ teaspoon carob powder (you can also use unsweetened cocoa)

Instructions
1. Mix crust ingredients in a food processor and form into a pie plate.
2. Mash 2 bananas and place in a blender with the apple, 3/4 cup of coconut, and vanilla. Blend until smooth.
3. Remove and place in bowl, slice the remaining bananas, and mix into the filling.
4. Pour into pie crust and sprinkle with carob and the remaining coconut.

Watermelon and Berry Skewers
Submitted by Darin Kliem, Kaiser Permanente, Senior Consultant, QRM/Quality Operations, Regional Offices, Pasadena, CA

Ingredients

Watermelon cut into 1-inch cubes

Instructions
1. Skewer berries from smaller to larger, then skewer 1 mint leaf, and lastly the watermelon.
2. Drizzle a plate with the balsamic vinegar and place the skewered fruit over the balsamic vinegar.
COMMENTARY

Special Report

New Kid on the Block Turns Ten! The Brief, Remarkable History of the National Physicians Alliance

Jean Silver-Isenstadt, MD, PhD

ABSTRACT

Founded in 2005 by General Surgeon Lydia J Vaias, MD, MPH, the National Physicians Alliance is a 501c3 public charity with a mission to create research and education programs that promote health and foster active engagement of physicians with their communities to achieve high-quality, affordable health care for all. The National Physicians Alliance offers a professional home to physicians across medical specialties who share a commitment to professional integrity and health justice. As the organization celebrates its tenth birthday, the history and scope of this mission-aligned group are described.

INTRODUCTION

It is not a coincidence that the National Physicians Alliance (NPA)—a nonpartisan, multispecialty organization of physicians and others committed to social justice and health care reform—was founded by a surgeon from Kaiser Permanente (KP). To hear Lydia Vaias, MD, MPH talk about KP is to hear the linkages laid bare:

“What’s great about [KP] is its alignment. [KP] allows me to practice in a model where I can focus on the values of medicine instead of on money. I get paid to do the right thing for the patient. Years ago, the [KP] system was mocked. People were once embarrassed to say they worked there. It wasn’t until very recently that people have come to see [KP] as a leading light, delivering health care around a set of values.” (Lydia Vaias, MD, MPH; personal communication; 2015 Jan 29.)

Ten years ago, Dr Vaias set out to organize physicians anew. “There are few physicians in this country who practice in settings that align the payors’, providers’, and hospitals’ incentives to keep patients at the center of care. I feel so lucky to be here at this time in history.” (Lydia Vaias, MD, MPH; personal communication; 2015 Jan 29.)

1993: THE CALL BEYOND CALL

Dr Vaias wasn’t looking for me when she called my house back in 2005. She was looking for her old medical school buddy, my husband Ari Silver-Isenstadt, MD, MSEd, with whom she and a few others had organized 6 separate chapters of the American Medical Student Association (AMSA) about a decade earlier. In October 1993, student chapters from Hahnemann, Jefferson, the Medical College of Pennsylvania, the Philadelphia College of Osteopathic Medicine, the University of Pennsylvania, and Temple University joined forces as “Philadelphia AMSA” and delivered an unprecedented regional conference that laid the groundwork for generational change in medicine. They called the conference “Physician Activism: The Call Beyond Call.”

Hoangmai Pham, then a 3rd-year student at Temple University and now Director of the Seamless Care Models Group at the Center for Medicare and Medicaid Innovation Center, served as Chair of the Programming Committee. The conference was a smash hit, drawing more than 600 registrants—and it did so without any pharmaceutical industry sponsorship or staff support. AMSA’s national president, David Evans, MD, set the event’s tone in the printed program’s welcome letter: “It is activism that rounds out our education …”

Philadelphia AMSA was the twinkle in the eye—the spark. Twelve years later, Dr Vaias was on the phone, bringing the band back together to launch the NPA.

I had helped with the conference too, although in 1993 I was not yet a medical student. At the University of Pennsylvania, I was a student at the Perelman School of Medicine, but I had also been a student at the University of Pennsylvania School of Nursing, and I had a background in public health. I was interested in social justice and health care reform, and I was eager to be part of something new.

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Pennsylvania, I was a doctoral student, studying the history and sociology of medicine, specifically 19th century health reform movements. I explored social change efforts led by utopian radicals and feminists—progressive troublemakers who challenged the use of corsets and bloodletting, who touted exercise and bathing, who fought for women’s right to education and self-ownership.

Across campus, my husband and his medical school classmates got to know their cadavers, took countless exams, and learned their way around the wards. Their professors recycled the old adage: Fifty percent of what we will teach you is wrong; we just don’t know which 50%. The lecturers were playfully referring to the content of their slide sets—acknowledging dynamic scientific change—but they may as well have been referring to the curricular priorities themselves, the physical plant and workflow of the hospital, the food in the cafeteria, the nature of clinical communication, the financing of health care, the workforce … or even the 50% estimate.

Dr Vaias went on to become a general surgeon with a master’s degree in public health. She moved to Long Beach, CA, joined the KP system and, in 2005, was just beginning a three-year term on the Board of the Southern California Permanente Medical Group. My husband became a Baltimore-based general pediatrician and I went to medical school myself. It was organized medicine’s muted response to the Terri Schiavo case (a nationally debated legal struggle involving prolonged life support)\(^1\) that led Dr Vaias to start rounding up past AMSA leaders. She was dismayed by the political grandstanding but even more so by the house of medicine, which seemed less engaged in repairing its own broken systems than in deepening ties with industry. Like many others, she saw the medical profession drifting from its core values. Patients were not at the heart of health care. I remember Ari and I were chopping stir-fry ingredients that spring evening ten years ago when Dr Vaias called with a characteristically modest proposal: “Let’s fix this.”

**Make No Small Plans**

The NPA’s first official organizing effort took place at AMSA’s 55th convention in Washington, DC, where many past student leaders had gathered to honor Paul R Wright, the organization’s beloved Executive Director who was retiring after 30 years in the position. In a dedicated side room reserved for the discussion, approximately thirty former leaders of the organization agreed that the time had come to build a new professional home for physicians across specialties—an organization that would not function as a trade association, but rather as a community whose first concern was patients. It was something AMSA members had imagined building since their split from the American Medical Association (AMA) 38 years earlier. (AMSA had begun in 1950 as a student branch of the AMA but split off in 1967 after its parent organization had opposed the creation of Medicare and showed insufficient support for the civil rights and community health movements.)\(^2\)

The group pledged $20,000 in immediate support of NPA’s launch and scheduled a follow-up meeting at AMSA’s headquarters in Reston, VA. During the next year, an executive planning committee met for 2-hour phone calls every Friday afternoon. It was a monumental gift of volunteer energy from practicing physicians, all inspired by Dr Vaias’s mantra (with a hat-tip to Joan Baez): “The antidote to despair is action.”

It helped that the group included longtime friends with a shared organizational history. It also helped that they had taken different professional paths. Stephen S Cha, MD, MHS—currently the Chief Medical Officer for the Center on Medicaid and CHIP Services—had recently completed his internal medicine residency at Montefiore in New York and was a Robert Wood Johnson Foundation Clinical Scholar at Yale. David V Evans, MD—now an attending physician at the University of Washington—had for the previous decade practiced family medicine in the small rural town of Madras, OR. David Grande, MD, MPA—now an attending physician of internal medicine at the University of Pennsylvania—was a Robert Wood Johnson Foundation Health and Society Scholar at the University of Pennsylvania; his policy research focused on the health of vulnerable populations. Kavita Patel, MD, MS—now Fellow and Managing Director at the Brookings Institution after two years at the White House and time on Capitol Hill—was working on health policy at the RAND Corporation. Alexa Oster, MD—now a Medical Epidemiologist in the Centers for Disease Control and Prevention’s Division...
of HIV/AIDS Prevention—was in the midst of her residency in primary care internal medicine at the University of California, San Francisco/San Francisco General Hospital. (I remember her often biking between clinical sites during our phone calls.) Stephen R Smith, MD, MPH—now retired from academia and practicing family medicine part-time at a community health center in New London, CT, was an Associate Dean at the Warren Alpert Medical School of Brown University when he joined the NPA's founding executive committee.

