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Imprinting Care and the Loss of Patient Narrative: Creation and Standardization of Medical Records

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Unrecognized Value of Carcinoembryonic Antigen in Recurrent Rectal and Sigmoid Colon Cancer: Case Series

Disseminated Herpes Simplex Masquerading as Hemophagocytic Lymphohistiocytosis: A Case Report

Pseudomyxoma Peritonei—An Unusual Cause of Ascites: A Case Report

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<td>From the 2016 American College of Surgeons National Surgical Quality Improvement Program (NSQIP). From phase 1 to phase 3, the authors report the following incidence of CIA in patients with non-Hodgkin lymphoma: 9.7% in phase 1, 22% in phase 2, and 27% in phase 3. In the future, the authors recommend that future research focus on understanding the factors that contribute to the development of CIA in patients with non-Hodgkin lymphoma.</td>
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Available at: [www.thepermanentejournal.org/about/permissions](http://www.thepermanentejournal.org/about/permissions)
41 Effect of Helicobacter pylori Treatment on Unexplained Iron Deficiency Anemia. Daniel S Tseng, MD, MS, FACP; Dan Li, MD; Sri M Cholleti, MD; Julia C Wei, MPH; Yves Jodesty, MD; Hung-Viet Pham, MD
A large number of patients with iron deficiency anemia have no known cause of their anemia despite a full evaluation. All adult patients with both unexplained iron deficiency anemia and Helicobacter pylori infection diagnosed 1/1/08-4/30/15 were identified; 488 patients were treated for H pylori. In contrast to the finding of previous studies, we found no evidence that H pylori is involved in causing iron deficiency anemia. Iron deficiency anemia resolved in most subjects regardless of H pylori treatment status.

55 A Daily Hospital Progress Note that Increases Physician Usability of the Electronic Health Record by Facilitating a Problem-Oriented Approach to the Patient and Reducing Physician Clerical Burden. James M Sutton, MD; Steven R Ash, MD; Akram Al Makki, MD; Rabih Kallakeche, MD
The framework is 3 sections: Subjective, Objective, and an Assessment and Plan section, subdivided by problem titles. The record would: 1) juxtapose to each problem title relevant medications, key dural results, and limitations; 2) enter in the running lists under Assessment and Plan most relevant information for that day; and 3) generate a flow sheet in a problem’s progress note for any key results tracked daily. The physician would enter only the analysis and plan and new information not included.

71 The Critical Response Team in Airway Emergencies. John F Damrose, MD, FACS; William Eropkin, RRT, RCP; Serena Ng, MD; Sheik Cale, DO; Subhendra Banerjee, MD, FACS
Successful outcomes of airway emergencies (AEs) in the hospital depend on rapid recognition and intervention before patients become unstable. The authors describe their medical center’s experience with a coordinated rapid response to AEs, including an illustrative case. This approach emphasizes early recognition of impending AEs and instantaneous activation of a team of specialists and operating room personnel to rapidly respond to AEs anywhere in our medical center.

SPECIAL REPORTS

48 The Kaiser Permanente Los Angeles Annual Research Week Abstracts. John J Sim, MD; Kristen Ironside, MA; Gary W Chien, MD

50 The Kaiser Permanente Los Angeles Annual Research Week Abstract Summaries.

Research is a standard for the Kaiser Permanente community and now part of its DNA. The history reflects a changing culture where recognition, emphasis, and support of research increases in the organization and training programs. If physicians are asked to change and improve the ways they practice medicine, the evidence must be there. This has fostered the growth of researchers as well as the recruitment and attraction of talented research-minded physicians.

REVIEW ARTICLES

61 Self-Management of Depression: Beyond the Medical Model. Harpreet S Duggal, MD, FAPA
Self-management is increasingly becoming the standard of care among people with chronic medical conditions. Its application to depression is mostly extrapolated from the paradigms used for nonpsychiatric medical illnesses. Such an approach fails short in addressing strength-based interventions that foster recovery in individuals with depression. This article describes a new paradigm of self-management, which is in line with the recovery model, is patient-centered, and goes beyond amelioration of clinical symptoms.

CLINICAL PRACTICES

77 How to Determine Whether Our Patients Can Function in the Workplace: A Missed Opportunity in Medical Training Programs. Edward C Alivio, MD; Taha Mansoor Ahmad, MD, MPH
Patients often have their physicians disability forms, and physicians too often struggle to complete them. Many physicians lack the training to complete these forms. This article aims to provide a clear understanding of impairment, limitations, restrictions, and disability. It explains how physicians can use skills they already possess to appropriately assess limitations, restrictions, and functional capacity, and it explains why accurate determinations are a vital part of good patient care.

CASE REPORTS

81 Percutaneous Endoscopic Necrosectomy of Complex Walled-Off Lateral Necrosis of the Pancreas with the Aid of Laparoscopic Babcock Forceps: A Case Report of an Endoscopic and Radiologic Team Approach. Andrew K Nguyen, MD, MBA; Andrew J Song; Tanya Swoopes, RN; Albert Ko, MD; Brian S Lim, MD, MCR
A 62-year-old woman presented with abdominal pain, nausea, and vomiting. After multiple admissions and repeated abdominal imaging, she was found to have laterally located, infected, walled-off pancreatic necrosis. Initially, a drainage catheter was placed by an interventional radiologist and was eventually upsized to a 28F catheter. Subsequently, a fully covered metal stent was placed in the gastrointestinal tract. Laparoscopic Babcock forceps were used under fluoroscopy to remove lodged debris from the ductest.
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85 ECG Diagnosis: Acute Myocardial Infarction in a Ventricular-Paced Rhythm. Ashley S. Abraham, David R. Vinson, MD, FACEP, FAAFP; Joel T. Lewis, MD, PhD, FACEP, FAAEM

Acute myocardial infarction is more difficult to diagnose in patients with ventricular-paced rhythms, often leading to delays in treatment and inferior outcomes. The Sgarbossa criteria can help identify ST-elevation myocardial infarction in these patients, many of whom may be candidates for timely reperfusion therapy. Sgarbossa et al further applied their criteria to ventricular paced rhythms, as pacing of the ventricle results in an intraventricular conduction delay similar to that seen with left bundle branch block.

88 Image Diagnosis: Disappearing Digits: Metabolic Bone Disease in End-Stage Renal Disease. Shilji Arora, MD, FACP; Fatihma Jahufar, MD

Metabolic bone disease is a common complication in chronic kidney disease. Low vitamin D levels, resistance of PTH-sensing receptors, and dysregulation of the fibroblast growth factor 23/PTH axis can all lead to prolonged excess secretion and synthesis of PTH, eventually leading to the development of metabolic bone disease. Current treatment options include correcting vitamin D deficiency, controlling dietary phosphorus intake, and prescribing phosphate binders and calcimimetics (cinacalcet).

HEALTH CARE COMMUNICATION

90 Help Your Patients Stay Healthy on Their Cruise Vacation: Suggestions for Primary Care Physicians from a Cruise Ship Physician. Lee Jacobs, MD

During the author’s 12 years of experience in caring for critically ill patients on cruise ships, he has learned that good advice and preparation by primary care physicians before sailing can prevent life-threatening situations from occurring when their patients are at sea. Good health is a major prerequisite, especially with the realization that most serious illnesses encountered on ships may be preventable.

93 Legal Perspectives on Telemedicine Part 1: Legal and Regulatory Issues. Christian D. Becker, MD, PhD; Katherine Dandy, Esq; Max Gauejan, Esq; Mario Fusaro, MD; Corey Scurluck, MD

In critical care approximately 20% of nonfederal adult intensive care unit (ICU) beds in the US today are supported by some form of tele-ICU coverage. The literature has shown with increasing clarity that correct tele-ICU implementation improves outcomes and has the potential to significantly improve the financial performance of health care systems. Part 1 of this series discusses legal and regulatory challenges of telemedicine in general, with a focus on tele-ICU. The second part will discuss the effects of telemedicine implementation.

96 Why I Treat Obesity. Adam Gilden Tsai, MD, MSCE, FACP

In this narrative, the author describes a patient who has lost 25% of her starting body weight and the behaviors that she practices to maintain this weight loss. Patients who have lost weight have reductions in metabolism that are out of proportion to their amount of weight loss. They also have increases in appetite. Physicians have to understand the physiologic and behavioral barriers to long-term weight loss, treat obesity as a chronic disease, and also be open to using medications to treat obesity.

99 Novel Use of Apple Watch 4 to Obtain 3-Lead Electrocardiogram and Detect Cardiac Ischemia. Cesar O. Avila, MD

Two male patients in the Emergency Department had ST-elevation myocardial infarction (STEMI) apparent on their electrocardiograms (ECGs). The patients’ real-time, Apple Watch 4-based, 3-lead ECG tracings matched the traditional ECGs demonstrating STEMI, confirming the potential ability of this device to uncover myocardial ischemia. In each patient, cardiac catheterization revealed severe, 100% occlusion of the right coronary artery. The Apple Watch 4 could lead to earlier detection of acute coronary artery disease, but sensitivity and specificity remain unknown.

GRAPHIC MEDICINE

106 Giving Bad News. Toney Welborn, MD, MPH, MS

This graphic medicine piece is a commentary on communication in medicine, health literacy, and how far we sometimes are from our patients in oral communication. This story is loosely based on the physician-author’s own experience of being diagnosed with bone cancer at age 15. At a writing retreat, she was encouraged to draw her story: Pairing words with images.

NARRATIVE MEDICINE

108 Before and After. Cecilia Runkle, PhD, MPH

I mentored Permanente Medical Group and Group Health physicians in teaching their colleagues how to have conversations about death and dying. In 2016, my partner of 36 years unexpectedly died. During this time, I wrote the following haiku about my experience.

BOOK REVIEWS

111 Writing to Improve Healthcare: An Author’s Guide to Scholarly Publication. H. Nicole Tran, MD, PhD; T. Stephanie Tran

If you are looking for advice on how to introduce your findings and interventions to your departments or publish them, look no further than this book. The dissemination of quality improvement research and analysis helps the medical community stay current in knowledge of innovation, provide positive health outcomes, and decrease waste in health services. In Writing to Improve Healthcare, Stevens proclaims that health care improvement is incomplete until it is published, and he provides a unique guide to publication for this new category of writers.
Reduced Health Care Utilization among Elderly Patients with Informal Caregivers

Caroline Carlin, PhD1-3; Guy David, PhD1

ABSTRACT
Context: Prior literature has focused on the impact of informal caregiving (presence of a family member in the home or nearby) on caregiver employment, but little research has analyzed the impact of informal caregiving on health care utilization patterns.

Objective: To study the effect of informal caregivers on postacute care and recovery of Medicare patients.

Design: We used cross-sectional Health Plan administrative data to measure differences in health care utilization for Medicare patients who did and did not have coresident adult caregivers available. We identified coresident caregivers as those residing at the same postal address as discharged patients. Analysis was a combination of Poisson and logit models.

Main Outcome Measures: Length of hospitalization, type of hospitalization (ambulatory-care sensitive vs not), likelihood of discharge to postacute care (skilled nursing facility or home health), and likelihood of hospital readmission and postdischarge Emergency Department visits.

Results: Patients with caregivers were discharged after shorter hospital lengths of stay and were less likely to require postacute emergency care, home health services, or discharge to skilled nursing facilities. Savings were smaller when caregivers were younger, in poor health, or female. We extrapolated the reduced utilization associated with a coresidential caregiver to estimate Medicare savings of $514 million in 2015.

Conclusion: By calculating the impact of informal caregiving on patterns of health care utilization, we support the need to integrate the availability of caregivers into discharge planning. Future quantification of differences by caregiver characteristics is important.

INTRODUCTION
Care at home is increasing because of an aging population, technologic advances, and reimbursement pressure. Caregiving in the home, both formal and informal, is the backbone of health care for elderly individuals. Effective postacute care after an inpatient stay is an important aspect of high-quality care and has been shown to prevent hospital readmissions and complications.1-3 The growing emphasis on safe discharge under Medicare’s Hospital Readmission Reduction Program reinforces the need for outstanding postacute care in the home. The presence of a family member in the home or nearby has been argued to serve as a substitute for both formal care and institutional monitoring.2,4 The literature primarily focuses on the impact of informal caregiving on caregiver employment.5-7 Some survey-based research documented characteristics of nonresidential8 and coresidential informal caregivers.9 However, because of challenges associated with linking residential information to individual medical records, there is very little research quantifying the benefits from informal caregiving by analyzing its impact on patterns of health care utilization.

This article helps fill this gap by studying the effect of informal caregivers on postacute care and recovery, using administrative data collected by a large Health Plan, linking residential information with insurance claims data. Specifically, we studied how the presence of an informal caregiver in the home affects care transition from an inpatient setting, and the extent to which these effects might be mitigated by the caregiver’s characteristics.

The outcomes of interest include the length of hospitalization, type of hospitalization (ambulatory-care sensitive [ACS] vs not), likelihood of discharge to postacute care (skilled nursing facility [SNF] or home health), as well as the likelihood of hospital readmission and Emergency Department (ED) visits after discharge.

METHODS
Our data were drawn from the administrative files of an upper Midwest Health Plan. The Health Plan offers managed Medicare, managed Medicaid, and commercial products. Our index members were managed Medicare enrollees who experienced an inpatient admission in 2014 or 2015. We excluded residents of long-term care facilities. (Members with a recorded place of service code 33 [custodial care] accounted for less than 1% of our initial sample.) Staff at the Health Plan identified coresident adults (“caregivers”) using an address matching process. They converted the addresses of index members to the US Postal Service standardized format. They then compared these addresses with US Postal Service standardized addresses from the entire adult Health Plan membership in the year of inpatient admission, including Medicare, Medicaid, and commercial products. This address-matching process generated precise and unique matches, even in multiunit housing.

This matching process identified coresident adults for 49% of our index members. Because 2.7% of caregivers were 18 or more years younger than the index member, some of these adults may actually be adult children or other nonspousal family members. The caregivers’ age averaged 8 months older for female index members and 3 years younger for male index members.