After my own years in the medical archives studying the audacious work of 19th-century health reformers, I found myself unexpectedly surrounded by health reformers focused on the 21st century. But more than that, I found myself surrounded by something crystalline and rare: a group of brilliant people who were full of initiative but not full of ego—collaborative, funny, optimistic physicians who were singularly focused on making health care better for their patients. And they worked like demons.

Unbranded Doctors

Developing an organizational structure, finalizing a mission and bylaws, building a Web site, formally incorporating, and myriad other details involved lengthy discussion. But one decision was easy: the NPA would not accept funding from pharmaceutical or medical device companies. Out of the gate, this made NPA unique among medical organizations. Everywhere, financial conflict of interest was compromising medical research, education, and practice.3 It was not only eroding patients’ trust in their physicians, but also eroding trust within the profession. Commitment to conflict-free leadership was an undisputed core value of the NPA; because it so clearly distinguished the organization from others, the “Unbranded Doctor Campaign” became our introductory calling card.

Through this advocacy campaign—an ally of the “No Free Lunch” movement and AMSA’s “PharmFree” efforts—NPA voiced loud concern over the scope and influence of pharmaceutical marketing tactics; supported full transparency regarding industry payments to physicians and medical institutions; challenged the AMA’s lucrative sale of personal Physician Masterfile records for industry data mining and the legitimacy of data mining itself; and called on physicians to take the reins and simply stop accepting industry largesse. These efforts all sought to ensure that medical education, research, and clinical decisions are guided by scientific evidence and not by marketing hype.

A different issue would have been an easier lift and surely a more enticing recruitment strategy—one that didn’t ask physicians to give up the comforts of free continuing medical education dinners at posh restaurants; coffee and donuts delivered right to the office by cheerful, healthy drug reps; generous speaking fees, etc—but the profession had grown complacent about these entanglements and therefore complicit in the marketing enterprise. This contamination of purpose had to be addressed. Just as the AMA was launching a $60 million new ad campaign depicting physicians as “everyday heroes,” the NPA’s Unbranded Doctor Campaign was pointing out the dirt under the rugs and the mold in the bathroom tiles. We were handing out buckets and mops by way of recruitment: join the NPA—help us clean our house. We knew the only way to restore trust in medicine would be to earn it.

Transparency about industry payments to physicians and hospitals is now mandated by the Sunshine Act section of the Affordable Care Act (ACA)—a component of the law that the NPA fought hard to include and continues to defend. This year, NPA President William B Jordan, MD, MPH, was featured on CSPAN commenting on how far we’ve come but also on what still goes unreported, for example free medication samples that remain at the heart of marketing but are unmentioned in the ACA’s Sunshine Act provisions. These provisions require manufacturers of drugs, medical devices, and biologics that participate in US federal health care programs to report certain payments and items of value given to physicians and teaching hospitals for inclusion in a content management system database known as Open Payments.7 The Open Payments Web site enables anyone to search physicians and institutions by name to learn the details of their financial relationships with industry. Thanks in many ways to the work of the NPA, it has become less comfortable for physicians to accept these payments, let alone make light of them. For the first time, researchers, journalists, policymakers, physicians, and patients are gaining access to alarming data about the magnitude and direction of industry cash flow in the system. It’s a necessary first step in opening up space for substantive reform.

Trust in a Trustworthy System

This “pharma work” often set the NPA apart from other physician organizations, testifying on panels and working with consumer advocacy groups quite literally opposite our professional siblings who were defending the status quo. It was then that we could most clearly see the void we were filling: patients needed physician allies.

From the outset, NPA’s founders were determined to protect the organization from ever becoming a doctors’ lounge. The board of directors was structured to include nonphysicians to ensure that no discussions of patients’ best interests would take place without patients. Very naturally, the NPA found itself working in regular coalition with groups ranging from Community Catalyst and the National Center for Health Research to the National Committee to Preserve Social Security and Medicare and the Law Center to Prevent Gun Violence. The NPA board was proud to be the first physician organization to join the Health Care for America Now! coalition in support of the ACA’s passage—a coordinated effort of more than 1000 national and state-based groups dedicated to achieving federal health reform and defending Medicare and Medicaid.
In 2014, the NPA was honored to have Consumer Reports host our 9th annual conference at their National Testing and Research Center in Yonkers, NY.

Warm relationships with such allies encouraged NPA members—who valued not only the organization’s bridge-building instincts, but also the NPA’s willingness to step outside the profession’s usual comfort zones—to struggle publicly with medicine’s problems and to champion civic engagement.

I will never forget Gene Copello, MSW, MDiv, PhD, late co-chair of NPA’s Secure Health Care for All campaign, softly assuring other members of the NPA’s board back in 2008: “The NPA will succeed because it has to succeed. Patients need NPA to succeed.” The room fell silent with the weight of this charge. Dr Copello, whose doctorate had focused on medical ethics and public policy, was then serving as the Executive Director of the AIDS Institute.

He died that year, unable to see the passage of the ACA; the NPA’s Copello Health Advocacy Fellowship was named in his memory.

It had become clear that if we wanted health reporters to interview physicians who voiced a different perspective from that of traditional guilds, we would have to provide advocacy, media, and communications training to physicians who viewed policy through the lens of its potential impact on patients. Becky Martin, NPA’s Director of Project Management and a seasoned community organizer, has for years connected NPA Fellows and other members to local opportunity and opened up relationships that fuel lasting change.

Advocacy, let alone “activism,” are terms rarely associated with white-coat professionalism. Yet our democratic society grants enormous social capital to the medical degree, and physicians are coming to understand advocacy skills as part of their responsibility to patients. The white coat itself may have more benefit for patients when worn at a public podium than when worn in the hospital.

The NPA’s immediate past president, James Scott, MD, discovered the organization at a 2009 health reform rally in Washington, DC, where NPA leaders David Evans, MD, and Valerie Arkoosh, MD, MPH, spoke boldly in support of federal health reform. Dr Scott had flown from Oregon to take part in the growing movement for quality, affordable health care for all. As he described it in a recent e-mail to me, “At a reception after the rally, I found real soul-mates—progressive doctors passionate about improving the system for everyone. I thought, after 40 years in medicine, I’ve found my people!” (James Scott, MD; personal communication; 2015 Jan 20)

For many physicians, the opportunity to meet with elected officials and to speak to public audiences on behalf of a like-minded cohort became a reason to deepen involvement with the organization. For others, it was the opportunity to focus on individual practice reform. Dr Smith was only half-kidding when he first proposed the idea that NPA generate “Top 5” lists—à la David Letterman—to highlight “things doctors keep doing even though they know better.” The board of directors was having lunch and brainstorming.

A longtime leader of NPA’s work to reduce professional conflicts of interest, Dr Smith wanted to see physicians take more responsibility for their role as stewards of limited clinical resources. This would require acknowledging overtreatment and waste—calling out bad habits. What if NPA developed a “Top 5” list of evidence-based, quality-improving, resource-sparing activities that could be incorporated into the routine practice of primary care physicians in family medicine, internal medicine, and pediatrics? Under Dr Smith’s leadership, the idea quickly took shape as the NPA’s Good Stewardship Project, funded by the American Board of Internal Medicine Foundation. A mouse that roared, this modest initiative has since blossomed under the American Board of Internal Medicine Foundation’s direction into the celebrated Choosing Wisely campaign. Conceiving and piloting this culture-changing project has been one of the NPA’s most significant contributions. More than 60 specialty societies have since developed lists of “tests or procedures commonly used in their field, whose necessity should be questioned and discussed.” Similar efforts are now happening abroad.

NPA’s Good Stewardship work challenged physicians to acknowledge and address prescribers’ responsibility for systemic waste and consequent patient harm. Organized medicine has begun to embrace stewardship as a core component of professionalism, and consumers have welcomed this awakening.

It was no trivial thing to shift the national conversation in this direction. The challenge now is to see these values broadly translated to practice. New and broad-ranging calls for price transparency and fairness are providing wind at the back of this push for high-value care. In short, as a nonprofit organization without a great deal of money, NPA has made a great deal of difference. With little more than stamina, purpose, and a value set that aligns the incentives of physicians with those of patients, the NPA has been able to make important contributions in a short period of time.

LOOKING AHEAD

At ten years old, the NPA continues to attract physicians who understand that the future of US health care will be shaped by those who show up to shape it—and that working with patients, we now have a historic opportunity to put health at the heart of medicine. There are gains to be defended and new battles to engage.

Relatively recent areas of NPA focus also continue to build momentum, including the creation of NPA national taskforces on gun violence prevention and on the FDA’s drug and medical device approval processes—two areas brought to the fore during Cheryl Bettigole, MD, MPH’s, tenure as NPA President. Although these issues may...
at first seem to have little to do with one another or with past NPA efforts to expand access to high-quality health care, they are united by the influence of corporate lobbying.

The National Rifle Association’s lobbyists have chinked off research funding for gun violence prevention and have successfully backed state laws that forbid physicians from asking standard screening questions about gun ownership and storage. Fracking companies have successfully backed the passage of state laws that require physicians to sign confidentiality agreements before learning what chemicals a sick patient may have been exposed to. Drug companies continue to press the FDA to approve applications on the basis of surrogate endpoint data and mathematical modeling rather than requiring full clinical trials. And far too many medical devices continue to reach the market without any clinical trials at all. These are areas that cry out for more attention from organized medicine to ensure patient safety.

For our federal watchdog agencies, our clinical guidelines, our pharmacopeia, our educational resources, our state laws, and our individual clinical relationships to be grounded in trust and science, physicians and patients will have to claim more power in these debates. It is fair to say that with my background in medicine and medical history, I never expected to become the Executive Director of a nonprofit organization. But I have always been drawn to the multispecialty band of visionaries. I had the good fortune to help unite this organization with the National Physicians Alliance.

We have a vision for the next ten years: sparking a transformation of the medical profession that returns us to the core value of serving patients. We have seen this vision made real at places like KP, but we will continue to press on until it is the default setting for health care in our country. Join us in October in Washington, DC, as we launch our second decade at our annual meeting, themed Truth to Power: Alliance for the Public Good.

You may learn more about the NPA’s past and future work at www.npalliance.org.

References

The True Physician

The true physician cannot remain outside the manifold of the events he observes.

— Alan Gregg, MD, 1890-1957, Associate Director of the Medical Education Division, Director of Medical Sciences Division and Vice President of the Rockefeller Foundation
Suicide is a Baobab Tree: A Narrative Medicine Case Study

Adriano Machado Facioli, PhD; Fábio Ferreira Amorim, MD, PhD; Karlo Jozefo Quadros de Almeida, MD; Eliana Mendonça Vilar Trindade, PhD

ABSTRACT

This case study is an example of applying narrative medicine as a useful tool for health professionals to manage an existential and complex scenario such as the suicide of a sibling. Some suicides are like baobab trees—these large and resilient trees grow deep roots for many years, only spreading their limbs above ground once they are firmly established. Like the baobab, when suicide or a suicide attempt occurs, suicidal ideations are well cultivated and have often already been repeatedly planted. Consequently, suicide is often difficult to prevent: once the death seed is planted, it is difficult to recreate life.

Every year, more than 800,000 people die by suicide worldwide (1.4% of all deaths), which is approximately 1 person every 40 seconds. These unexpected deaths, predominantly occurring among young and middle-aged adults, have a continuing ripple effect and result in a huge economic, social, and psychological burden for individuals, families, communities, and countries. The complexity of suffering and pain experienced by suicidal individuals and their families, regardless of the success or failure of the suicidal act, is intensified by strong stigmas attached to traditional concepts of sin and eternal damnation. This unfortunate reality emerges in the narrative as a tragic family drama, which is permeated by deep feelings of helplessness.

But suicide is preventable. Prevention requires 3 important factors: knowledge, public support, and creation of strategies to enact social change. Now is the time to act and make suicide prevention an imperative goal.

CASE STUDY

Some suicides are like baobab trees—these trees are large and almost indestructible once established. They grow deep roots for many years, only spreading their limbs to the sky when they are firmly entrenched. Like the baobab, when suicide or a suicide attempt occurs, suicidal ideations are well cultivated and have often already been repeatedly planted. Consequently, suicide is often difficult to prevent. How can one prevent something that has become part of an individual’s identity and constitution?

Many suicidal individuals have planned their own death for years in the form of impulses and constant thoughts of how they will end their lives. Personally and professionally, I have witnessed the life course of individuals who showed, many years before they actually committed suicide, clear signs that one day they would kill themselves. I remember quite well my older brother, Edu, at age 18 saying life was often not worth it, because it was very unfair and full of suffering. My mother disagreed with him.

At that time she said, “I think it [suicide] is an act of extreme selfishness. One kills himself and doesn’t think about the suffering of those who are left behind.”

Edu replied, “Selfishness is when people think they are the owners of the life of the one who is killing himself. Whose life is it anyway?”

This conversation took place in 1988, ten years before my brother died.

Five years before his death, in 1993, Edu also reportedly told a few friends, as they sat at the banks of the university lake, that it was “a beautiful place to die.” His death took place nearby in 1998.

I also remember Edu occasionally joking about other people’s suicide threats. “Do you really want to commit suicide?” he would ask mockingly. “So hang yourself with a steel wire coated with grease. If you do that, there is no turning back.” Edu spoke as someone who believed most people who threatened suicide would not really do it, and that they used their threats only as a means to manipulate others. And he never threatened to kill himself.

For the ten years before Edu’s death, I dealt with an extremely unpleasant fear that he would one day kill himself, but this dread was not enough to rid me of the devastating surprise of the reality of his suicide. Although we had clearly talked about suicide, I was not spared the shock of dealing with this kind of misfortune.

Five years before his death, Edu and I had a conversation in which he expressed concern about the possibility of me being suicidal. I was 21, and he was 23 years old. I said to him, “Brother, let’s make it clear, the suicidal individual here is you and not me.”
Suicide is a Baobab Tree: A Narrative Medicine Case Study

The only thing I can guess is he really cared about me, as the loving older brother he was, and because he worried about how much suffering his suicide would bring me.

PREVENTING A SUICIDE

Years later I learned, through his death and in my professional practice, the basics of preventing a suicide. Suicide is a very lonely act. Suicidal people are, in general, socially isolated and radically lonely in their pain. In the Sidebar: Years Later, I have included my attempt to further explore Edu’s world of loneliness and pain.

Edu loved being with me and our youngest brother, but he was alone in his town, far from us and with no easy communication available. In Brazil in 1998, our family had no cell phones or personal computers or wireless Internet that allowed us to reach anyone at any time. We were separated by hundreds of miles, by several days without talking to each other, by our ignorance about suicide and the danger that was haunting Edu’s life. He suffered with all these distances. During a phone call some days before his death, he said, probably knowing our recent visit was the last time he would see us, “It was very hard for me to see you leaving …”

Now I know that in these moments it is crucial to have loved ones close by and part of our lives. Social gratifications are possibly the most relevant ones in a human being’s life. We are social animals, fed by social interactions—healthy social interactions. We need to love and be loved. We need real love, which at its root involves proximity, being close and together, being present, interacting, and pushing the ghosts of unhealthy loneliness away.

When suffering comes, life takes a sudden stop and everything starts moving slowly. Time takes too long to pass and weighs on us unbearably. There, at this time, you are, fully and without escape, feeling all the pain you can experience. When this most extreme part of suffering goes away, another wave comes, although less intense: it is the echo of that past suffering. This is when the blanket of love that others weave for us plays a decisive role. If this blanket is effective, real, and supportive, we will feel that life is worthwhile despite all the pain and injustice in the world. This love is not a crumb of pleasure immersed in the suffering soup of existence deluding us. It is actually the base, often subtle, of a happy life.

It seems to me that this structure of a happy life remains primarily a history of comfortable and supportive relationships, largely provided by parents (or our first caregivers), that teach us how to love and be loved. Edu felt so safe when in contact with me and our youngest brother. We two seemed to offer a family structure that could support an important part of Edu’s psychological well-being.

Long-gestated suicides, thought out and planned numerous times, often for years, grow like a baobab tree, acquiring and building size along with the person’s identity. I think these deep-rooted intentions are the most difficult to prevent. They come from a long daily routine that feeds them for years.

For those of us left behind, what remains are the ashes, our feelings of helplessness and guilt, and, in my case, a lot of good
memories. Edu was an inexhaustible source of ideas, beauty, creativity, art, and surprise. Despite all his faults, he was a rare, beautiful, explosive, surprising, and all-too-brief event that passed through our lives and helped form who I am.