The Health Plan extracted detailed enrollment and claims information for claims incurred and paid between January
2013 and July 2016. We used 2013 and 2014 data to identify members’ baseline health status before 2014 and 2015 admissions using resource utilization bands identified by the Johns Hopkins ACG System (www.hopkinsacg.org). To minimize the likelihood of reverse causality, we measured health status for patients in the year before the admission, although we used current-year health status for their coresident caregivers. We captured data through July 2016 to ensure we observed completed claims-associated care after discharge. The Health Plan matched members’ neighborhood characteristics from the American Community Survey to the enrollment data at members’ census tract or block group level (depending on the statistic). All geographic identifiers were stripped before the dataset was delivered to the research team. The study was deemed exempt from review by the parent organization’s (Quorum Health Corp, Brentwood, TN) institutional review board.

**Measures**

For index members, we identified the first admission in 2014 to 2015 preceded by at least 180 days without inpatient services, defining the beginning of an episode of inpatient services. For each of these index admissions, we identified the length of hospitalization and designated whether or not the admissions were ACS. ACS admissions are those with diagnoses for which timely and effective outpatient care can help to reduce the risks of hospitalization (www.ahrq.gov/downloads/pub/ahrqpp/qpiguide.pdf). The ACS admissions were determined using the methods available at http://wagner.nyu.edu/faculty/billings/acs-algorithm.

We defined use of transition care after discharge by place of service codes identifying SNF or home health care (HHC) use. Use of a SNF was recorded if it began on the day of inpatient discharge or the subsequent day. The number of HHC visits after an inpatient admission was defined as the number of unique HHC service dates in the 100 days after discharge.

Emergent care after discharge was identified as ED use or an inpatient readmission within 30 and 90 days of the inpatient discharge. Readmissions excluded rehabilitation and chemotherapy admissions, which are often planned.

**Empirical Strategy**

Our data are cross-sectional, comprising one index admission per member. Inpatient length of stay (LOS) was modeled using a Poisson regression. All other variables were binary indicators, modeled using logit regression.

The variable of interest was the presence of a caregiver in the home; our baseline

<p>| Table 1. Summary of population characteristics by family status |
|----------------------------------|------------------|---------|</p>
<table>
<thead>
<tr>
<th></th>
<th>No informal caregiver in home</th>
<th>Informal caregiver in home</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of index members</td>
<td>10,141</td>
<td>9674</td>
<td>19,815</td>
</tr>
<tr>
<td>Number of informal caregivers</td>
<td>0</td>
<td>9674</td>
<td>9674</td>
</tr>
<tr>
<td>Percentage of patients with an informal caregiver</td>
<td>0</td>
<td>100.0</td>
<td>48.8</td>
</tr>
<tr>
<td>Member characteristics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average age (SD)</td>
<td>76.3 (7.9)</td>
<td>75.1 (6.4)</td>
<td>75.7 (7.2)</td>
</tr>
<tr>
<td>Percent female</td>
<td>59.5</td>
<td>41.7</td>
<td>50.8</td>
</tr>
<tr>
<td>Health status distribution</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healthy/low risk</td>
<td>5.0</td>
<td>5.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Medium risk</td>
<td>36.9</td>
<td>39.6</td>
<td>38.2</td>
</tr>
<tr>
<td>High risk</td>
<td>31.0</td>
<td>30.1</td>
<td>30.5</td>
</tr>
<tr>
<td>Very high risk</td>
<td>27.2</td>
<td>25.3</td>
<td>26.3</td>
</tr>
<tr>
<td>Percentage with dual Medicare/Medicaid coverage</td>
<td>7.1</td>
<td>1.7</td>
<td>4.5</td>
</tr>
<tr>
<td>Neighborhood characteristics (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>87.4</td>
<td>89.9</td>
<td>88.6</td>
</tr>
<tr>
<td>Less than high school diploma</td>
<td>8.9</td>
<td>7.9</td>
<td>8.4</td>
</tr>
<tr>
<td>High school diploma/GED</td>
<td>62.8</td>
<td>63.1</td>
<td>62.9</td>
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<tr>
<td>4-y college degree</td>
<td>28.3</td>
<td>29.0</td>
<td>28.6</td>
</tr>
<tr>
<td>Under the federal poverty limit</td>
<td>11.3</td>
<td>10.0</td>
<td>10.7</td>
</tr>
<tr>
<td>Speaking English only</td>
<td>91.9</td>
<td>93.2</td>
<td>92.5</td>
</tr>
<tr>
<td>Informal caregiver characteristics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average age (SD)</td>
<td>73.6 (8.0)</td>
<td>73.6 (8.0)</td>
<td></td>
</tr>
<tr>
<td>Percent female</td>
<td>59.3</td>
<td>59.3</td>
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<td>Medium risk</td>
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<td>49.5</td>
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<tr>
<td>High risk</td>
<td>25.6</td>
<td>25.6</td>
<td></td>
</tr>
<tr>
<td>Very high risk</td>
<td>15.7</td>
<td>15.7</td>
<td></td>
</tr>
<tr>
<td>Admission and care transition outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average index admission length of stay (SD)</td>
<td>3.21 (3.05)</td>
<td>3.11 (2.99)</td>
<td>3.16 (3.02)</td>
</tr>
<tr>
<td>Percentage of index admissions ACSa</td>
<td>23.32</td>
<td>17.95</td>
<td>20.70</td>
</tr>
<tr>
<td>Percentage of discharges to SNF</td>
<td>1.21</td>
<td>0.50</td>
<td>0.86</td>
</tr>
<tr>
<td>Percentage of discharges with HHC within 100 days</td>
<td>2.64</td>
<td>0.61</td>
<td>1.65</td>
</tr>
<tr>
<td>Percentage of discharges with readmissions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 30 days</td>
<td>1.23</td>
<td>0.33</td>
<td>0.79</td>
</tr>
<tr>
<td>Within 90 days</td>
<td>5.86</td>
<td>3.93</td>
<td>4.91</td>
</tr>
<tr>
<td>Percentage of discharges with ED use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 30 days</td>
<td>12.93</td>
<td>11.31</td>
<td>12.14</td>
</tr>
<tr>
<td>Within 90 days</td>
<td>22.41</td>
<td>18.83</td>
<td>20.66</td>
</tr>
</tbody>
</table>

a “Informal caregiver” is defined as an adult coresident with the index member, as identified in the enrollment data held by the health plan.

b Ambulatory-care sensitive admissions were determined using the methods available at http://wagner.nyu.edu/faculty/billings/acs-algorithm.

ACS = ambulatory-care sensitive; ED = Emergency Department; GED = General Educational Development; HHC = home health care; SD = standard deviation; SNF = skilled nursing facility.
results predict care patterns as a function of this indicator and control variables. Control variables included annual trend; the index member’s age, sex, and health status (lagged a year to prevent confounding with current care patterns); type of Medicare coverage; and the patient’s neighborhood characteristics. These included distributions of race/ethnicity and education, and measures of poverty and language.

Our supplemental model interacts the presence of a caregiver with the caregiver’s age, sex, and health status to test the influence of these characteristics. For example, if the caregiver’s health status was poor, his/her caregiving effectiveness may be compromised.

RESULTS

Descriptive Results

Summary statistics are displayed in Table 1. Members without an identified caregiver were a year older on average, more likely to be female, and likelier to have dual Medicare/Medicaid coverage compared with members with an identified caregiver. The distributions of health risk and neighborhood characteristics were similar for both groups.

Those with a caregiver had a shorter average LOS in the hospital, had fewer ACS admissions, relied less on postacute care (SNF, HHC), and were less likely to require emergent care (readmissions, ED use) after discharge.

In addition, we have summarized the most frequent 10 diagnosis-related groups for index admissions and for 90-day readmissions in Table 2. The presence of joint replacement as a frequent diagnosis-related group in the 90-day readmission list emphasizes that not all readmissions are related to the index admission. We also included in Table 3 the 10 most frequent categories of ACS admissions, which were based on the Billings algorithm used. There was a strong concentration in ACS admissions; 75% were clustered in the top 4 conditions.

Impact of a Caregiver on Inpatient Admission and Care Transitions

Results of our multivariate analysis agree with those of the descriptive analysis. Figures 1 and 2, and the baseline results in Table 4, display the impact of having a caregiver on the index admission. Table 4 shows a small but statistically significant decline in average LOS (−0.10 days; p < 0.001; Figure 2) and a 3.6 percentage-point decline in the probability of an ASC admission associated with the presence of a caregiver (p < 0.001; Figure 3). We also estimated the impact of having a caregiver by type of ASC condition (data available on

Table 2. Most frequent diagnosis-related groups (DRGs) for index admissions and readmissions

<table>
<thead>
<tr>
<th>DRG</th>
<th>DRG description</th>
<th>Frequency, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>470</td>
<td>MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY W/O MCC</td>
<td>10.82</td>
</tr>
<tr>
<td>247</td>
<td>PERC CARDIOVASC PROC W DRUG-ELUTING STENT W/O MCC</td>
<td>2.68</td>
</tr>
<tr>
<td>871</td>
<td>SEPTICEMIA OR SEVERE SEPSIS W/O MV 96+ HOURS W MCC</td>
<td>2.50</td>
</tr>
<tr>
<td>392</td>
<td>ESOPHAGITIS, GASTROENT &amp; MISC DIGEST DISORDERS W/O MCC</td>
<td>2.42</td>
</tr>
<tr>
<td>378</td>
<td>GASTROINTESTINAL HEMORRAGE WITH CC</td>
<td>1.8</td>
</tr>
<tr>
<td>194</td>
<td>SIMPLE PNEUMONIA &amp; PLEURISY W MCC</td>
<td>1.85</td>
</tr>
<tr>
<td>872</td>
<td>SEPTICEMIA OR SEVERE SEPSIS W/O MV 96+ HOURS W MCC</td>
<td>1.64</td>
</tr>
<tr>
<td>310</td>
<td>CARDIAC ARRHYTHMIA &amp; CONDUCTION DISORDERS W/O CC/MCC</td>
<td>1.36</td>
</tr>
<tr>
<td>460</td>
<td>SPINAL FUSION EXCEPT CERVICAL W/O MCC</td>
<td>1.34</td>
</tr>
<tr>
<td>292</td>
<td>HEART FAILURE &amp; SHOCK W CC</td>
<td>1.31</td>
</tr>
</tbody>
</table>

Most frequent DRGs for 90-day readmissions

<table>
<thead>
<tr>
<th>DRG</th>
<th>DRG description</th>
<th>Frequency, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>470</td>
<td>MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY W/O MCC</td>
<td>5.39</td>
</tr>
<tr>
<td>871</td>
<td>SEPTICEMIA OR SEVERE SEPSIS W/O MV 96+ HOURS W MCC</td>
<td>4.78</td>
</tr>
<tr>
<td>291</td>
<td>HEART FAILURE &amp; SHOCK W MCC</td>
<td>2.35</td>
</tr>
<tr>
<td>392</td>
<td>ESOPHAGITIS, GASTROENT &amp; MISC DIGEST DISORDERS W/O MCC</td>
<td>2.26</td>
</tr>
<tr>
<td>194</td>
<td>SIMPLE PNEUMONIA &amp; PLEURISY W CC</td>
<td>2.17</td>
</tr>
<tr>
<td>385</td>
<td>PSYCHOSES</td>
<td>2.17</td>
</tr>
<tr>
<td>872</td>
<td>SEPTICEMIA OR SEVERE SEPSIS W/O MV 96+ HOURS W MCC</td>
<td>2.00</td>
</tr>
<tr>
<td>378</td>
<td>GASTROINTESTINAL HEMORRAGE WITH CC</td>
<td>1.74</td>
</tr>
<tr>
<td>190</td>
<td>CHRONIC OBSTRUCTIVE PULMONARY DISEASE W MCC</td>
<td>1.74</td>
</tr>
<tr>
<td>292</td>
<td>HEART FAILURE &amp; SHOCK W CC</td>
<td>1.48</td>
</tr>
</tbody>
</table>

Cardiovascular = cardiovascular; CC = complications and comorbidities; Digest = digestive; Gastroent = gastroenteritis; MCC = major complications and comorbidities; MISC = miscellaneous; MV = mechanical ventilation; PERC = percutaneous; PROC = procedure; W = with; W/O = without.

Table 3. Most frequent conditions indicating an ambulatory-care sensitive admission

<table>
<thead>
<tr>
<th>Billings code</th>
<th>Condition</th>
<th>Frequency, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>23</td>
<td>Secondary dehydration</td>
<td>23.16</td>
</tr>
<tr>
<td>11</td>
<td>Congestive heart failure</td>
<td>20.17</td>
</tr>
<tr>
<td>9</td>
<td>Bacterial pneumonia</td>
<td>17.70</td>
</tr>
<tr>
<td>8</td>
<td>Chronic obstructive pulmonary disease</td>
<td>12.55</td>
</tr>
<tr>
<td>14</td>
<td>Cellulitis</td>
<td>6.28</td>
</tr>
<tr>
<td>21</td>
<td>Kidney/urinary infection</td>
<td>6.05</td>
</tr>
<tr>
<td>27</td>
<td>Secondary nutritional deficiencies</td>
<td>2.25</td>
</tr>
<tr>
<td>10</td>
<td>Asthma</td>
<td>2.20</td>
</tr>
<tr>
<td>22</td>
<td>Primary dehydration</td>
<td>1.93</td>
</tr>
<tr>
<td>12</td>
<td>Hypertension</td>
<td>1.59</td>
</tr>
</tbody>
</table>

Figure 1. Projected average length of stay by caregiver status.

* Statistical significance of difference is p < 0.001.

Figure 2. Projected average length of stay by caregiver status.

Figure 3. Projected average length of stay by caregiver status.

Figure 4. Projected average length of stay by caregiver status.

Figure 5. Projected average length of stay by caregiver status.
request to the corresponding author ([CSC]) and found consistently negative marginal effects across conditions, although our statistical power weakened.