DISCUSSION

We make sense of the world and the things that happen to us by constructing narratives to explain and interpret events both to ourselves and to other people. Furthermore, narratives also play an important role in touching readers. As a literary genre, the narrative is an important field of arts. A fundamental function of arts in our lives is awakening and vivifying our slumbering feelings, inclinations, and passions of every kind.\(^2\) In this context, narrative medicine emerges as a medical practice model based on narrative competence: the capacity of human beings to acknowledge, to absorb, to interpret, and to react to stories that provide resources for the understanding of stories’ meanings, leading to solutions and indicating a way to provide better holistic care.\(^3\,6\) Moreover, narrative medicine uses patient stories as a diagnostic, therapeutic, and educational tool. Our narrative is an example of applying narrative medicine as a useful tool to manage an existential and complex scenario such as the suicide of a sibling.

Some suicidal thoughts grow slowly from recurrent unconscious conflicts that do not arise from nothing.\(^7\,8\) Freud proposed inevitable intrapsychic conflicts from Eros (life drive) and Thanatos (death drive).\(^7\) The complexity of suffering and pain experienced by suicidal individuals and their families, regardless of the success or failure of the suicidal act, is intensified by the strong stigmas attached to traditional concepts of sin and eternal damnation.\(^9\,10\) This unfortunate reality emerges in our narrative as a tragic family drama permeated by profound feelings of helplessness.

A GROWING BAOBAB TREE

In our narrative, this suicide construction was compared to a growing baobab tree. The baobab is one of nature’s oldest trees, native to Madagascar, mainland Africa, and Australia. Capable of living for thousands of years, this tree grows to 40 to 75 feet tall with a trunk diameter of 35 to 60 feet. Baobabs are hardy and seemingly indestructible—they are renowned for being difficult to kill and will even regrow bark if stripped of it or burnt. In one chapter of *The Little Prince,*\(^1\) the classic novel by Antoine de Saint-Exupéry, the Little Prince and the author have a very important conversation about baobab trees. The Little Prince talks about how they are a constant threat to his tiny planet, and he has to pull up the little baobab saplings every morning. The Little Prince points out that these trees start out as tiny seedlings, but if not uprooted and discarded when they are small, they firmly take root and can even cause a planet to split apart. Saint-Exupéry states that the lesson to be learned from the story of the baobab is so important that he has drawn them more carefully than any other drawing in the book.\(^1\) On a metaphorical level, the baobabs stand for unpleasant things in our human nature—if we don’t spot these unpleasant elements and weed them out early, they will take firm root and distort our personality. Edu’s suicide grew and became like a baobab tree. His suicidal ideation was left to grow stronger and stronger, and it took root in his personality. His ideation grew for ten years or more in silence, in his and his family’s silence. When his suicide happened, his ideation had been repeatedly planted long before. Some members of our family only realized its enormity when it happened.

PUBLIC HEALTH PROBLEM

Suicide is an important public health problem that causes immeasurable pain, suffering, and loss to individuals, families, friends, and communities in the world.\(^13,14\) Every year, more
than 800,000 people die by suicide worldwide (1.4% of all deaths), approximately one person every 40 seconds. It is one of the top 10 causes of death in the US. Globally, suicide is the 15th leading cause of death and the 2nd leading cause of death between the ages of 15 and 29 years; and it accounts for 50% of all violent deaths among men and 71% among women. Death by suicide is only a small part of the problem—for every person who dies from suicide, there are more than 30 others who attempt it. The heavy burden of long-lasting physical and emotional problems associated with suicidal behaviors affects countless individuals: family members of the person with suicidal behaviors, friends, coworkers, and others in the community. There is also a large economic impact, related to medical care costs and productivity loss. In Canada, it has been estimated that direct and indirect costs due to suicide are over $2.4 billion ($850,000 for each suicide). Another concerning fact is that almost 75% of suicides occur in low- and middle-income countries, where health services and resources for identification, treatment, and support are often scarce and limited. Indeed, suicide has a great impact on the most vulnerable populations, especially because of its high prevalence in minority, marginalized, and discriminated-against society groups, such as indigenous peoples, displaced persons, and individuals who are lesbian, gay, bisexual, transgender, or questioning their sexual identity (LGBTQ). For instance, LGBTQ youths have a 3- to 4-fold higher suicide risk, and those who have been rejected by their families are 8 times more likely to commit suicide. These striking facts make suicide a global health problem that must be considered a priority.

“SUICIDE”

In 1642, Sir Thomas Browne, a physician and philosopher, coined the term “suicide” in his famous work, *Religio Medici.* People have worked to understand suicide throughout history and across disciplines of knowledge, such as philosophy, sociology, psychoanalysis, and psychiatry. Social representations regarding suicide have also changed with time: a constituent element of tradition or acceptable option in certain cultures and means (such as pesticides, firearms, and certain medications) impulsively in moments of crisis, and ready access to suicide preventive responses lies in the identification of suicide risk factors and the relief of these risk factors by implementing appropriate interventions. Strategies to counter risk factors are of three types: 1) universal prevention strategies, which are designed to reach an entire population; 2) selective prevention strategies, which target vulnerable individuals; and 3) indicated prevention strategies, which target specific vulnerable individuals with community support. Among all risk factors for suicide, a prior suicide attempt is the single most important in the general population. In these cases, follow-up care by health caregivers through regular contact, including by phone or home visits, together with community support, is essential. Decreasing access to suicide means is another way to reduce suicide rates. Context is imperative to understanding suicide risk. Many suicides occur impulsively in moments of crisis, and ready access to suicide means (such as pesticides, firearms, and certain medications) can determine whether a person lives or dies. Other effective
measures include responsible suicide reporting in the media, avoiding language that sensationalizes suicide and avoiding explicit descriptions of methods used. 11,12,22-25

In a recent report, the World Health Organization recommended that countries get a range of government departments involved in the development of a comprehensive coordinated response to prevent suicide. 11 Furthermore, high-level commitment is needed, not just in the health care sector but also within the education, social welfare, employment, and judicial sectors. 11 One recommended milestone is to place suicide prevention under national strategy, and to develop standards and guidelines with a multidisciplinary approach that addresses suicide in a comprehensive manner. Implementing timely and effective suicide prevention strategies can considerably reduce suicide rates. 11 It is necessary to respond rapidly when a person in crisis is identified. Youths-focused efforts to reduce suicide have reported up to a 40% decrease in deaths by suicide. Among the elderly, these strategies have decreased suicide rates by 33%. 10,11,13 In the World Health Organization Mental Health Action Plan 2013-2020, 10 World Health Organization member states have pledged to implement actions to reduce the suicide rate by 10% by 2020.

CONCLUSION

Every suicide is a tragedy. These unexpected deaths, occurring predominantly among young and middle-aged adults, have a continuing ripple effect and result in a huge economic, social, and psychological burden for individuals, families, communities, and countries. Suicide is preventable, and prevention requires social change. To create social change, three important factors are required: knowledge (both scientific and informed by practice), public support (political will), and a social strategy (such as a national response to accomplish suicide prevention goals). Every life lost to suicide is one too many. The time to act and to make suicide prevention an imperative goal is now. 10,11,14 If we attend to suicide when it is already too late, a baobab forest will have grown and we may never be able to get rid of it.

Disclosure Statement

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

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Suicide is a Baobab Tree: A Narrative Medicine Case Study
Why a Hanging Man Dances

Gurpreet Kaur Padam, MD

“Do you know why a hanging man dances?” asked Mr B. He was once an intensely independent man, now 80 years old and afflicted with end-stage lung disease. At first observation, he appeared tired, repositioning himself with great effort from lying down and then reclining in his bed. He then shifted to sitting at the edge of the bed, tightly holding onto the bed sheets as if clenching to a life that was slowly escaping him. He positioned his right hand on his chest, gasping for air, and appeared frighteningly distressed. I picked up the nasal cannula and the tubing connected to the oxygen tank sitting beside him. He thrust his outstretched palm towards me and said, “No. I don’t want anything that will make me live longer.” Despite the explanation that the flowing air would help him with the sensation of air hunger, he still refused the readily available oxygen.

He had a furrowed brow. He was clearly trying to catch his breath with his mouth open and mentioned that he was also in pain from a sacral decubitus ulcer. Working through his anguish, he muttered a few bitter words and requested a “magic injection” to end it all. While gasping for air between words, his pauses for rest seemed like minutes. Mr B debated out loud as if answering his own questions, his predicament that his spiritual belief prohibited him from taking his own life and risking reincarnation. To him, rebirth meant inevitably reliving his current situation. That would not be tolerable for him.

His eyes opened wide. Through the glossy haze of the sclera, his baby blue pupils dilated and held my gaze as he expressed great fear of eternal suffering if he chose to shorten his life. He managed to gather together the energy to reveal that he lived alone at home and did not think he could return there, as this was the beginning of the end.

We discussed symptom management options for dyspnea. He let out a sigh of relief that there were alternatives to suicide but was disappointed that we had not figured out a way to circumvent the dying process. “That is why a hanging man dances, he is looking for something to step on,” he said.

In his agony, Mr B knew there wasn’t much time left and when “see you later” slipped from my tongue as I bid farewell, he responded swiftly that he would not be here the next day but perhaps we may meet in another lifetime. The next day at the hospital, I visited Mr B’s empty bed. I bid good-bye to the unoccupied and neatly made bed where I imagined his last moments.

While I hoped that our meeting was as meaningful to him as it was to me, I prayed for him to be at peace. This encounter left me with more questions than answers. Did he appear frightened and distressed to me because I was? He seemed so comfortable with the notion of death and knowing that it hovered nearby. Perhaps I perceived him to be clenching to life not because he was scared to die but because I was afraid to let him down? Perhaps the one clenching to life was me, while he had resolved to let go.

I am humbled with gratitude that Mr B unknowingly assisted in making me a better person and a more compassionate physician. When I find myself sitting at the edge of the bed in the early morning, I often think of him and what he must have felt. An asthmatic yearns for air as the chest becomes tighter with each cough; most of us experience transitional dyspnea or discomfort when we are afflicted with the flu or a cold. This heightened sense of awareness used to cause anxiety, but now I can channel it as motivation to improve the delivery of my care and our system for those who need it the most.

Mr B left a mark on my soul as if through the looking glass he gave me another vital glimpse of my own mortality. After all, I will be at the receiving end one day.

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BOOK REVIEW

The Body Keeps the Score: Brain, Mind, and Body in the Healing of Trauma
by Bessel van der Kolk, MD

Review by Albert Ray, MD

This valuable book is an informative primer about the ways traumatic life events affect us as human beings. The impact of physical and emotional trauma on brain, mind, and body is examined thoroughly by the author, Bessel van der Kolk, MD, through numerous real life examples that arouse our clinical interest. In our modern age, when we so often hear the term “posttraumatic stress disorder,” this book takes us back in time to its historic origins and the past efforts of some of the icons of psychiatry who attempted to explain and treat trauma in dealing with their patients. What becomes clear very quickly is that individuals can be forever branded with a historic score that travels with them for the remainder of life. The body indeed keeps that score as a permanent record unless something is done to address its tattoo. Although we all deal with the results in our practices, the origins are rarely recognized.

As a result, treatment of such trauma-affected patients today is mostly based on the use of powerful medications to lower the score pharmacologically rather than by exploring underlying causality and thereby creating an individual who feels understood. On the surface, it would appear to be easier to deliver treatment as a “medicating practitioner” rather than as a “talking practitioner.” But unless one gets down into the action through discovering and understanding the patient’s experience, one cannot truly help the healing process begin in a successful manner.

On the basis of this foundation, this book explores the ways that both patients and healers can develop the skills to appropriately evaluate historic traumatic events and how to successfully begin treating them. For the scientifically oriented physician, the biochemical, physiologic, and anatomic effects of trauma on the body are well explored in this detailed exposé. What is more importantly emphasized, though, is the invisible mark that is embedded permanently on mind and body by past traumatic events. Through its case examples, this book helps us appreciate this over and over again. It is only with this understanding of the toll on the human being that the score can be altered, resulting in victory. Van der Kolk methodically reviews how our body keeps as a permanent record the history of any “adverse experiences” in a locked account. It is imperative for the clinician to find the key to unlocking that safe, so the individual can remember and emote an experience of past trauma, and deal with it in a healing fashion that is permanent and nonthreatening. It is only in this way that the brain, mind, and body can begin to heal and restart the game with no remnant of points left on the scoreboard. Trauma victims are often unable to recover fully on their own without causal understanding and guidance because our minds and bodies have not been trained to open up new pathways to lead us out of the maze. Instead, patients are often numbed with medications to help them live with the stress of trauma, while numerous unsuccessful visits to health care professionals take place for a myriad of somatic complaints. This has had a major effect on the cost of providing health care. The techniques in this book teach helpful methods that should instead be considered, including mediation, yoga, eye-movement desensitization and re-processing, neurofeedback, and play, to return the patient to a healthy state of wellness. It is never too late to learn to help a person tap into their inner strength through teaching the use of breathing, movement, and touch as an art for healing.

Ultimately, the goal of this book is to learn how to help traumatized patients, and to guide their healers to bring a feeling of safety, calm, and acceptance to their patients as we assist them with remembering memories of horrible events that they have experienced. Whether that patient is a child, a war veteran, an abused spouse, a sexually traumatized

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individual, or a victim of poverty, the roadmap for discovery and healing are much the same and can be achieved without the often ineffectiveness of resorting to multiple courses of potent medications or repeated outpatient visits, which avoid the underlying pathology. Those who use this book and who would find its content useful include not only traumatized individuals and their loved ones, but physicians, health care workers, mental health professionals, policy makers, law enforcement, educators, and military personnel. We are all shocked to hear on the daily news, horrific events involving murder and suicide that have past trauma as their underlying etiology. We need a new paradigm to effectively deal with this horror, and this book begins to provide that for us.

The world has advanced and retreated throughout its history as a result of monumental events, many of which have been quite traumatic. Success and defeat, agony and ecstasy are familiar to all of us, collectively or individually. A thorough reading of The Body Keeps the Score offers us a new window to help recognize, interpret, and better comprehend how a traumatic event in the past, based not on genetics but rather caused by life experiences, can be explored and successfully overcome so that the individual is no longer a victim but a hero.

I encourage you to become an active player in the game, and not an observer, by employing the teachings that this enjoyable, easy-to-read book has to offer. I congratulate the author on taking such a complex subject, making it easy to understand and practical at the same time, so that in the end the brain, mind, and body are healed and no longer have to keep the score. ✶
A 59-year-old man presented to the gastroenterology clinic with 2 weeks of worsening lower back pain. There was associated poor appetite, fatigue, night sweats, and chills. The patient’s medical history was significant for well-controlled hypertension and sigmoid diverticulosis. He had been smoking half a pack of cigarettes per day for 30 years. Physical examination was remarkable for fever (100.7°F), periumbilical tenderness, and a soft epigastric bruit. Laboratory evaluation, including complete blood count, lipase, liver and renal function, electrolytes, and lactate, were within normal limits. Ultrasound of the abdomen with venous duplex was performed to evaluate the epigastric bruit. The ultrasound revealed a nonocclusive thrombus in the splenic vein (Figure 1).

A computed tomography (CT) scan with intravenous contrast confirmed a thrombus in the inferior mesenteric vein (IMV) (Figure 2) extending to the confluence of the IMV with the splenic vein (Figure 3). Inflammatory changes around the sigmoid colon with a hyperdense diverticulum were also noted on CT scan (Figure 4), suggestive of diverticulitis. No evidence of intestinal obstruction or infarction was seen on imaging, which indicated only partial vein occlusion and/or early IMV thrombosis. The thrombosis probably resulted from inflammation in the adjacent diverticulum. The patient was given ciprofloxacin and metronidazole for 10 days and was started on warfarin therapy, initially bridged with heparin.

A CT scan of the patient’s abdomen was performed 15 weeks after his initial visit and treatment. The CT scan...
CLINICAL MEDICINE

Image Diagnosis: Inferior Mesenteric Vein Thrombosis

showed a smaller IMV without any collateral vein formation, indicating resolution of the thrombus (Figure 5). At 30 weeks, ultrasound of the patient’s abdomen showed a patent splenic vein with normal flow (Figure 6). The patient had a comprehensive workup for thrombophilia, which was unremarkable. Warfarin therapy was stopped after resolution of the thrombus.