Likewise, these baseline results in Table 4 show a 0.33 percentage-point decrease in the likelihood of a hospital discharge to SNF (p < 0.05; Figure 3) and a 1.46 percentage-point reduction in the likelihood of receiving HHC visits when a caregiver was present (p < 0.001; Figure 3). Finally, baseline results in Table 4 show a projected reduction in emergent care when a caregiver was present. Ninety-day readmissions were reduced by 0.82 percentage points (p < 0.05; Figure 4) and ED use within 90 days was reduced by 2.26 percentage points (p < 0.001; Figure 4). Smaller, 30-day measures are shown in Figure 4, which were statistically significant only for ED use.

Economic Value of Informal Caregiving

We calculated the dollar-denominated savings from informal caregiving as the product of average payments with the marginal effects of caregivers. We averaged the total paid by the plan and the member across our sample years for SNF admissions, HHC visits, ED visits, and readmissions. The payments for post- patient SNF were $5240 per admission, $3593 per postinpatient HHC episode, $410 per ED visit within 90 days of discharge, and $5524 per readmission within 90 days of discharge. Multiplying these payments by the marginal effect of informal caregiving, we compute a savings of $124.31 per index inpatient discharge. Although this is a small dollar amount per individual, the national impact is substantial. There were 9,743,275 Medicare inpatient discharges in 2015. We use a 15% readmission rate to estimate 8,472,000 index admissions. Assuming our computed savings per discharge and 48.8% caregiver prevalence are representative of national averages, Medicare benefited from $514 million in savings from informal caregiving in 2015.

Differences in Impact by Spousal Characteristics

To test how these impacts vary by caregiver characteristics, we reestimated our model, including interactions with the caregiver’s age, sex, and health status. The final column of Table 4 shows these differences by caregiver type, displayed next to the average impact from our baseline model. The reference caregiver in this model has low health risk, is male, and is in the age group 65 to 74 years. The impact of this reference caregiver is shown on the “Informal caregiver present” line for each outcome. To obtain the net impact for other types of caregivers, the increments listed should be added to this reference amount. For example, the reference 70-year-old, male, healthy caregiver is expected to reduce the probability of HHC use by 3.46 percentage points. In
Reduced Health Care Utilization among Elderly Patients with Informal Caregivers

In contrast, a 70-year-old, male, high-health risk caregiver would reduce the probability of HHC use by only 1.92 percentage points \((-0.0346 + 0.0154)\).

The heterogeneity of the caregiver’s impact on LOS is mixed. Sicker caregivers are associated with a shorter LOS; female caregivers, with a longer LOS; and the variance by age is nonlinear.

Among the other outcomes, the presence of a caregiver who is of high health risk increases the probability of HHC use, relative to the presence of a healthy caregiver. Female caregivers are associated with a greater probability of an ACS admission and a higher probability of a 90-day readmission, relative to the presence of a male caregiver. Caregivers under age 65 years are associated with a higher probability of an ACS admission and a greater need for HHC use.

### Table 4. Differences in impact of informal caregiver’s presence caused by characteristics of the informal caregiver

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Baseline model</th>
<th>With informal caregiver characteristics</th>
<th>Outcome</th>
<th>Baseline model</th>
<th>With informal caregiver characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in average length of stay, d</td>
<td>Informal caregiver present</td>
<td>-0.10*</td>
<td>-0.12*</td>
<td>Informal caregiver present</td>
<td>-0.0146*</td>
</tr>
<tr>
<td></td>
<td>Increment if informal caregiver is at high/very high health risk</td>
<td>-0.12*</td>
<td></td>
<td>Increment if informal caregiver is at high/very high health risk</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increment if informal caregiver is female</td>
<td>0.12*</td>
<td></td>
<td>Increment if informal caregiver is female</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increment if informal caregiver is in age range, y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Less than 55</td>
<td>0.18</td>
<td></td>
<td>Less than 55</td>
<td>0.1177*</td>
</tr>
<tr>
<td></td>
<td>55-64</td>
<td>-0.32*</td>
<td></td>
<td>55-64</td>
<td></td>
</tr>
<tr>
<td></td>
<td>65-74</td>
<td>Reference</td>
<td></td>
<td>65-74</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>75-84</td>
<td>0.05</td>
<td></td>
<td>75-84</td>
<td>0.0058</td>
</tr>
<tr>
<td></td>
<td>85 or older</td>
<td>-0.04</td>
<td></td>
<td>85 or older</td>
<td>0.0175</td>
</tr>
<tr>
<td>Change in probability of ambulatory-care sensitive admission, pp</td>
<td>Informal caregiver present</td>
<td>-0.0361*</td>
<td>-0.0606*</td>
<td>Informal caregiver present</td>
<td>-0.0082*</td>
</tr>
<tr>
<td></td>
<td>Increment if informal caregiver is at high/very high health risk</td>
<td>0.0049</td>
<td></td>
<td>Increment if informal caregiver is at high/very high health risk</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increment if informal caregiver is female</td>
<td>0.0235*</td>
<td></td>
<td>Increment if informal caregiver is female</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increment if informal caregiver is in age range, y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Less than 55</td>
<td>0.0664*</td>
<td></td>
<td>Less than 55</td>
<td></td>
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<tr>
<td></td>
<td>55-64</td>
<td>0.0174</td>
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<td>55-64</td>
<td>-0.0180</td>
</tr>
<tr>
<td></td>
<td>65-74</td>
<td>Reference</td>
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<td>-0.0001</td>
</tr>
<tr>
<td></td>
<td>75-84</td>
<td>0.0181</td>
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<td>75-84</td>
<td>0.0071</td>
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<td></td>
<td>85 or older</td>
<td>0.0108</td>
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<td>85 or older</td>
<td>0.0062</td>
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<tr>
<td>Change in probability of skilled nursing facility use, pp</td>
<td>Informal caregiver present</td>
<td>-0.0033*</td>
<td>-0.0073*</td>
<td>Informal caregiver present</td>
<td>-0.0226*</td>
</tr>
<tr>
<td></td>
<td>Increment if informal caregiver is at high/very high health risk</td>
<td>0.0019</td>
<td></td>
<td>Increment if informal caregiver is at high/very high health risk</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increment if informal caregiver is female</td>
<td>0.0032</td>
<td></td>
<td>Increment if informal caregiver is female</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increment if informal caregiver is in age range, y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Less than 55</td>
<td>-0.0036</td>
<td></td>
<td>Less than 55</td>
<td></td>
</tr>
<tr>
<td></td>
<td>55-64</td>
<td>0.0002</td>
<td></td>
<td>55-64</td>
<td>0.0407</td>
</tr>
<tr>
<td></td>
<td>65-74</td>
<td>Reference</td>
<td></td>
<td>65-74</td>
<td>-0.0253</td>
</tr>
<tr>
<td></td>
<td>75-84</td>
<td>0.0018</td>
<td></td>
<td>75-84</td>
<td>-0.0021</td>
</tr>
<tr>
<td></td>
<td>85 or older</td>
<td>0.0105</td>
<td></td>
<td>85 or older</td>
<td>-0.0008</td>
</tr>
</tbody>
</table>

* The “Informal caregiver present” impact in the baseline model is the average across all informal caregivers.

# The “Informal caregiver present” impact in this model is for a reference informal caregiver who is healthy or at low health risk, male, and aged 65 to 74 years. Increments listed are added to this reference change in length of stay or probability to get the impact for informal caregivers of other characteristics.

1. p < 0.001.
2. p < 0.01.
3. p < 0.05.
4. p < 0.1.
5. -0.01 = 1 percentage-point decrease in probability.
6. pp = percentage point.
Robustness Testing
To test the robustness of our results, we reestimated our baseline model using populations in which the spouse was less likely to still be on an employment-based Health Plan from another carrier, and thus missingness of data should be reduced (females only, members aged 70 years and older). In these subgroups, we found that the impact of caregivers on patterns of care were nearly identical to those presented here.

Discussion
The reductions in utilization when a coresident caregiver is present, although small at the member level, are meaningful when aggregated to the national level. Moreover, the heterogeneity in the effect of informal caregiving on care utilization by caregiver characteristics deserves further discussion.

In general, we would expect to see the greatest reductions in utilization when the caregiver is young and in good health and, because of caregiving acculturation, when the caregiver is female. However, our results show that this is not always the case. Specifically, we found that the index admission had a shorter LOS when the caregiver was in poor health, a longer LOS when the caregiver was female, and the impact of caregiver age on LOS was nonlinear. We found increased probability that the index admission was an ambulatory-care-sensitive admission when the caregiver was female and/or under age 65 years. Unexpected outcomes in postdischarge care occurred with higher readmission rates for female caregivers and higher home health use for caregivers under age 65 years.

We can develop possible conceptual models that explain these initially counterintuitive results. For example, caregiving acculturation may make female caregivers more sensitive to changes in patient health and more likely to advocate for aggressive care, leading to more ambulatory-care-sensitive admissions, higher frequency of readmissions, and longer lengths of stay. Longer lengths of stay and more HHC use when the caregiver was younger than age 65 years may indicate conflict between caregiving and continued employment. Finally, shorter lengths of stay when the caregiver was in poor health may indicate reciprocal caregiving, with the admitted patient anxious to be discharged and get home to care for an ailing spouse. It is clear that additional quantitative and qualitative research is needed to help us understand these complex patterns.

Limitations
Our data came from a single Midwest carrier; hence, our results may not be generalizable to other regions across the nation. In addition, we have chosen to focus on Medicare patients because of the higher relevance of inpatient use for those older than age 65 years. The impact of family support is likely different when the index population is younger.

It is important to note that this carrier’s Medicare coverage was a Medicare cost product, not a Medicare Advantage product. Although this distinction primarily affects the way the carrier is reimbursed by Medicare and does not directly affect the way the carrier reimburses providers, there may be situations where there is a trickle-down impact. This risk to generalizability may be greater when the carrier and the providers are vertically integrated.

In our data, we identified an adult in the home through address matching by the Health Plan. Because most caregivers in our data are spouses, it is reasonable to expect they received their Medicare coverage from the same carrier. Nevertheless, it is possible that a caregiver was not identified in our sample because s/he was uninsured or was insured by carriers other than the Health Plan contributing data to our study. This is particularly likely when one member reached age 65 years and qualified for Medicare while his/her younger spouse still received employment-based coverage through a different carrier. We were also unable to identify sources of support who were not coresident with the index member. However, unidentified caregivers will bias our parameter estimates toward zero; therefore, our results can be viewed as a lower bound on the impact of caregivers.

In addition, the address of record may not reflect the residence of the patient. Although the carrier nominally records both address of residence (used for address matching) and mailing address, it is possible that these are confounded. The risk is greatest in situations such as the patient residing in custodial care with paperwork sent elsewhere, or an adult child receiving mail to provide financial and logistical support to his/her parents. In the latter case, we would have a similar bias toward zero as discussed in the preceding paragraph. To address the former scenario, we minimized the risk of treating a patient in custodial care as a patient without a caregiver by removing all observations in which the patient received any care with placement of service code 33, indicating custodial care. We believe it is unlikely that a patient would have both incorrectly recorded addresses and an index inpatient admission without any in-home care before or after the admission reflecting the placement of service code 33, but recognize that there is a risk of this misidentification.

Finally, it should be noted that the observed readmission rates we identified are dramatically lower than published statistics for Medicare populations. There are a number of explanatory factors, including the very low readmission rates in our geographic region and the index admission selection process we use, but none completely explain this difference. Because this is a Medicare cost product, there is a real risk that our use of claims data means that we are unable to observe all readmissions. This, again, biases our estimate of the impact of caregivers toward a lower bound.

Policy Implications
The need for and provision of care at home has been on the rise because of the aging of the US population, prevalence of chronic conditions, and shorter hospital stays. About 66 million Americans in 2011 benefited from 1 or more unpaid
caregivers, typically family caregivers. By 2030, 1 in 5 adults will be aged 65 years or older, increasing the demand for caregiving—formal and informal.

The important role that families play in discharge planning has been discussed but not quantified. By calculating the impact of informal caregiving on patterns of health care utilization, we support the need to integrate the availability of caregivers as an input into discharge planning. Our documentation of differential impact by caregiver characteristics suggests this is an important area for future investigation. Although continued systematic integration of informal caregivers into discharge planning decisions is suggested to yield important benefits for complex and frail patients in the US and abroad, our findings that patients are more likely to be discharged sooner and to home settings when a caregiver is present suggest that the discharge process is already, at least to some degree, attentive of informal caregiving.

**CONCLUSION**

We estimated the impact of informal caregivers after an inpatient discharge to be substantial when aggregated to the national level. Continued integration of caregivers into discharge planning, taking into account the differences in caregiver characteristics, is an important factor in the efficient delivery of health care.

**Disclosure Statement**

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

**Acknowledgments**

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**References**


**Come Alive**

Don’t ask what the world needs. Ask what makes you come alive, and go do it.

Because what the world needs is people who have come alive.

— Howard Thurman, 1899-1981, author, philosopher, theologian, educator, and civil rights leader
Mastectomy or Breast-Conserving Therapy: Which Factors Influence A Patient’s Decision?

David Moiel, MD; John Thompson, MD; Kenneth D Larsen, MD, PhD

E-pub: 06/14/2019

ABSTRACT

Background: The choice between mastectomy and breast-conserving therapy (BCT) is a first step for patients with breast cancer who are confronting decisions about treatment. Objectives: To identify the most important determinants in treatment decision making by patients with breast cancer. Methods: Between 2003 and 2013, a total of 5258 patients with breast cancer were recorded in Kaiser Permanente Northwest’s cancer registry. Patients had similar clinical-pathologic profiles, education, and insurance coverage, and were managed by 1 surgical group. A total of 2604 patients with invasive breast cancer chose mastectomy or BCT as they met unambiguous criteria for equivalent outcomes with either option. We examined the influence of the patient’s surgeon on patient preferences. Results: Our retrospective analyses examined a study population that had similar risk profiles (age, family history of breast cancer, T category on tumor-node-metastasis staging system, tumor size, physical examination findings), surgeons consulting on similar patient types, and managed by surgeons with similar surgical performance patterns (case volumes, reexcision rates, number of reoperations, and ability to meet patient’s expectations). Patients who preferred mastectomy were strongly influenced by tumor size (p < 0.001) and abnormal physical examination findings (palpable mass; p = 0.004), rather than age, family history of breast cancer, T category, or surgeon. Conclusion: Physical examination findings and tumor size were statistically significant determinants influencing patients to choose mastectomy. Because geographic and practice style explanations fail to explain these variations, surgeons can identify, anticipate, and consider these factors when counseling patients about mastectomy and BCT therapeutic equivalency.