DISCUSSION

Acute mesenteric vein thrombosis is responsible for 6% to 9% of cases of acute mesenteric ischemia. IMV thrombosis is relatively uncommon and constitutes 4% to 11% of cases of acute mesenteric vein thrombosis.\(^1\) However, IMV thrombosis carries a 15% to 23% risk of mortality.\(^4-6\) It is usually seen in the setting of thrombophilia or local inflammation, and IMV thrombosis on abdominal imaging should prompt workup for these conditions.\(^7\) Initial management involves bowel rest, pain control, intravenous hydration, and therapeutic anticoagulation with bridging from heparin to warfarin.\(^7\) Surgical resection is reserved for patients with progressive intestinal dilatation or peritoneal signs.

IMV thrombosis is an uncommon but potentially life-threatening complication of sigmoid diverticulitis. Prompt diagnosis and management of IMV thrombosis can prevent mesenteric infarction or surgical intervention.

Disclosure Statement

The authors have no conflict of interest to disclose.

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Pneumomediastinum Diagnosed on Ultrasound in the Emergency Department: A Case Report

Hilary FH Beason, MD; Joshua E Markowitz, MD, RDMS, FACEP

ABSTRACT
An emergency ultrasound performed at bedside helped to confirm and expedite the diagnosis of esophageal perforation in a 23-year-old man. Early diagnosis was essential for prompt treatment and consultation because the patient's underlying pathology created the potential for him to become critically ill. By serving as a quick, bedside tool for the diagnosis and evaluation of patients in the Emergency Department, bedside ultrasound allows emergency physicians to care for critically ill patients without delays or the need to send patients out of the department for imaging studies. Although the use of ultrasound in diagnosing soft-tissue pathologies is a core competency, the diagnosis of pneumomediastinum by ultrasound has been reported in the literature in only a few case reports. To our knowledge, this is the first published report of using ultrasound as an aid in the diagnosis of Boerhaave syndrome by diagnosing pneumomediastinum in an adult male.

INTRODUCTION
Ultrasound is an essential tool for emergency physicians because of its use for diagnosis, resuscitation, monitoring, and adjunct treatment in core areas of practice, including trauma, deep vein thrombosis, and thoracic, abdominal, and soft-tissue pathologies.1,2 This article presents a case in which the use of bedside ultrasound aided in a prompt diagnosis of pneumomediastinum, which led to a diagnosis of postemesis esophageal rupture. Cases of esophageal rupture have a high risk of morbidity and mortality, and early, definitive diagnosis leading to definitive management improves outcomes. Definitive diagnosis is most often made with imaging, including x-ray and computed tomography scans. These modalities may lead to delays in diagnosis or, in many cases, may require the potentially unstable patient to leave the Emergency Department (ED). This case demonstrates that with a high degree of clinical suspicion and utilization of bedside ultrasound, the emergency physician may 1) more confidently provide earlier interventions including antibiotics and surgical consult, and 2) limit time out away from the department (for imaging) in a patient who may be critically ill.

CASE REPORT
A 23-year-old man with a history of asthma and alcohol and marijuana use presented to the ED with 2 hours of severe, sharp right-sided chest pain. The pain started suddenly after the patient choked on a large piece of steak and subsequently coughed once and vomited forcefully. On physical examination, the patient appeared uncomfortable and was noted to have reproducible tenderness over the right anterior chest wall and anterior neck. Initially, no other findings on physical exam were noted, but on repeat evaluation after an echocardiogram was performed, the patient had crepitus over his anterior neck. No other positive physical findings were noted. His echocardiogram showed normal sinus rhythm.

Using a SonoSite MicroMaxx (SonoSite, Inc, Bothell, WA) machine and a P38 probe, a bedside ultrasound of the soft tissue of the neck was performed 26 minutes later to confirm the physical examination finding of crepitus over the anterior neck. Examination of the anterior neck revealed subcutaneous hyperechoic white foci suggestive of air bubbles in the soft tissue (Figure 1). After confirmation of free air in his anterior neck, the patient was given a diagnosis of subcutaneous hyperechoic white foci suggestive of air bubbles in the soft tissue (Figure 1). After confirmation of free air in his anterior neck, the patient was given a diagnosis of subcutaneous pneumomediastinum and a diagnosis of likely esophageal rupture consistent with Boerhaave syndrome. The patient was started on piperacillin/tazobactam. Portable x-ray was not
initially available; a chest radiograph was obtained 2 hours and 13 minutes after presentation to the ED (Figure 2). The on-call surgeon was notified of the radiograph findings and the patient was admitted to the Surgical Intensive Care Unit. The diagnosis of pneumomediastinum was further evaluated using a computed tomography scan with contrast (Figure 3), and eventually with an esophagram from the Surgical Intensive Care Unit. These images demonstrated a right pleural effusion, mild emphysema and pneumomediastinum in the chest, and subcutaneous emphysema, in the neck. On the day after admission to the ED, a repeat esophagram was performed that showed that the patient’s perforation had spontaneously closed. The patient was managed medically and was discharged home on hospital day 2.

DISCUSSION
Boerhaave syndrome is defined as spontaneous transmural rupture and perforation of the esophagus or post-emesis esophageal rupture.3,4 The most common causes of esophageal rupture include chest trauma (blunt or penetrating), local trauma from swallowed foreign bodies or caustic agents, spontaneous rupture, anastomotic breakdown, and iatrogenesis.3 Boerhaave syndrome has a high rate of morbidity and mortality due to mediastinal contamination, with 20% to 50% of cases resulting in death even when properly treated.3,5 If a significant esophageal tear occurs, the definitive management is surgical.3,4 In our case, the patient reported forceful vomiting, which probably caused the esophageal perforation. Our patient had only a small perforation, which closed spontaneously and required no surgical intervention. However, prompt diagnosis was aided by bedside ultrasound, allowing for the early initiation of antibiotic therapy. These were critical steps in this patient’s hospital course. The physical examination finding of crepitus raised our suspicion for free air; ultrasound confirmed this finding, which, in conjunction with the patient’s presenting history, led to a presumptive diagnosis of pneumomediastinum.

The diagnosis of Boerhaave syndrome requires a high clinical suspicion and can often be overlooked. Patients typically present with severe chest or abdominal pain that can mirror other pathologies, thus causing early examination findings to be nonspecific. The classic physical findings associated with Boerhaave syndrome often present late and include a systolic crunch (Hamman sign) and crepitus that is palpable in the neck or along the chest wall.3 Common chest x-ray findings include widening of the mediastinum, pneumothorax, pneumomediastinum, and/or pleural effusions (usually left-sided).3,4 Emergency ultrasound is an accepted practice for the primary assessment of ED patients.6 Although ultrasound may not be able to definitively diagnose Boerhaave syndrome, sonography has been used to identify some of its common features. Using sonography in the diagnosis of pneumothorax and pleural effusion is common practice. Ultrasound has also been used to identify subcutaneous air bubbles in necrotizing fasciitis and subcutaneous air caused by surgical procedures.7,8 However, the ability to diagnose pneumomediastinum with ultrasound has only been reported in a few case reports and is more often associated with children.9-13

The diagnosis of pneumomediastinum can be challenging with bedside ultrasound and is operator dependent. Thoracic ultrasound poses its own challenges because of limitations caused by bone and by air in the lungs. However, the ability to visualize free air in the soft tissue of the neck is often more straightforward. Differential diagnoses to consider for free air in the neck include...
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direct local extension (such as from a line placement), infection from a gas-producing bacteria, pneumothorax, or pneumomediastinum. In our case, use of ultrasound led to early treatment and allowed for close patient monitoring before the patient left the department for further imaging. In an unstable patient, transportation to the Radiology Department would increase risk to the patient, and the use of ultrasound could make an even greater difference in patient mortality.

Our patient was young and of appropriate body mass index, which allowed for the thorough physical examination that identified crepitus in his neck. In patients with severely elevated body mass indexes and those considered morbidly obese, findings such as subcutaneous emphysema may be equivocal or even absent on palpation, thus making it more difficult to properly diagnose this condition. In these cases, ultrasound is an even greater tool for identifying subcutaneous air because it can have greater sensitivity than physical examination alone.