INTRODUCTION

Patients with breast cancer are presented and must understand complicated information about the disease and treatment choices before deciding on treatment. Mastectomy continued to be the most common breast cancer surgical operation performed up to and during the 1980s, even though early results of a randomized controlled trial comparing radical mastectomy surgery and breast-conserving therapy (BCT; ie, lumpectomy, lymph node dissection, and radiotherapy) in 1977 showed that recurrence and survival rates were comparable.1 2 3 With the introduction of mammographic screening (1960s),2 breast ultrasonography (1980s),3 and magnetic resonance imaging (1990s),4 5 6 the size of breast cancers detected decreased. Advances in tissue biopsy (core biopsy, needle localization,7 and fine-needle aspiration8 9) as well as tissue handling (staining, marking, sectioning, imprints, and specimen radiography) and pathologic interpretation contributed to the shift to BCT over mastectomy. The transition from a 2-stage to 1-stage BCT procedure also influenced patients. By 1990 the National Cancer Institute reported follow-up results, measured by patients’ local recurrence and survival rates for tumor-node-metastasis (TNM) staging (T1N0, T2N0, T3N0),10 11 which confirmed that mastectomy and BCT were therapeutically equivalent.

The transition from the Halsted concept that breast cancer was a localized disease to our current understanding that it is a systemic disease was difficult for the public, patients, and many surgeons.12 13 Although estimates that three-fourths of patients with invasive breast cancer are candidates for BCT, rates of BCT varied nationally.14 With the controversy about the surgical mastectomy and BCT equivalency over, it was unclear why substantial national geographic variations persisted as rates of mastectomy and prophylactic mastectomy increased. We therefore sought to examine the surgeon’s influence on patient choice of treatment of breast cancer.15 Was the patient preference predicated on her personal risk profile or by her surgeon?2 Did surgeon-specific performance (BCT and reexcision rates, secondary reexcision strategies, and case volumes) influence the patient decision making?16 17 18 19 20 21 We studied a series of patients with similar risk profiles in 1 health care entity using measurable standardized processes to assess the influence of age, family history of breast cancer, T category, tumor size, physical examination (PE) findings, and the surgeon on treatment choices.

METHODS

Information on all patients with breast cancer (2003-2013) was drawn from the Kaiser Permanente Northwest (KPNW) cancer registry,19 electronic medical record, and pathologic and imaging reports. The study included patients with invasive breast cancer (Table 1) who met study criteria in which there was an outcome universally considered equivalent for either a mastectomy or BCT. Certain patient, tumor pathology, and treatment factors were excluded from the study to ensure we compared a uniform set of patients. The excluded patient factors were men, women younger than age 30 years or older than age...
89 years, those with a personal history of prior breast cancer, and those with a BRCA gene mutation or family history of BRCA mutation. The pathologic factors excluded were lobular carcinoma in situ, intraductal carcinoma, and anomalous pathologies (clear-cell, giant-cell, non-small cell, and signet-ring cell carcinomas; inflammatory breast cancer; melanoma; Paget disease of the nipple; phyllodes tumors; sarcoma; squamous cell breast cancers), TNM stage 4 tumors (> 70 mm),\textsuperscript{20} and multicentric and bilateral breast cancers. Patients who refused treatment, had neoadjuvant therapy, underwent mantle-field or chest radiation therapy, or had a history of breast reduction or augmentation were excluded.

All the preoperative counseling was performed by 38 board-certified surgeons. Although all new cancers were reviewed by regional tumor boards, case discussions focused on cases of general interest, complexity, rarity, or close or positive margins, or at the request of clinicians. Surgeons usually recommended reexcision for close margins because margins less than 5 mm were inadequate and too close because of the risk of local recurrence, although consensus guidelines about the adequacy of margins have evolved during the study period. To assess the surgeon’s influence on patient preferences, we extracted surgeon-specific performance metrics from the registry database. Surgeon profiles included documentation of successful mastectomy (no tumor on margin) or lumpectomy (margins > 1-2 mm); number of BCT operations (1-4 reoperations); reexcision cascade (unsuccessful lumpectomy, reexcision, second or third unsuccessful reexcisions, and follow-up mastectomy or bilateral mastectomy); percentage of patients who were successfully managed to their BCT preference; and data successful mastectomy, or bilateral mastectomy (contralateral prophylactic) rates. There were 13 surgeons in continuous practice during the whole study period who were defined as high-volume (75-169 patients). The remaining 25 low-volume (12-74 patients) had discontinuous breast cancer practices as subspecialists, retirees, and new hires.

JASP Version 0.8.5 software (University of Amsterdam, Amsterdam, The Netherlands) was used for statistical analyses of linear and logistic regression, analysis of variance (ANOVA), and \( \chi^2 \) tests.

### RESULTS

#### Historical Performance

The overall KPNW BCT rates for all patients with breast cancer, increased from 28% (1980-1989), to 50% (1990-1999), and then to 61% (2000-2009). The overall KPNW BCT preference rate for the study’s patients was 78% (2003-2013). Using the same exclusionary criteria that defined our study population, we determined that KPNW’s local recurrence rates for mastectomy and BCT local recurrence rates were similar (1990-1999 operative cohort: Mastectomy, 1.8%; BCT, 3.1%; 2000-2009 operative cohort: Mastectomy, 1.0%; BCT, 1.9%; 2010-2013 operative cohort: Mastectomy, 0.4%; BCT, 0.4%), demonstrating a statistically significant (\( p < 0.0001 \) by \( \chi^2 \) test) decline between 1990 and 2013. Of note, the local recurrence rates for mastectomy and BCT were remarkably lower than the 10% rate reported decades earlier.\textsuperscript{21,22}

#### Patient Profiles

All 2604 study patients had invasive breast cancer; were insured in the same prepaid health maintenance organization (HMO); were provided a similar preoperative educational experience; counseled by members of 1 surgical group; met the same selection criteria (sex, age, pathology, PE findings, and family history; Table 1); and offered equivalent treatment choices of either mastectomy or BCT. A linear regression analysis was employed to see if there was a change in any variable during the study period, including age, family history of breast cancer, PE findings, tumor size, T category, and patient preference for surgical therapy (Table 2). As shown in Table 3, ANOVA was used to see if patient characteristics varied across surgeons. There was no finding of significance for any of the variables, meaning the different surgeons saw a similar population of patients.

#### Surgeon Performance

In examining surgeon-specific performance (case volumes, reexcision rates, and success rates of achieving initial patient preferences), there was no evidence that

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**Table 1. Profile of the 2604 study patients**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, y</strong></td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>83 (3)</td>
</tr>
<tr>
<td>40-49</td>
<td>369 (14)</td>
</tr>
<tr>
<td>50-59</td>
<td>713 (27)</td>
</tr>
<tr>
<td>60-69</td>
<td>800 (31)</td>
</tr>
<tr>
<td>70-79</td>
<td>436 (17)</td>
</tr>
<tr>
<td>80-89</td>
<td>203 (8)</td>
</tr>
<tr>
<td><strong>TNM T category</strong></td>
<td></td>
</tr>
<tr>
<td>T1mic: (&lt; 1 mm)</td>
<td>66 (3)</td>
</tr>
<tr>
<td>T1A: (&gt; 1 mm to ≤ 5 mm)</td>
<td>186 (7)</td>
</tr>
<tr>
<td>T1B: (&gt; 5 mm to ≤ 10 mm)</td>
<td>527 (20)</td>
</tr>
<tr>
<td>T1C: (&gt; 10 mm to ≤ 20 mm)</td>
<td>1126 (43)</td>
</tr>
<tr>
<td>T2: (&gt; 20 mm to ≤ 50 mm)</td>
<td>685 (26)</td>
</tr>
<tr>
<td>T3: (&gt; 50 mm)</td>
<td>14 (1)</td>
</tr>
<tr>
<td><strong>Family history of breast cancer</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1057 (41)</td>
</tr>
<tr>
<td>No</td>
<td>1547 (59)</td>
</tr>
<tr>
<td><strong>Physical examination finding (mass)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1243 (48)</td>
</tr>
<tr>
<td>No</td>
<td>1345 (52)</td>
</tr>
<tr>
<td><strong>Unknown</strong></td>
<td>16 (&lt; 1)</td>
</tr>
<tr>
<td><strong>Patient preference</strong></td>
<td></td>
</tr>
<tr>
<td>Breast-conserving therapy</td>
<td>2039 (78)</td>
</tr>
<tr>
<td>Mastectomy</td>
<td>565 (22)</td>
</tr>
</tbody>
</table>

**Table 2. Linear regression of year vs patient variables during the 2003-2013 study period showing no significant change over time**

<table>
<thead>
<tr>
<th>Model</th>
<th>Patient variable</th>
<th>Unstandardized</th>
<th>SE</th>
<th>Standardized</th>
<th>t</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>(Intercept)</td>
<td>2007.895</td>
<td>0.454</td>
<td>4422.064</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Age</td>
<td>-9.689</td>
<td>0.005</td>
<td>-0.004</td>
<td>-0.187</td>
<td>0.852</td>
</tr>
<tr>
<td></td>
<td>Family history</td>
<td>-0.034</td>
<td>0.125</td>
<td>-0.005</td>
<td>-0.023</td>
<td>0.785</td>
</tr>
<tr>
<td></td>
<td>PE finding</td>
<td>0.086</td>
<td>0.137</td>
<td>0.014</td>
<td>0.626</td>
<td>0.935</td>
</tr>
<tr>
<td></td>
<td>Tumor size</td>
<td>0.010</td>
<td>0.010</td>
<td>0.001</td>
<td>1.005</td>
<td>0.315</td>
</tr>
<tr>
<td></td>
<td>T category</td>
<td>-0.008</td>
<td>0.104</td>
<td>-0.033</td>
<td>0.082</td>
<td>0.935</td>
</tr>
<tr>
<td></td>
<td>Patient preference</td>
<td>0.011</td>
<td>0.153</td>
<td>0.001</td>
<td>0.069</td>
<td>0.945</td>
</tr>
</tbody>
</table>

PE = physical examination; SE = standard error.
Mastectomy or Breast-Conserving Therapy: Which Factors Influence A Patient’s Decision?

surgeon performance influenced patient preference. The ratio of total number of surgeries required to satisfy the patient’s preference (2016/1530) was similar for the 13 highest-volume surgeons (1.32 ± 0.05, not significant). Achieving BCT success varied by tumor size, with the greater difficulty occurring with the smallest (< 5 mm) and largest tumors (> 50 mm to < 71 mm; Figure 1). Most surgeons recommended a reexcision for positive or close margins (> 1 mm to < 10 mm), consistent with tumor board recommendations. The reoperative rates for close or positive margins was similar for both palpable and nonpalpable lesions (Figure 2). We observed no significant variation in the reoperative patterns during the study period (Figure 3). The 8 reoperative strategies included reexcision, mastectomy, or bilateral mastectomy. From 2003 to 2013, BCT, as the first procedure, was successful 63% of the time. Seventy-eight percent of patients preferred the BCT strategy.

**Decision-making Determinants**

Patient preference (for mastectomy or BCT) vs other patient characteristics was analyzed with logistic regression to see which, if any, factors were related to preference (Table 4). Tumor size and palpability (size and PE findings) were significantly related to patient preference (Figure 4). The surgeon was not related to patient choice, nor was family history, age, or cancer stage. Preoperative palpable findings usually correlated with tumor size and T category, although we noted that some larger tumors had no PE findings and abnormal PE findings were described for some small tumors. The absence of an association of BCT preference with size and not T category may be explained by how T category is defined by using a size range, thus reducing the importance of tumor size measurements. The association between PE findings and tumor size and patient preference over a long study time period have been consistent, as have the reoperative strategies supporting patient’s initial preferences.

**DISCUSSION**

As increasing and ever-changing treatment options for patients with breast cancer have made decision making more complex, surgeons are expected to meet patient expectations. In our review of the last 3 decades at KPNW, more than 50% of the breast cancers were diagnosed preclinically (no palpable mass),23 BCT rates slowly increased,24 patient preference for BCT was frequently met at the same rate over time, and there was a decline in the rates of reexcision and local recurrence. We believe these achievements are a consequence of increased mammography screening, standardization of patient educational materials, multidisciplinary care coordination, and improvements in surgical performance.

Even though there has been universal acceptance of BCT and mastectomy equivalency for most new patients with breast cancer, BCT national rates have

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**Table 3. ANOVA test of surgeons vs patient variables showing no significant difference in patient characteristics between surgeons**

<table>
<thead>
<tr>
<th>Patient variable</th>
<th>Sum of squares*</th>
<th>df</th>
<th>Mean square</th>
<th>F</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage</td>
<td>923.702</td>
<td>5</td>
<td>184.740</td>
<td>1.539</td>
<td>0.174</td>
</tr>
<tr>
<td>PE finding</td>
<td>255.809</td>
<td>1</td>
<td>255.809</td>
<td>2.131</td>
<td>0.144</td>
</tr>
<tr>
<td>Age</td>
<td>5789.444</td>
<td>59</td>
<td>98.126</td>
<td>0.818</td>
<td>0.838</td>
</tr>
<tr>
<td>Family history</td>
<td>2.777</td>
<td>1</td>
<td>2.777</td>
<td>0.023</td>
<td>0.879</td>
</tr>
<tr>
<td>Patient preference</td>
<td>20.827</td>
<td>1</td>
<td>20.827</td>
<td>0.174</td>
<td>0.677</td>
</tr>
<tr>
<td>Tumor size</td>
<td>6992.241</td>
<td>62</td>
<td>112.778</td>
<td>0.940</td>
<td>0.611</td>
</tr>
<tr>
<td>Residual disease</td>
<td>296,920.868</td>
<td>2474</td>
<td>120.017</td>
<td>0.611</td>
<td>0.611</td>
</tr>
</tbody>
</table>

* Type II sum of squares.