Many facilities have access to portable x-ray machines, a useful tool in diagnosing free air in the soft tissues. However, there are occasions when this modality may be unavailable. Some EDs may not have access to portable x-ray machines at all. In either of these cases, the ability to use ultrasound becomes crucial in helping to identify and to diagnose emergent conditions. Although it may not be the only imaging modality that can diagnose free air, ultrasound may compliment current available technology because there are times when it is the most accessible imaging modality.

Early intervention reduces morbidity and mortality in cases of Boerhaave syndrome. The use of ultrasound at bedside can help lead to early diagnosis of certain aspects of the syndrome, such as pneumomediastinum. Although definitive imaging such as computed tomography and barium esophagram may still be required, particularly before surgical intervention, bedside diagnosis with ultrasound allows for prompt initiation of antibiotics, critical in the treatment of Boerhaave syndrome.

Disclosure Statement
The author(s) have no conflict of interest to disclose.

References
ABSTRACT
A previously healthy patient was seen in the Emergency Department for evaluation of a one-month history of cough and one-day history of hemoptysis. A computed tomography scan of the thorax found a mass on the right lower pulmonary lobe and a mass on the left upper lobe. A biopsy specimen of the right lobe lung mass, obtained during bronchoscopy, demonstrated papilloma. This case report, from a pulmonologist’s perspective, includes a comprehensive review of the patient’s clinical presentation and outcome, as well as a discussion of recurrent respiratory papillomatosis.

INTRODUCTION
Recurrent respiratory papillomatosis (RRP) is an uncommon clinical entity. The incidence rate is 1.8 cases per 100,000 adults and 4.3 cases per 100,000 children. Recurrent respiratory papillomatosis is caused by human papillomavirus (HPV) serotypes 6 and 11 (the same serotypes responsible for more than 90% of genital condylomata) and serotypes 16, 18, 31, and 33 (the serotypes associated with genital and aerodigestive tract malignancies). A double-stranded DNA virus in the Papovaviridae family, HPV infects the mucosal basal layer and induces cellular proliferations via activation of host replication genes through the epidermal growth factor receptor pathway. This results in thickening of the basal layer. Papilloma appears grossly as velvety or exophytic “cauliflower.”

CASE REPORT
A 43-year-old man presented to the Emergency Department with a 1-day history of dark burgundy-colored sputum and a cough. The patient had the cough as well as a 2.7-kg (6-pound) weight loss in the month before admission. He denied fever, night sweats, or change in the tone of his voice. He had no remarkable medical history and no prior surgery. He was not taking any medications. He did not know his family history because he is adopted. His social history included substantial secondhand smoking exposure. He had multiple drug use in the past that included marijuana, cocaine, lysergic acid diethylamide, and amphetamine. He had multiple female sexual partners.

A chest x-ray film obtained on admission showed a right-sided lung mass. Computed tomography scan of the chest was subsequently performed for better visualization. Chest computed tomography (Figure 1) demonstrated a right lung mass measuring 5.4 cm x 5.2 cm x 6.1 cm at the superior segment of the right lower lobe with associated “tree-in-bud” nodularity, as well as a lesion in the left upper lobe measuring 1.7 cm in diameter. The inpatient pulmonary team was consulted for assistance with the diagnosis. The patient underwent bronchoscopy, which identified a polypoid lesion on the right vocal cord (Figure 2) and an endobronchial mass at the right lower lobe (Figure 3). The right lung mass was biopsied. Pathologic findings revealed squamous cell papillomatosis.

Figure 1. Computed tomography scan of chest showing masses in right lower and left upper pulmonary nodes.

Figure 2. Bronchoscopy demonstrating polypoid lesion on right vocal cord.

Figure 3. Bronchoscopy showing view of endobronchial mass at right lower lobe.
The patient had 4 hospitalizations for treatment of recurrent pneumonia in the next 6 months, with 19 inpatient days accounted for by this complication. A thoracic surgeon was consulted, and the decision was made to perform a right-sided lobectomy via video-assisted thoracoscopic surgery. A biopsy was performed from the gross specimen obtained at the lobectomy (Figure 4). Results demonstrated squamous cell carcinoma. The patient was subsequently referred to an oncologist for a discussion of treatment options for squamous cell carcinoma of the lung.

**DISCUSSION**

The incidence of RRP is bimodal, with the juvenile-onset form typically first occurring in children aged 2 to 4 years and adult-onset RRP typically occurring in adults aged 20 to 40 years. Juvenile-onset RRP is thought to be caused from peripartum exposure through an infected birth canal. Cesarean delivery appears to lower the risk of RRP in newborns but does not eliminate the risk. Risk factors for juvenile-onset RRP include being firstborn, being born via normal spontaneous vaginal delivery, and being born to a teenage mother. Risk factors for adult-onset RRP include multiple lifetime sexual partners as well as a high frequency of oral sex. There was no statistically significant difference in illicit drug use between patients with adult-onset RRP vs a control group in a study by Ruiz et al.

Human papillomavirus has a predilection for the junction between squamous and ciliated epithelium. RRP affects, from the most common site to the least common site, the true vocal cord, oral cavity, trachea, bronchi, and esophagus. Therefore, patients present most commonly with hoarseness followed by stridor, cough, and dyspnea. Pediatric patients may present with failure to thrive as well. Talierco et al reported 100% of patients with adult-onset RRP had concurrent HPV infection of the oral cavity; however, our patient had no evidence of oral cavity HPV infection on physical examination or bronchoscopy findings.

The diagnosis of lesions typically is first made through visualization by imaging modalities such as computed tomography of the chest, followed by biopsy of suspicious lesions through laryngoscopy, nasopharyngolaryngoscopy, or bronchoscopy. The gross appearance of papilloma is exophytic, with white or pink lesions with frondlike projections. Histologically, papilloma is described as projections of nonkeratinized stratified squamous epithelium over a fibrovascular core (Figure 5).

The primary treatment of RRP is surgical removal of the papilloma to reduce the tumor burden. Surgical techniques include cold steel excision, carbon dioxide or argon laser, endoscopic microdebrider, and pulsed dye laser. Potential side effects of carbon dioxide or argon laser include active viral DNA in the laser smoke, which potentially can expose the practitioner performing the procedure and the staff to HPV and spread HPV to the patient’s previously unaffected body parts. Other side effects of laser therapy include damage to surrounding tissue causing vocal glottis edema or vocal cord scarring, as well as the potential for the laser to cause an explosion when mixed with oxygen-rich supply from the

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**Figure 4.** Gross specimen from right lobectomy demonstrating squamous cell carcinoma.

**Figure 5.** Pathologic specimen from right lower lobe lesion demonstrating squamous cell papillomatosis. Immunostaining was positive for tumor suppressor protein p16. Fingerlike projections of nonkeratinized stratified squamous epithelium appear with fibrovascular core.
endotracheal tube. Tracheostomy might be needed for patients with airway obstruction. However, tracheostomy is to be avoided if at all possible because of a risk of activating or contributing to the spread of RRP because tracheostomy creates a squamocolumnar junction.

Medical therapy is considered adjuvant to surgical therapy. The criteria for medical therapy include more than 4 surgeries performed per year, spread of the disease to a distant site, or rapid growth of lesions. Medical therapy includes interferon, ribavirin, acyclovir, and intralesional injection of cidofovir. Additional new adjuvant medical therapy under investigation includes bevacizumab and HPV vaccine. Injection of bevacizumab to vocal cord RRP lesions enhanced photodynamic laser treatment of RRP and was found to be safe without additional complications related to laser treatment. For patients who had rapidly growing laryngeal papilloma, adjuvant therapy with 3 doses of quadrivalent prophylactic HPV vaccine (Gardasil, Merck Co, New York, NY) was approved in the US for prevention of cervical cancer caused by HPV infection. Gardasil theoretically should prevent RRP and future studies should focus on the role of vaccination to prevent RRP.