ANOVA = analysis of variance; df = degrees of freedom; PE = physical examination.
plateaued or declined in some geographic and practice settings since 1998. These trends stimulated the question: Why, when three-fourths of women are BCT candidates, are fewer patients choosing BCT? Authors have attributed this phenomenon to numerous possible factors. They include evolution of roles in the informed consent process and inadequacy of patient educational materials, insurance coverage, access to care and treatment facilities, radiation therapy, length of treatments, travel time for treatment and work loss, marital status, a woman’s sexuality and body image, education, socioeconomic status, race, surgeon’s sex, primary counseling by resident trainees and lack of face-to-face time with the surgeon, previous cancer surgery, increased preoperative use of magnetic resonance imaging, and anxiety and fear.

This investigation, focusing on a large equal-risk population managed by 1 surgical group, assessed the influence of common metrics for tumors and surgical performance. Patients, physicians, and surgeons were contending with the shift from the “physician-as-expert” decision-making process to a patient-centered approach. This was awkward, time-consuming, and a challenge for many clinicians. Increasingly, patients came to their surgeon having “researched” their options from friends, pamphlets, breast cancer calculators, and information from the Internet. Although some patients appeared prepared, many were unable to recall basic information. Recognizing this, clinicians encouraged patients to bring partners, family members, and friends to the visit because the process is overwhelming. By providing standardized breast cancer treatment information packets and access to computer information, we were better able to assess the influence of the surgeon on the patient’s decision making.

Our study reviewed the preferences of patients with invasive breast cancer who were excellent candidates for either mastectomy or BCT (Table 1), excluding patients in whom decision making was more complicated. KPNW provided expert care at low out-of-pocket cost to patients with breast cancer with access to multiple specialists (plastic surgeons, second opinions, genetics and cancer counselors, support groups, and recently navigators for patients with breast cancer) and had a standard informed consent process. Patients were insured by the same insurer, were provided with standardized preoperative education tools, and had similar personal risk profiles (age, pathology, tumor size, T category, family history of breast cancer, and PE findings).

We studied whether and how patient-specific variables of age, T category, tumor size, PE palpable findings, family history of breast cancer, and the surgeon influenced a patient’s decision for mastectomy or BCT. The discovery of a palpable mass by self-examination, during mammography, or on clinical examination is a statistically significant factor in a patient’s choice of mastectomy, despite evidence that a BCT strategy provided equivalent outcomes. Tumor size was also an influential factor leading women to favor mastectomy. These 2 variables stand out as predictors of distress. Because tumor size and PE findings are available to surgeons, surgeons should acknowledge their influence on BCT decision making and can tailor discussions to allay fears. Patients must be clear about common misconceptions about breast cancer and treatments. Reported rates of reexcision, ipsilateral breast tumor recurrence, lifetime risk of contralateral breast
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CONCLUSION

Patients with breast cancer must manage the anxiety and fears of their new diagnosis and must search for their best treatment options. Physicians and other health support systems can provide information and expertise as patients consider their next steps. We assume that patients consider the information and data we provide, although they may be making their decisions through the lens of anxiety and fear. We examined the influence of age, family history of breast cancer, TNM category, tumor size, PE findings, and surgeon experience to understand whether any of these factors play a significant role when patients decide between a mastectomy and BCT. We identified tumor size and the presence of PE findings as the most significant contributors to a mastectomy choice. By recognizing these risk factors, surgeons can anticipate and then explicitly address these factors as they partner with their patients. If surgeons consider these known factors as they begin counseling patients about mastectomy and BCT equivalency, the rates of BCT may increase, reducing unexplained geographic and practice variations.

“Doctors search for supportive signs in the medical laboratories to develop a therapeutic attack plan, while I searched through my memory and psyche.”

—Entry from the diary of a patient with breast cancer, 1979

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

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How to Cite this Article

References
Habit of Operating

I personally am in the habit of operating for cancer arising in the breast thusly: I make the patient lie down; then I incise the healthy part of the breast beyond the cancerous area and I cautere the incised parts. … Following amputation of the entire breast, I cautere again all areas until all bleeding has ceased.

— Aëtius of Amida, 502 AD-575 AD, Byzantine Greek physician and medical writer
Original Research & Contributions

Rapid Implementation of Intraoperative Ultrasonography to Reduce Wire Localization in The Permanente Medical Group

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Abstract

Context: Preoperative wire localization (WL), the most common localization technique for nonpalpable breast lesions, has drawbacks including scheduling constraints, cost, and patient discomfort.

Objective: To reduce WL use in our health care system, we investigated using hydrogel clips to facilitate intraoperative ultrasonography-guided lumpectomies.

Design: We retrospectively reviewed electronic medical records of patients with nonpalpable, ultrasound-visible breast lesions who underwent lumpectomy by 7 surgeons at 4 pilot sites in Kaiser Permanente Northern California between January 2015 and October 2015. Hydrogel clips, used for several years before the study period, were placed routinely during core-needle biopsy in all patients with nonpalpable, ultrasound-visible breast lesions.

Main Outcome Measures: Localization method, lesion size, margin positivity, and receipt of neoadjuvant therapy.

Results: One hundred forty-three patients underwent hydrogel clip placement and lumpectomy by pilot-site surgeons. Localization consisted of intraoperative ultrasonography alone, preoperative skin marking, or WL. Of the 143 patients, 71.3% did not need WL (60.8% ultrasonography alone and 10.5% skin marking). The non-WL and WL groups had similarly sized lesions, and the positive margin rate was 7.2% overall, with no significant difference between the non-WL and WL groups (5.9% vs 11.5%, p = 0.33). Of the 12 patients who underwent neoadjuvant chemotherapy, 8 (67%) did not require WL.

Conclusion: A multifacility protocol using intraoperative ultrasonography to visualize hydrogel clips was implemented, which decreased WL procedures and produced no significant difference in margin positivity between the WL and non-WL groups. This technique can be a cost-effective alternative to WL in patients who are candidates for hydrogel clip placement.

Introduction

The number of nonpalpable breast lesions detected on routine screening has increased with improving imaging technology, creating new challenges as surgeons must localize these lesions before removing them. The most common localization technique is preoperative placement of a wire, which has major drawbacks, including patient discomfort and delays to the operating room (OR) on the day of surgery.

Alternatives to wire localization (WL) include radioactive seed placement, placement of nonradioactive seeds, intraoperative ultrasonography, and intraoperative ultrasonography aided by an ultrasound-visible clip. Radioactive seeds have been used with excellent results. Unfortunately, the resources required to manage radioactive seeds can outweigh the benefits of the technique. Furthermore, seed placement requires a second procedure before surgery. Several nonradioactive seed products have come onto the market, but data on these products are limited, the seeds can be very expensive, and they too require a second procedure for seed placement before surgery.

Another approach is intraoperative ultrasonography. One advantage of this technique is that most hospital systems already have ultrasonography machines, which minimizes additional costs. The main downside is that intraoperative ultrasonography alone is very operator dependent, and this technique can be difficult to implement across large, diverse medical systems.

Several groups have described using hydrogel-based, ultrasound-visible clips (HydroMARK, Leica Biosystems, Cincinnati, OH) to facilitate intraoperative ultrasonography. When the clip is placed during biopsy, it looks like a typical metal clip. Within a few days after deployment, the biodegradable hydrogel polymer that surrounds the clip absorbs fluid from adjacent tissue, creating a hypoechoic, ultrasound-visible “bubble.” Excision rates, specimen sizes, and complication rates are comparable between this technique and traditional WL. Furthermore, this technique does not require extra equipment other than the clip, and patients do not undergo procedures beyond the initial biopsy. Previous studies have described single-center and/or single-surgeon experiences. We hypothesized that we could rapidly implement intraoperative ultrasonography aided by hydrogel clips across a large, diverse health care system to decrease WL use without sacrificing quality measures.

Methods

As part of a performance improvement project to decrease WL, 4 Kaiser Permanente Northern California (KPNC) pilot sites used hydrogel clips in combination with intraoperative ultrasonography for patients undergoing lumpectomy. The breast imaging teams at each of these facilities had used hydrogel clips routinely for several years before initiation of this study to...
percutaneously mark all lesions undergoing biopsy using ultrasound guidance. Postbiopsy mammograms were performed after each biopsy to assess the accuracy of clip placement. Our study focused on nonpalpable, ultrasound-visible lesions identified during diagnostic workup of abnormalities identified on screening mammography. Patients with malignant, high-risk, or benign but discordant biopsy results were referred to the respective facility's Surgery Department, and pilot-site surgeons performed office-based ultrasonography during the initial office consultation to determine whether these patients were candidates for intraoperative ultrasonography. If the surgeon could visualize the clip and/or the mass easily with ultrasonography in the office, no additional localization procedures were performed before surgery. If the surgeon could not visualize the clip and/or mass as well, preoperative skin marking (SM) or WL was requested. Localization procedures (SM or WL) were performed by breast imagers on the day of surgery, before patients went to the OR. In the OR, the surgeon performed a lumpectomy using intraoperative ultrasonography (SM or WL) were performed by breast imagers on the day of surgery, before patients went to the OR. In the OR, the surgeon performed a lumpectomy using intraoperative ultrasonography alone, intraoperative ultrasonography guided by SM, or WL with no intraoperative ultrasonography.

Breast imaging, biopsy, and pathology workflows at each facility followed standard KPNC protocols with comparable equipment at each site. Pilot-site surgeons had different breast surgery volumes and varying levels of experience with breast ultrasonography (Table 1), but all surgeons had access to ultrasonography machines in both the office and the OR.

We performed a retrospective review of the electronic medical records of all candidate patients from January 2015 to October 2015. Inclusion criteria were as follows: Nonpalpable, ultrasound-visible lesion; placement of a hydrogel clip during biopsy; and lumpectomy by 1 of the 7 pilot-site surgeons.

We examined localization type, lesion size, margin positivity, and whether patients received neoadjuvant chemotherapy. Comparisons were made between the group that required WL and the group that did not. Statistical analysis was performed using statistical software (Stata 13, StataCorp, College Station, TX). We used a Pearson $\chi^2$ test for comparison of categorical variables and a t-test for continuous variables, with statistical significance defined as a p-value less than 0.05.

This study was conceived and performed as a quality improvement project, and all activities in this study were carried out as part of routine clinical care. Thus, it was deemed by our institution not to require review by the institutional review board.

### RESULTS

A total of 143 patients met inclusion criteria. All the patients were women, with ages ranging from 25 to 82 years. The distribution of lesion types is summarized in Table 2. Of the patients, 87 underwent only intraoperative ultrasonography and 15 had preoperative WL by the breast imaging team. In total, 71.3% (n = 102) of the patients avoided WL. Preoperative migration of the hydrogel clip, noted on postbiopsy mammogram, was seen in 3 cases (1.7%). Only 1 of these 3 patients required WL, because of the extent of clip migration and the surgeon’s inability to visualize the lesion under ultrasound guidance.

The mean lesion size on imaging was 1.32 cm$^2$ (range = 0.5-5.2 cm$^2$). There was no statistically significant difference in lesion size between patients requiring WL and those patients whose lesions were localized with ultrasonography alone (Table 3). There also was no significant difference in mean tissue volume excised between the groups (Table 3). Most importantly, there was no significant difference in the rate of positive margins (Table 3).

Most of the pilot-site surgeons had experience with breast ultrasonography (Table 1). We did not track how many cases each surgeon performed before developing the confidence to use...
intraoperative ultrasonography instead of WL. Notably, at our South San Francisco site, 1 of the 2 pilot-site surgeons began the study with minimal ultrasonography experience. During the course of 8 months, combining the data for both surgeons, we observed a steady decrease in the number and percentage of WL procedures, with no WL performed for ultrasound-visible lesions in the final 4 months and with a consistent case volume for each surgeon (Figure 1).

Twelve patients underwent neoadjuvant chemotherapy. The mean time from biopsy to surgery was 179.8 days. Only 4 patients (33%) required WL. Those who required WL had a longer interval before surgery (mean = 191 days) than those who did not require WL (mean = 174 days), although this difference was not significant (p = 0.26). One patient did not require WL despite clip placement 209 days before surgery.

DISCUSSION

This study is the first to examine the implementation of an intraoperative ultrasonography/hydrogel clip protocol for breast lumpectomies across a large, integrated health care system, in contrast to the single-surgeon and/or single-institution reports published in the literature.11-13 Most surgeons in this study had some previous experience with ultrasonography, although the level of training ranged from no formal training to breast ultrasonography certification. For those with less experience, proficiency was achieved in a short time. The surgeon who had the least initial experience in breast ultrasonography was able to move completely away from WL for ultrasound-visible lesions within 5 months of starting the protocol. The combination of intraoperative ultrasonography and hydrogel clips reduced the need for WL in patients with ultrasound-visible, nonpalpable lesions, so that more than 70% of these patients did not need WL. We found no significant difference in lesion size, volume of tissue excised, or margin positivity between those patients who required WL and those who did not. The intraoperative ultrasonography/hydrogel clip technique also was effective in patients who required neoadjuvant therapy. Only 4 (33%) of these 12 patients required WL. This rate is consistent with the findings of other groups.11,13,14 Surprisingly, we found hydrogel clips to be visible on images for up to 209 days.

Interestingly, many of the pilot-site surgeons reported that the hydrogel clip served as a training tool, which helped increase their confidence in intraoperative ultrasonography in general. However, clip migration can be a concern. In our series, radiographic-evident preoperative clip migration was documented in only 3 instances (1.7%). One of the patients had substantial enough clip migration combined with poor ultrasonographic visualization of the index lesion to require a WL procedure. Klein et al15 found only 2 cases (6.4%) of true radiographic–proven clip migration, but they also found that extrusion of the biopsy marker intraoperatively during transection of the biopsy tract occurred up to 45.2% of the time. We did not review our clip extrusion rates. However, surgeons reported that although they could visualize the clip well by intraoperative ultrasonography and could remove the tumor successfully, sometimes they did not see the clip on the specimen mammogram. Presumably, this lack of visualization was caused by extrusion or accidental suction catheter removal of the clip. This suggests that another benefit of the technique is to eliminate the use of the hydrogel clip after an initial training period. Placing clips only in lesions that meet appropriate size and visibility criteria can increase the cost-effectiveness of the overall strategy.

The rapid learning curve and the decreasing dependence on the hydrogel clip are important considerations, especially because US surgeons have a wide spectrum of ultrasonography training and experience. Sclafani et al15 surveyed breast surgeons who completed fellowship training between 2005 and 2009. Even in this highly selected group of fellowship–trained breast surgeons, 31% of those who responded felt "poorly prepared," 17% felt "moderately prepared," and only 31% felt "well prepared" to use ultrasonography in practice. Extrapolating to the population of surgeons performing breast surgery in the US, most of whom are not fellowship trained,16 we can assume the level of comfort with ultrasonography is probably even more variable. We found that one of the strengths of the intraoperative ultrasonography/hydrogel clip technique is the ease and rapidity of adoption, independent of initial ultrasonography experience.

Our study has several limitations. First, the surgeons involved in the pilot study were volunteers interested in using cost-effective

<table>
<thead>
<tr>
<th>Variable</th>
<th>All patients</th>
<th>Wire localization</th>
<th>Ultrasound alone</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients, No. (%)</td>
<td>143 (100)</td>
<td>41 (28.7)</td>
<td>102 (71.3)</td>
<td></td>
</tr>
<tr>
<td>Mean lesion size, cm³</td>
<td>1.2</td>
<td>1.1</td>
<td>1.3</td>
<td>0.24</td>
</tr>
<tr>
<td>Mean volume excised, cm³</td>
<td>96.9</td>
<td>103.5</td>
<td>94.3</td>
<td>0.68</td>
</tr>
<tr>
<td>Positive margin rate for malignant diagnoses, %</td>
<td>7.2</td>
<td>11.5</td>
<td>5.9</td>
<td>0.33</td>
</tr>
</tbody>
</table>
alternatives to WL to decrease their WL rates. The general population of surgeons may not be as motivated to try intraoperative ultrasonography because this technique has a learning curve, requires practice, and necessitates coordination with a supportive Radiology Department. In a fee-for-service environment, breast imagers may not be as motivated to minimize WL use, as this could potentially compromise their revenue stream. In addition, we performed retrospective chart review rather than a randomized prospective study, which likely introduced selection bias. Tumors with better-circumscribed margins may have been more amenable to intraoperative ultrasonography, and these features could have contributed to the trends toward smaller lumpectomy volumes and lower rates of positive margins in the ultrasonography group. Notably, we did not attempt to correlate tumor type or other variables such as the depth and location of the tumor with positive margin rates or the need for WL, because the sample sizes were too small to make meaningful comparisons. Finally, ultrasonography is an operator-dependent modality, although the presence of an easily visualized hydrogel clip helps to mitigate the difficulty of identifying a breast lesion. Despite these limitations, the success of our pilot initiative as a proof of concept has led to an expansion of the project throughout KPNC. The next phase will include a formal training course for all breast surgeons in KPNC. We plan to track intraoperative ultrasonography use and outcomes both before and after training, and to develop a prospective database that will help us define variables that contribute to the success or failure of this technique.

CONCLUSION

We implemented an intraoperative ultrasonography/hydrogel clip alternative to WL for breast surgery in a large health care delivery system, with excellent outcomes. This required the coordination of surgeons and breast imagers across multiple facilities but was relatively easy to accomplish because of the strong integration of the KPNC health care system. Although we did not collect data on the patient day-of-surgery experience for our study, eliminating WL for many patients likely improved their surgical experience because WL can be a source of substantial distress and discomfort on the day of surgery.17

This technique is cost-effective. Our teams, using existing equipment, simplified OR scheduling, reduced ultrasound-guided WL procedures by more than 70%, and freed radiology resources for other breast imaging procedures. Collaboration with our breast imaging team was both feasible and beneficial in our integrated group practice, because time saved by not placing wires on the day of surgery allowed breast imagers to perform more screening and/or diagnostic breast examinations. With standard KPNC protocols, the elimination of 1 WL procedure frees resources to perform 4 screening mammograms, 2 breast ultrasonograms, and 1 screening mammogram, or 2 diagnostic workups. Our study demonstrates that intraoperative ultrasonography/hydrogel clip lumpectomy is a useful technique that surgeons across the nation can adopt easily.
Epidemiology of Chemotherapy-Induced Anemia in Patients with Non-Hodgkin Lymphoma

Kim Cannavale, MPH; Hairong Xu, MD, PhD; Lanfang Xu, MS; Olivia Sattayapiwat, MPH; Roberto Rodríguez, MD; Chet Bohac, MD; John Page, MD, ScD; Chun Chao, PhD

ABSTRACT

Introduction: Anemia is a common adverse effect of myelosuppressive chemotherapy, and the development of chemotherapy-induced anemia (CIA) is more common in patients with hematologic malignant tumors.

Objective: To assess the incidence and treatment pattern of CIA in patients diagnosed with non-Hodgkin lymphoma (NHL) from a large managed care organization in California.

Methods: Patients diagnosed with NHL between 2010 and 2012 were studied to provide an updated picture of CIA in current hematology-oncology practice. Trends in anemia treatment patterns were examined from 2000 to 2013. All data were collected from Kaiser Permanente Southern California electronic health records.

Results: Of 699 chemotherapy-treated patients with NHL diagnosed between 2010 and 2012, 36.9% and 11.6% developed moderate (hemoglobin < 10 g/dL) and severe (hemoglobin < 8 g/dL) CIA during chemotherapy, respectively. Proportions of moderate CIA events treated with erythropoiesis-stimulating agents (ESAs) decreased from 2000 to 2013: 34% in phase 1 (January 1, 2000, to December 31, 2006), 22% in phase 2 (January 1, 2007, to March 24, 2010), and 6% in phase 3 (March 25, 2010, to June 30, 2013). An increasing trend of red blood cell transfusion was observed: 12% in phase 1, 22% in phase 2, and 27% in phase 3. Similar calendar trends were observed for management of severe CIA events.

Discussion: In contrast to previous European reports, we note a higher incidence of CIA in patients with NHL in this US community practice setting.

Conclusion: Moderate to severe CIA is common in patients with NHL receiving chemotherapy. Multiple ESA-related policy changes occurred from 2000 to 2013. A large proportion of CIA episodes were currently not treated with ESA, and transfusions have become more common. Further studies are needed to determine associations between CIA symptom burden and CIA treatment as they relate to patient outcomes and quality of life.

INTRODUCTION

Anemia is a common adverse effect of myelosuppressive chemotherapy. Compared with patients with solid tumors, the development of chemotherapy-induced anemia (CIA) is more common in patients with hematologic malignant tumors. Anemia can have a negative effect on a patient’s quality of life, causing symptoms that include fatigue, drowsiness, depression, dyspnea, tachycardia, and dizziness. Prior studies suggest a link between the occurrence of anemia and inferior survival in patients with cancer treated with chemotherapy.

Several previous studies reported the incidence of CIA in patients with non-Hodgkin lymphoma (NHL). Coiffier et al conducted a retrospective medical record survey of anemia among both solid tumor and hematologic cancers at 24 centers in France. They reported that 37.1% of the patients had baseline hemoglobin (Hb) levels indicative of some degree of anemia, and by cycle 3, the prevalence of anemia (defined as the cumulative proportion of patients with moderate [Hb 8 to < 10.5 g/dL] to severe [Hb < 8 g/dL] anemia any time after the start of chemotherapy) increased to 54.1% of patients and remained > 50% through cycles 4 to 6. There are no comparable studies that document the occurrence of anemia in NHL in current hematology-oncology practice in the US, especially anemia episodes associated with chemotherapy treatment.

Anemia during chemotherapy was historically treated using red blood cell (RBC) transfusions. In 1993, erythropoiesis-stimulating agents (ESAs) were approved for correcting mild to moderate anemia in the US and reduced the need for RBC transfusions in patients with nonmyeloid malignant tumors. Beginning in 2003, studies suggested that ESA use was associated with decreased overall patient survival and/or tumor progression or recurrence in patients with breast, lymphoid, cervical, head and neck, and non–small cell lung cancers. These findings led to a series of changes in the US regarding how to prescribe ESAs in patients with cancer, including the implementation of the Risk Evaluation and Mitigation Strategy (REMS) program in March 2010. Several studies have reported decreased use of ESAs immediately after policy changes in the setting of CIA in numerous cancer types. In addition, Hb concentrations are typically lower among patients with cancer receiving myelosuppressive chemotherapy. Additional data are needed to evaluate the long-term effects of these policy changes on clinical management of CIA.

In this article, we report the patterns of occurrence of CIA in patients diagnosed with incident NHL in a large managed care organization in California. Patients diagnosed with NHL between 2010 and 2012 and treated by June 2013 were included to provide an updated picture of CIA in current hematology-oncology practice. We also evaluated how management of CIA episodes changed over time from 2000 to 2013, as the recommendations for ESA use evolved.

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Keywords: anemia, erythropoiesis-stimulating agents, lymphoma, non-Hodgkin lymphoma, transfusion
METHODS

Study Setting Population

Kaiser Permanente Southern California (KPSC) is an integrated managed care organization that provides comprehensive health services for more than 4 million racially/ethnically and socioeconomically diverse enrollees who broadly represent the population in Southern California.21 KPSC maintains electronic records of health care received by their members. These electronic databases include laboratory data, diagnosis codes, medical procedures, pharmacy files, and disease registries, such as the cancer registry. KPSC’s Surveillance, Epidemiology, and End Results–affiliated cancer registry routinely collects information on age, sex, race/ethnicity, cancer type, histologic type, and stage at diagnosis. All data for this study were collected from KPSC electronic health records. All KPSC health record data became electronically available in all service areas for both inpatient and outpatient settings by the end of 2008.

For the examination of incidence of CIA, patients were included if they 1) were diagnosed with incident NHL at age 18 years or older at KPSC between March 25, 2010 (ie, after the implementation of REMS), and December 31, 2012; 2) initiated chemotherapy at KPSC before June 30, 2013 (only the first chemotherapy course was included in this evaluation); and 3) had at least 1 laboratory measurement of Hb during the first course of chemotherapy. Of those who met the inclusion criteria, patients were excluded if they 1) had less than 12 months of KPSC membership before the start of chemotherapy; 2) had missing information on cancer stage or chemotherapy regimen or agents; 3) had a diagnosis of myelodysplastic syndrome before chemotherapy initiation assessed with International Classification of Diseases, Ninth Revision (ICD-9) codes; 4) had a diagnosis of inherited anemia; 5) had an Hb concentration < 10 g/dL within 3 months before chemotherapy initiation (ie, had baseline anemia for any reason, including nutritional deficiency); 6) had a transfusion within 2 weeks before chemotherapy initiation; 7) received radiotherapy within 4 months before chemotherapy initiation; and 8) received bone marrow transplantation within 12 months before chemotherapy initiation or during the chemotherapy course. These exclusion criteria ensure the patients evaluated had sufficient clinical information and anemia events (if any) that were most likely related to chemotherapy.

To examine changes in the treatment pattern of patients with CIA over time, we included patients with NHL who were 1) diagnosed at age 18 years or older and treated in the 3 KPSC medical centers in San Diego, Orange County, and Fontana between January 1, 2000, and December 31, 2012 (we restricted the sample to these 3 medical centers because of their completeness of outpatient and inpatient chemotherapy data before 2007); 2) initiated chemotherapy before June 30, 2013; and 3) developed anemia in the first course of chemotherapy. The same exclusion criteria described above were applied to this secondary study population.

This study was approved by the KPSC institutional review board.

Data Collection

Data on patient demographic characteristics, cancer stage, length of KPSC membership, chemotherapy information, and Hb concentrations were collected using the KPSC cancer registry and clinical databases. History of comorbidities was assessed using ICD-9 diagnosis codes noted in the 12-month prechemotherapy period. Information on body mass index and chemotherapy regimens and cycle were collected from the KPSC oncology pharmacy dispensing systems. For CIA treatment, we considered RBC transfusion, ESA use, and prescription nutritional supplements, including iron (intravenous or oral), folate (intravenous or oral), and B₁₂ (intravenous or oral) prescriptions. Use of RBC transfusion was captured using ICD-9, Current Procedural Terminology 4, and KPSC internal procedure codes. Use of ESA and prescription nutritional supplements was captured using the KPSC oncology drug dispensing systems and general pharmacy databases.

Statistical Analysis

Distributions of demographic characteristics, cancer characteristics, and number of chemotherapy cycles were calculated to describe the study cohort. Anemia was defined as an Hb level < 14 g/dL for men and < 12 g/dL for women. Following the National Cancer Institute’s Common Terminology Criteria for Adverse Events,22 CIA events were classified by severity: Grade 1 (10 g/dL to lower limit of normal; ie, 14 g/dL for men and 12 g/dL for women), grade 2 (8.0–9.9 g/dL), grade 3 (6.5–7.9 g/dL), and grade 4 (< 6.5 g/dL). Anemia episode was defined to start when an Hb measurement met the definition of anemia and to end when the anemia was resolved (a single measurement of Hb reached normal), when the Hb measurement reached a more severe anemia grade (eg, a grade 2 anemia became a grade 3 anemia), or 60 days after the last dose of chemotherapy.