A literature review of RRP case reports (Table 1) revealed that patients usually have the diagnosis of RRP many years before evidence of malignant transformation. In contrast, our patient had evidence of malignant transformation about six months after diagnosis of respiratory papillomatosis. Our patient received primary therapy for RRP, which was surgical removal of papilloma that was causing infectious complications. However, once malignant transformation to squamous cell carcinoma was diagnosed in the surgical specimen, adjuvant therapy for RRP would have been inappropriate, and the focus was therefore shifted toward treatment of squamous cell carcinoma.

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

Acknowledgment
The authors would like to thank the Kaiser Permanente Los Angeles Medical Center Department of Pulmonary and Critical Care for supporting its resident and fellow writing this case report.

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

Table 1. Comparison of our case report to case reports from the literature

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Comparison</th>
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<tbody>
<tr>
<td>Martina et al, 2014</td>
<td>Their patient had a history of laryngeal papillomatosis since childhood. Our patient did not have a history of papillomatosis from childhood.</td>
</tr>
<tr>
<td>Azadarmaki et al, 2013</td>
<td>Both our patient and theirs had malignant transformation of respiratory papillomatosis. However, their case report featured a transplant recipient.</td>
</tr>
<tr>
<td>Hasegawa et al, 2013</td>
<td>Both patients had malignant transformation of respiratory papillomatosis to squamous cell carcinoma. However, their case report featured a transplant recipient.</td>
</tr>
<tr>
<td>Lin et al, 2010</td>
<td>Both patients had malignant transformation of respiratory papillomatosis to squamous cell carcinoma. However, their case report featured a transplant recipient.</td>
</tr>
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</table>

References

CASE REPORTS

Case Report: Pulmonary Papillomatosis in a Patient Presenting with Cough and Hemoptysis
CME Evaluation Program

Section A.

Article 1. (page 21) “Getting off the Bus Closer to Your Destination”: Patients’ Views about Pharmacogenetic Testing

Which of the following was not a main finding of this article?

☐ a. participants saw the potential value of pharmacogenetic testing but expressed concerns about privacy and discrimination based on genetic information

☐ b. participants worried that physicians might overvalue pharmacogenetic test results and dismiss patients’ reports about how a medication is working

☐ c. participants did not believe that pharmacogenetic testing should be implemented

☐ d. participants wanted to know whether the results of pharmacogenetic testing could be used for purposes other than guiding prescribing decisions

Which of the following did participants not identify as potential risks of pharmacogenetic testing?

☐ a. employment discrimination

☐ b. breach of confidentiality

☐ c. inability to obtain disability or long-term care insurance

☐ d. misuse of genetic information by law enforcement

☐ e. cloning

Article 2. (page 29) A Community-Based Hip Fracture Registry: Population, Methods, and Outcomes

What are the most common surgical procedures used to treat fractures of the femoral neck subtrochanteric region?

☐ a. internal fixation and hemiarthroplasty

☐ b. total hip arthroplasty and hemiarthroplasty

☐ c. hip resurfacing and internal fixation

☐ d. internal fixation and total hip arthroplasty

The Hip Fracture Registry monitors primary hip fractures treated surgically and subsequent revisions for what period of time?

☐ a. for 1 year

☐ b. for 2 years after surgery

☐ c. for 5 years after surgery

☐ d. for the patient’s lifetime

Section B.

Referring to the CME articles, how likely is it that you will implement this learning to improve your practice within the next 3 months?

Objective 1
Integrate learned knowledge and increase competence/confidence to support improvement and change in specific practices, behaviors, and performance.

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<th>Article 1</th>
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Objective 2
Lead in further developing “Patient-Centered Care” activities by acquiring new skills and methods to overcome barriers, improve physician/patient relationships, better identify diagnosis and treatment of clinical conditions, as well as, efficiently stratify health needs of varying patient populations.

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Objective 3
Implement changes and apply updates in services and practice/policy guidelines, incorporate systems and quality improvements, and effectively utilize evidence-based medicine to produce better patient outcomes.

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- Complete the evaluation and provide your contact information
ORIGINAL RESEARCH & CONTRIBUTIONS

4 Characteristics of Newly Enrolled Members of an Integrated Delivery System after the Affordable Care Act.

Elizabeth A Bayles, MD, MPH; Jennifer L Elia, MPH, Mary J Stoebel, RN, MBA; Deanna B McQuillan, MA; Irene B Novache, PhD; Jennifer C Barnes, MSPH, Anne Beck, PhD
Of 99,259 newly enrolled non-Medicare members, 25.3% completed the Brief Health Questionnaires between 11/2014, and 03/2015. Of these, 38,381 respondents were insured through Medicaid, 9,348 through the individual health exchange, and 561 through primary commercial plans. Of Medicaid, exchange, and commercial members, 19.5%, 7.7%, and 5.3%, respectively, self-reported tar or poor health; 12.8%, 2.0%, and 3.3% of each group self-reported 2 or more. Emergency Department visits during the previous year; and 8.8%, 4.3%, and 4.4% self-reported an inpatient admission during the previous year.

21 Metrics Taxonomy and Reporting Strategy for Rule-Based Alerts.

Michael Koiz, MD, MS; Alexandre Gerace
An action-oriented alerts taxonomy according to structure, actions, and implicit or explicit process outcomes using a set of 333 rule-based alerts at Kaiser Permanente Northwest (KPNW) was developed. The authors identified 9 major and 17 overall classes of alerts and developed a specific metric approach for 5 of these classes, including the most numerous ones in KPNW, accounting for 22.4% (47) of the alerts.

22 Getting off the Bus Closer to Your Destination: Patients’ Views about a Randomized Controlled Trial.

Sarah Brown Trudell, MA; Tara B Cut- ten, MS; Stephanie M Fullarton, DT, DH; James Kalton, MD, MPH; Carl F Lipnick, MD, PhD; Eric B Larson, MD, MPH
The authors conducted focus groups with patients prescribed antidepressants (print session plus 2 focus groups, n = 27), patients prescribed carbamazepine (2 focus groups, n = 17), and healthy patients (2 focus groups, n = 17). Although participants understood the potential advantages of pharmacogenetic testing, many felt that the risks (discrimination, stigmatization, physician overreliance on genomic results, and denial of certain medications) may outweigh the benefits. These concerns were shared across groups but were more strongly expressed among participants with chronic mental health diagnoses.

29 A Community-Based Hip Fracture Registry: Population, Methods, and Outcomes.

María C Inacio, PhD; Jennifer M Nava, MD; Alex Mira, MD; Jessica I Hart, MD; Gary L Ziehm, MD; Elizabeth R Porter, MD
Cases of hip fracture recorded from 2010/2011 were ascertained using the Kaiser Permanente Hip Fracture Registry. The registry collects information on patient, procedure, surgeon, facility, and surgical outcomes. The population (n = 12,562) was predominately white, women, and older (75 years), and 32% had at least 1 comorbidity. The average length of follow-up was 1.1 years. Hip arthroplasty was the most common procedure (33.1%). Most fractures were treated by medium-volume surgeons at high-volume facilities. The 30-day readmission rate was 2.1%, and the mortality rate was 12.2%.

33 Utility of the Multinational Association for Supportive Care in Cancer (MASCC) Risk Index Score as a Criterion for Nonadmission in Febrile Neutropenic Patients with Solid Tumors.

Roger A Blair, MD, MPH
Febrile neutropenic episodes in patients with solid tumors were identified electronically from 10/2008 to 11/2010. Inclusion criteria were met in 188 episodes. Sensitivity, specificity, and positive and negative predictive values of the MASCC risk index score vs complications were, respectively, 84%, 29.6%, 57.7%, and 82.1% vs a MASCC risk index score of 2 or greater could not be used as a criterion for “no complication” to avoid an admission criterion.

48 Evidence-Based Referral: Effects of the Revised “Youth Fit 4 Life” Protocol on Physical Activity: Outcomes: A Randomized Controlled Trial.

James J Annesi, PhD, FASAHP, FICS, FAPA; Linda L Vaughn, MS, MBA
The authors contrasted 2 physical activity/cognitive and self-efficacy theory, and a cognitive theory-based intervention. The Original Youth Fit For Life treatment on baseline. Inclusion criteria were met in 188 episodes. Sensitivity, specificity, and positive and negative predictive values of the MASCC risk index score were, respectively, 84%, 29.6%, 57.7%, and 82.1% vs a MASCC risk index score of 2 or greater could not be used as a criterion for “no complication” to avoid an admission criterion.

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