The incidence proportions of CIA (of different severities) and corresponding 95% confidence intervals (CIs) were estimated by cancer stage at diagnosis, chemotherapy regimen, and cycle. Incidence proportion of CIA at the patient level was calculated as the proportions of patients who ever experienced a CIA event during the first course of chemotherapy. Incidence proportion of CIA at the chemotherapy cycle level was calculated as the proportions of patients in a specific cycle of chemotherapy who had experienced a CIA episode during that cycle of chemotherapy. Related 95% CIs for each incidence proportion were estimated using normal approximation. For the patient-level and cycle-level incidence proportion calculation, the most severe grade of CIA a patient experienced was used for the calculation of incidence proportion by CIA severity. This same anemia event was then characterized for its morphologic characteristic using mean corpuscular volume (MCV) and mean corpuscular hemoglobin (MCH): Microcytic anemia (MCV < 80 fL), normocytic anemia (MCV 80–100 fL), macrocytic anemia (MCV > 100 fL), hypochromic anemia (MCH < 27 pg/cell), normochromic anemia (MCH 27–31 pg/cell), and hyperchromic anemia (MCH > 31 pg/cell).25

To describe anemia treatment patterns in patients with NHL, the following calendar periods were evaluated: January 1, 2000, to December 31, 2006 (before the issue of the ESA black box warning) (period 1); January 1, 2007, to March 24, 2010 (before REMS implementation) (period 2); and March 25, 2010, to June 30, 2013 (after implementation of REMS).
Epidemiology of Chemotherapy-Induced Anemia in Patients with Non-Hodgkin Lymphoma

Because more than 1 treatment approach can be used for the same anemia episode, proportions of mutually exclusive combinations of the above-mentioned treatment strategies were also evaluated. Proportions of anemia episodes treated with different management strategies were calculated for any anemia and by the severity of anemia. These analyses were repeated for patients with stage 4 NHL, in whom the burden of CIA may be greater.

A logit model, using generalized estimating equations, was used to evaluate the trends in CIA management pattern across calendar periods while accounting for potential changes in the population characteristics (ie, age, sex, race, and comorbidities). The independent error structure was used with this model.

All analyses were conducted using SAS statistical software, version 9.2 (Statistical Analyses System Inc, Cary, NC, USA).

RESULTS
Incidence of Chemotherapy-Induced Anemia

A total of 1675 incident cases of NHL diagnosed between March 25, 2010, and December 31, 2012, at KPSC were identified. Of these, 1255 patients met the exclusion criteria, leaving a total of 699 patients for the examination of the incidence proportion of CIA. The mean (standard deviation [SD]) age at diagnosis was 61.1 (13.9) years (Table 1). More than half the patients were men and of non–Hispanic white race/ethnicity. Most patients were diagnosed with stage III (22.6%) or IV (38.9%) disease. The mean (SD) Hb level before chemotherapy was 12.9 (1.5) g/dL. The mean (SD) number of chemotherapy cycles received was 5 (2.4). The most common comorbid conditions before starting chemotherapy were hypertension (46.4%), diabetes (22.6%), and renal disease (11.2%). The most common regimen was cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP)/rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) (58.7%), followed by bendamustine with or without rituximab (11%).

Approximately 90% of patients with NHL developed CIA (any grade) during the first course of chemotherapy. Of these patients, 58.9%, 28.2%, 11.2%, and 1.8% had grades 1, 2, 3, and 4 as the most severe grade, respectively (Table 2).

Of these CIA were normocytic, macrocytic, and microcytic, respectively; and 53%, 41%, and 6% were normochromic, hyperchromic, and hypochromic, respectively. When we examined the incidence proportion of moderate CIA (Hb < 10 g/dL) by stage at diagnosis, the incidence proportion increased from 27.3% in stage I NHL to 44.5% in stage IV NHL. The incidence proportion of severe CIA

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patients with NHL* (N = 699)</th>
</tr>
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<tbody>
<tr>
<td>Age at cancer diagnosis, mean (SD), y</td>
<td>61.1 (13.9)</td>
</tr>
<tr>
<td>Male</td>
<td>405 (57.9)</td>
</tr>
<tr>
<td>Length of membership before chemotherapy, mean (SD), y</td>
<td>16.7 (13.5)</td>
</tr>
<tr>
<td>Baseline hemoglobin, mean (SD), g/dL</td>
<td>12.9 (1.5)</td>
</tr>
<tr>
<td>Body mass index, mean (SD)</td>
<td>26.4 (8.4)</td>
</tr>
<tr>
<td>No. of chemotherapy cycles, mean (SD)</td>
<td>5.0 (2.4)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td>Non-Hispanic white: 394 (56.4); Black: 53 (7.6); Hispanic: 178 (25.5); Asian/Pacific Islander: 69 (9.9); Other/unknown: 5 (0.7)</td>
</tr>
<tr>
<td>Cancer stage at diagnosis</td>
<td>I: 146 (20.9); II: 123 (17.6); III: 158 (22.6); IV: 272 (38.9)</td>
</tr>
<tr>
<td>History of comorbidities before chemotherapy</td>
<td>Congestive heart failure: 28 (4.0); COPD/emphysema: 76 (10.9); Diabetes: 158 (22.6); Liver disease: 18 (2.6); Renal disease: 78 (11.2); Hypertension: 324 (46.4); Myocardial infarction: 34 (4.9); Peripheral vascular disease: 27 (3.9); Thrombosis: 9 (1.3); Peptic ulcer disease: 11 (1.6); Cerebrovascular disease: 19 (2.7); Chemotherapy regimen</td>
</tr>
</tbody>
</table>

* Data are presented as number (percentage) of patients unless otherwise indicated.

CHOP = cyclophosphamide, doxorubicin, vincristine, and prednisone; COPD = chronic obstructive pulmonary disease; CVP = cyclophosphamide, vincristine, and prednisone; NHL = non-Hodgkin lymphoma; SD = standard deviation.
Epidemiology of Chemotherapy-Induced Anemia in Patients with Non-Hodgkin Lymphoma

(Hb < 8 g/dL) increased from 6.1% in stage I NHL to 14.0% in stage IV NHL.

Figure 1 shows the cycle-level incidence proportion of CIA by chemotherapy cycle in patients receiving the CHOP/R-CHOP regimens. The incidence proportion of overall CIA events and moderate CIA events increased from cycles 1 (13%) to 5 (21%) and decreased in cycle 6 (14%). The incidence proportion of severe CIA (Hb < 8 g/dL) continued to increase through cycle 6 (1% in cycle 1 to 6% in cycle 6).

**Treatment Pattern of Chemotherapy-Induced Anemia**

There were 1560 patients with incident NHL who initiated chemotherapy in the KPSC medical centers in San Diego, Orange County, and Fontana between January 1, 2000, and June 30, 2013. After applying the exclusion criteria, 989 patients with NHL were included in the treatment pattern analyses. Their demographic and clinical characteristics were similar to the patient population used to evaluate the incidence of CIA (Table 3). The numbers of observed CIA episodes were 914 in phase 1, 441 in phase 2, and 506 in phase 3. The numbers of moderate anemia episodes were 313 in phase 1, 144 in phase 2, and 140 in phase 3. Among moderate CIA, proportions of episodes with ESA use decreased...

<table>
<thead>
<tr>
<th>Stage</th>
<th>Incidence proportion of any CIA (95% CI)</th>
<th>Incidence proportion of CIA by grade (% among patients with CIA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Grade 1</td>
</tr>
<tr>
<td>Any stage</td>
<td>89.7 (87.4-92.0)</td>
<td>52.8 (58.9)</td>
</tr>
<tr>
<td>Stage I</td>
<td>87.7 (82.3-93.0)</td>
<td>60.3 (68.8)</td>
</tr>
<tr>
<td>Stage II</td>
<td>91.9 (87.0-96.7)</td>
<td>59.4 (64.4)</td>
</tr>
<tr>
<td>Stage III</td>
<td>88.0 (82.9-93.0)</td>
<td>51.9 (59.0)</td>
</tr>
<tr>
<td>Stage IV</td>
<td>90.8 (87.4-94.2)</td>
<td>46.3 (51.0)</td>
</tr>
<tr>
<td>CHOP with or without rituximab</td>
<td>92.7 (90.2-95.2)</td>
<td>53.7 (57.9)</td>
</tr>
</tbody>
</table>

CHOP = cyclophosphamide, doxorubicin, vincristine, and prednisone; CI = confidence interval; CIA = chemotherapy-induced anemia.

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<tbody>
<tr>
<td>Age at cancer diagnosis, mean (SD), y</td>
<td>62.7 (14.52)</td>
<td>64.3 (13.18)</td>
<td>63.2 (13.35)</td>
<td>63.2 (13.88)</td>
<td>0.51</td>
</tr>
<tr>
<td>Male</td>
<td>269 (57.11)</td>
<td>144 (59.26)</td>
<td>186 (67.64)</td>
<td>599 (60.57)</td>
<td>0.016</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Non-Hispanic white</td>
<td>345 (73.25)</td>
<td>173 (71.19)</td>
<td>176 (66.4)</td>
<td>694 (70.17)</td>
<td>0.09</td>
</tr>
<tr>
<td>Black</td>
<td>26 (5.52)</td>
<td>10 (4.12)</td>
<td>12 (4.36)</td>
<td>48 (4.85)</td>
<td>0.85</td>
</tr>
<tr>
<td>Hispanic</td>
<td>73 (15.5)</td>
<td>39 (16.05)</td>
<td>60 (21.82)</td>
<td>172 (17.39)</td>
<td>0.79</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>27 (5.73)</td>
<td>21 (8.64)</td>
<td>26 (9.45)</td>
<td>74 (7.48)</td>
<td>0.48</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (0.36)</td>
<td>1 (0.1)</td>
<td>0.1</td>
</tr>
<tr>
<td>Cancer stage at diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>119 (25.27)</td>
<td>56 (23.05)</td>
<td>55 (20)</td>
<td>230 (23.26)</td>
<td>0.63</td>
</tr>
<tr>
<td>II</td>
<td>92 (19.53)</td>
<td>55 (22.63)</td>
<td>54 (19.64)</td>
<td>201 (20.32)</td>
<td>0.08</td>
</tr>
<tr>
<td>III</td>
<td>101 (21.44)</td>
<td>53 (21.81)</td>
<td>69 (25.09)</td>
<td>223 (22.55)</td>
<td>0.38</td>
</tr>
<tr>
<td>IV</td>
<td>159 (33.76)</td>
<td>79 (32.51)</td>
<td>97 (35.27)</td>
<td>335 (33.87)</td>
<td>0.84</td>
</tr>
<tr>
<td>No. of chemotherapy cycles, mean (SD)</td>
<td>5.0 (1.96)</td>
<td>5.2 (2.23)</td>
<td>5.4 (2.71)</td>
<td>5.1 (2.26)</td>
<td>0.17</td>
</tr>
<tr>
<td>No. of CIA episodes, mean (SD)</td>
<td>2.0 (1.32)</td>
<td>1.9 (1.37)</td>
<td>1.7 (1.01)</td>
<td>1.9 (1.26)</td>
<td>0.03</td>
</tr>
<tr>
<td>History of comorbidities before chemotherapy</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>70 (14.86)</td>
<td>52 (21.4)</td>
<td>66 (24)</td>
<td>188 (19.01)</td>
<td>0.01</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>7 (1.49)</td>
<td>8 (3.29)</td>
<td>7 (2.55)</td>
<td>22 (2.22)</td>
<td>0.27</td>
</tr>
<tr>
<td>COPD/emphysema</td>
<td>27 (5.73)</td>
<td>20 (8.23)</td>
<td>35 (12.73)</td>
<td>82 (8.29)</td>
<td>0.01</td>
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<tr>
<td>Renal disease</td>
<td>59 (12.53)</td>
<td>46 (18.93)</td>
<td>42 (15.27)</td>
<td>147 (14.86)</td>
<td>0.07</td>
</tr>
<tr>
<td>Diabetes</td>
<td>68 (14.44)</td>
<td>35 (14.4)</td>
<td>59 (21.45)</td>
<td>162 (16.38)</td>
<td>0.03</td>
</tr>
<tr>
<td>Liver/peptic ulcer disease</td>
<td>14 (2.97)</td>
<td>1 (0.41)</td>
<td>11 (4)</td>
<td>26 (2.63)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

* Data are presented as number (percentage) of patients unless otherwise indicated.

**Table 3. Demographic and clinical characteristics of the study population used to describe the treatment pattern of chemotherapy-induced anemia in patients with non-Hodgkin lymphoma by calendar year**

**Table 2. Proportion of patients with non-Hodgkin lymphoma developing anemia during chemotherapy by anemia severity, with selected chemotherapy regimen, and by cancer stage and anemia severity grade**
Epidemiology of Chemotherapy-Induced Anemia in Patients with Non-Hodgkin Lymphoma from 2006 to 2013: 34% in phase 1, 22% in phase 2, and 6% in phase 3 (ESA use without transfusion: 29% in phase 1, 15% in phase 2, and 3% in phase 3 [Figure 2A]). An increasing trend of RBC transfusion use was observed: 12% in phase 1, 22% in phase 2, and 27% in phase 3. Similarly, among severe CIA (Hb < 8 g/dL), proportions of episodes with ESA use decreased from 2006 to 2013: 44% in phase 1, 27% in phase 2, and 5% in phase 3 (ESA use without transfusion: 33% in phase 1, 11% in phase 2, and 0% in phase 3 [Figure 2B]). An increasing trend of RBC transfusion use was observed: 26% in phase 1, 62% in phase 2, and 62% in phase 3. Use of iron, folate, or B₁₂ supplement was uncommon across all calendar periods. The proportion of untreated anemia episodes increased from 57% in phase 1 to 70% in phase 3 for moderate anemia. The proportion of untreated severe anemia episodes decreased from 38% in phase 1 to 27% in phase 2 and then increased back to 38% in phase 3.

The observed number of anemia episodes in patients with stage IV NHL was 316 in phase 1, 153 in phase 2, and 199 in phase 3. The number of moderate anemia episodes in patients with stage IV NHL was 114 in phase 1, 56 in phase 2, and 56 in phase 3. We observed similar trends in

Figure 1. Incidence proportion of anemia by chemotherapy regimens and cycles among patients with non-Hodgkin lymphoma (NHL). CHOP = cyclophosphamide, doxorubicin, vincristine, and prednisone; Hb = hemoglobin; R-CHOP = rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone.

Figure 2. Proportions of anemic episodes with erythropoiesis-stimulating agent use, red blood cell transfusion, red blood cell transfusion and erythropoiesis-stimulating agent use, use of supplements, and no treatment among all patients with non-Hodgkin lymphoma receiving chemotherapy (A and B; above) and patients with stage IV non-Hodgkin lymphoma receiving chemotherapy (C and D; next page).

ESA = erythropoiesis-stimulating agents; Hb = hemoglobin; RBC = red blood cell.
CIA treatment patterns in these patients with stage IV NHL as in the overall patients with NHL. Although the proportion of untreated moderate CIA episodes increased from 59% in phase 1 to 63% in phase 3 (Figure 2C), the proportion of untreated severe CIA episodes decreased 42% in phase 1, 38% in phase 2, and 27% in phase 3 (Figure 2D).

In adjusted logistic regression analyses (using generalized estimating equations), the decreasing use of ESA was statistically significant compared with phase 1 (Table 4), whereas an increasing use of RBC transfusion was not statistically significant. For ESA use, the odds ratio was 0.59 (95% CI = 0.37-0.93) for phase 2 and 0.08 (95% CI = 0.04-0.18) for phase 3. For RBC transfusion, the odds ratio was 1.54 (95% CI = 0.93-2.56) for phase 2 and 1.56 (95% CI = 0.96-2.54) for phase 3.

**DISCUSSION**

In this study, we examined the patterns of severe CIA incidence in patients diagnosed with NHL in a large, integrated health care system. We found in the first course of chemotherapy that 37% of patients with NHL developed moderate CIA, whereas more than 10% developed severe anemia. These incidence patterns largely reflected patients who received CHOP-based therapy because most patients received CHOP/R-CHOP therapy. Consistent with previous studies, we found an increase in severe CIA in patients whose cancer was diagnosed at advanced stages, who may have had greater myelosuppression because of the treatment as well as the disease. As patients progressed with their chemotherapy cycles, a steady increase in overall CIA incidence was observed between cycles 1 and 5, but this incidence decreased afterward, in part because of discontinuation of chemotherapy. The highest incidence proportion of severe CIA was noted in cycle 6. We also evaluated how CIA management changed as the recommendations for ESA use, in the CIA setting, evolved. We found limited use (ie, < 3% of CIA) of ESAs after the implementation of REMS, even among patients with stage IV NHL (≤ 5% of CIA) for whom ESA is more likely to be indicated. RBC transfusion use increased significantly. Although the proportion of untreated severe CIA episodes did not increase over time (and in fact decreased in patients with stage IV NHL), a significant proportion of severe CIA (approximately 40%) episodes remained not actively treated.

Previous studies have examined the incidence of anemia in patients with NHL.
in European populations. In a prospective study, Birgegard et al\(^5\) conducted a survey of patients with lymphoma and multiple myeloma in European cancer centers and reported anemia prevalence, incidence, treatment patterns, and risk factors. In their study, the patients (with lymphoma and multiple myeloma) who were not anemic at enrollment, 55.4% of those who began their first chemotherapy and underwent at least 2 chemotherapy cycles during the survey became anemic (Hb < 12 g/dL). In patients with NHL specifically, Birgegard et al\(^6\) found that 62.3% had developed anemia by cycle 6. Haiont et al\(^\text{16}\) conducted an observational study in 14 European countries and Australia of anemia management in patients with NHL receiving CHOP/R-CHOP. They found that overall 11% were anemic (Hb < 10 g/dL) at the start of chemotherapy, whereas 33% of patients were anemic during chemotherapy. Compared with these studies conducted in Europe and Australia, we found a significantly higher incidence of overall CIA as well as moderate CIA among patients with NHL. These differences may be attributable to evolution of chemotherapy regimens used to treat NHL or differences among countries and regions and differences in standards of care for treating anemia. Thus, in contrast to previous understanding of the occurrence of CIA based on European studies, our estimates indicate a higher incidence of CIA in patients with NHL in this US community practice setting.

Several previous studies have examined CIA treatment in all tumor types before and after the 2007 Centers for Medicare & Medicaid Services release of the national coverage determination (NCD).\(^9\) We were not able to find any studies that looked specifically after the REMS program pertaining to ESA use in CIA was launched in March 2010. In a study conducted by Henry et al\(^19\) among patients with solid tumors, the post-NCD patients reached significantly lower Hb levels during chemotherapy and had higher odds of receiving a transfusion. Hess et al\(^18\) compared the frequency of myelosuppressive chemotherapy treatment, ESA administrations, and RBC transfusions before and after the NCD in patients with CIA in several cancers. Although exposure to myelosuppressive chemotherapy was not different, ESA administrations significantly decreased and blood transfusions significantly increased after implementation of the NCD. Although our study looked at the periods before and after the 2007 Centers for Medicare & Medicaid Services release of the NCD, we also included the period after the REMS program was launched in March 2010. We found a steady decrease of ESA use after the implementation of the NCD and REMS. There was little use of ESAs after the implementation of REMS, including for patients with stage IV NHL for whom ESAs may be indicated. Along with the increased use of transfusion, the proportion of untreated CIA did not increase from phase 1 to phase 3 for severe CIA events. However, there appears to be an increase in untreated moderate CIA events across the calendar periods in patients with NHL. The clinical implications for this increase in untreated moderate CIA are unclear.

We evaluated the use of prescription iron, folate, or B\(_{12}\) supplement in the management of CIA. Although the National Comprehensive Cancer Network guidelines suggest evaluation of nutritional deficiency in the setting of cancer-induced anemia and CIA,\(^24\) the clinical guideline on the use of nutritional therapy for CIA still remains inconclusive because of insufficient evidence.\(^25,26\) Therefore, the use of nutritional therapy was likely limited in the setting of CIA in this KPSC population. Given the potential risks associated with the use of ESA and RBC transfusion, it may be worth exploring the potential benefit of these nutritional supplements for improving anemia in patients who had iron, folate, or B\(_{12}\) deficiency in this setting. Related to this notion is our finding on the morphologic subtypes of CIA. We reported that most (90%) CIA is normocytic. Almost all the CIA is characterized as hyperchromic (41%) and normochromic (53%), which is what we expected for CIA cases. Up to 10% of cases of CIA were of microcytic or macrocytic subtypes, and 6% were hypochromic subtype. The data suggest a possible role for nutritional deficiencies to a fraction of anemia during chemotherapy. Although these morphologic subtypes may not be strictly linked to nutritional causes, these data suggest nutritional causes for anemia should be routinely evaluated for and treated where appropriate.

Our study has potential limitations that should be considered when interpreting the results. Given the retrospective, observational nature of this study, patients did not receive equal numbers of Hb measurements, and the Hb measurements were not obtained at equal intervals. Thus, CIA episodes in asymptomatic patients may have been missed because of a lack of Hb testing. The degree of this misclassification is likely small because 95% of the chemotherapy cycles evaluated in this study had at least 1 Hb measurement. We were unable to capture use of over-the-counter iron, folate, or B\(_{12}\) supplements because these can

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**Table 4. Treatment of anemia episodes by calendar period among patients with non-Hodgkin lymphoma receiving chemotherapy**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Calendar period</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESA</td>
<td>Period 1 (1/1/2000 - 12/31/2006)</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Period 2 (1/1/2007 - 3/24/2010)</td>
<td>0.59 (0.37-0.93)</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>Period 3 (3/25/2010 - present)</td>
<td>0.08 (0.04-0.18)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>Period 1 (1/1/2000 - 12/31/2006)</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Period 2 (1/1/2007 - 3/24/2010)</td>
<td>1.54 (0.93-2.56)</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>Period 3 (3/25/2010 - present)</td>
<td>1.56 (0.96-2.54)</td>
<td>0.08</td>
</tr>
<tr>
<td>Supplement</td>
<td>Period 1 (1/1/2000 - 12/31/2006)</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Period 2 (1/1/2007 - 3/24/2010)</td>
<td>0.25 (0.05-1.21)</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>Period 3 (3/25/2010 - present)</td>
<td>0.41 (0.10-1.67)</td>
<td>0.21</td>
</tr>
</tbody>
</table>

*Reference group is period 1.  
\(^{a}\)Model ran taking into account age, sex, race, and comorbidities, including cardiovascular disease, cerebrovascular disease, chronic obstructive pulmonary disease/emphysema, renal disease, diabetes, and liver/peptic ulcer disease. Liver/peptic ulcer disease is not included in the non-Hodgkin lymphoma supplement use model because of zero cells. CI = confidence interval; ESA = erythropoiesis-stimulating agents; OR = odds ratio.
Epidemiology of Chemotherapy-Induced Anemia in Patients with Non-Hodgkin Lymphoma

How to Cite This Article

References
ABSTRACT

Context: The high prevalence and negative implications of resident physicians’ burnout is well documented, yet few effective interventions have been identified.

Objective: To document resident and faculty perspectives on resident burnout, including perceived contributing factors and their recommended strategies for attention and prevention.

Design: We conducted 14 focus groups with core faculty and residents in 5 specialties at a large integrated health care system in Southern California. Training programs sampled included family medicine, internal medicine, obstetrics and gynecology, pediatrics, and psychiatry. Discussions were recorded, transcribed, and analyzed using a matrix-based approach to identify common themes.

Main Outcome Measures: Resident and faculty perspectives regarding causes of burnout, preventive factors, and potential intervention strategies.

Results: Five themes captured the range of factors participants identified as contributing or protective factors for resident burnout: 1) having or lacking a sense of meaning at work; 2) fatigue and exhaustion; 3) cultural norms in medicine; 4) the steep learning curve from medical school to residency; and 5) social relationships at and outside work. Recommended intervention strategies targeted individuals, residents’ social networks, and the learning and work environment.

Conclusion: We engaged residents and core faculty across specialties in the identification of factors contributing to burnout and possible targets for interventions. Our results highlight potential focus areas for future burnout interventions and point to the importance of interventions targeted at the social environments in which residents’ work and learn.

INTRODUCTION

The high prevalence and negative effects of burnout among resident physicians are well documented. Previous research cites suicide as the first and second leading cause of death among male and female residents, respectively, and other studies link burnout to additional poor resident health outcomes and suboptimal patient care.

Outcomes research regarding effective interventions of resident burnout, however, remains limited and produces mixed results. Additionally, research has focused more on causes than protective factors, leaving us with a better understanding of pathology than prevention. Researchers recommend engaging residents and faculty in the identification of contributing and protective factors to inform future approaches for improving the well-being of residents. This approach could identify specific targets for intervention, yielding insights into the most favorable and feasible approaches, and, by involving key stakeholders in the design and implementation, could reduce burnout.

To date, few studies have engaged both residents and faculty, focusing mostly on residents. Faculty may have differing insights given their vantage point, exposure to multiple cohorts of residents, connection to leadership, and the power to enact systematic change. Our study aimed to understand how residents and faculty from various specialties understand resident burnout and what they recommend as strategies for addressing it.

METHODS

From October 2016 to February 2017, we conducted 14 focus groups with core faculty and residents in 5 specialties at a large integrated health care system in Southern California. Participants were recruited from medical centers in 2 cities: Los Angeles and Fontana. Sampled programs included family medicine, internal medicine, obstetrics and gynecology, pediatrics, and psychiatry. One focus group per program was conducted with core faculty and another with residents.

All residents and core faculty from included programs were emailed invitations to participate in a focus group at a predetermined time. Anyone who presented the day of the focus group was allowed to participate. Focus groups were held in a private room at the medical center. Separate guides were developed for faculty and resident discussions (see Appendix, available online at: www.thepermanentejournal.org/files/2019/18-185-App.pdf). The moderator (KI) had no reporting relationships with residents or faculty in any of the participating programs and a neutral note taker was present during each focus group. Participants provided oral informed consent before discussions began. Focus groups were audio recorded and transcribed; all identifiers were removed before analysis. After each focus group, participants were provided with information on available resources for addressing burnout. The organization’s institutional review board approved the study.

The study team developed a preliminary code list on the basis of the topic guides and used this to code several transcripts. The team then revised the code list, incorporating new codes with definitions.
Resident and Faculty Perspectives on Prevention of Resident Burnout: A Focus Group Study

RESULTS

Among residents, 72 (40%) of 181 who were eligible participated. Among core faculty, 48 (52%) of 92 eligible faculty members participated. On average, there were 10 participants per resident group (range = 6-16), and 7 per faculty group (range = 3-12). Of residents in the sample, 42% were men; 33% were postgraduate year (PGY) 1, 33% were PGY 2, 31% were PGY 3, and 3% were PGY 4, similar to the proportions for residents overall in the programs. More than half (54%) of the faculty in the sample were men, which is similar to the proportion for core faculty overall in the programs. Participants identified multiple factors as contributing to and protecting residents from burnout (Figure 1). We found similarities in factors identified among faculty and residents, as well as between medical specialties. Five cross-cutting themes tied these factors together.

Sense of Meaning and Purpose

Time spent on administrative tasks vs direct patient care resulted in disengagement and residents’ reduced sense of meaning in their work, which contributes to burnout: “The administrative [work] is 85% to 90% of my day … the 10% I get to be with patients is why I did medicine (R4).” Residents believed that faculty overemphasize administrative tasks, which they attribute to regulatory pressures, and felt scrutinized based on the accuracy of medical coding over their performance in patient care.

Poor follow-through with patients also detracts meaning from a resident’s work and becomes a missed opportunity for learning and improvement around patient care: “They [residents] don’t actually see the patients that they admit, so even [if] they could’ve followed the patient … there is no feedback and reinforcement of how you did, you just get dinged if you missed coding (F4).” Job-related factors that make work meaningful include seeing positive outcomes, a sense of progress, feeling contributions are appreciated and important, learning, feeling part of a team, diversity in work tasks including opportunities to teach, and having input into decision making. Additionally, both faculty and residents described individual factors influencing residents’ ability to find meaning in their work: Possessing a positive outlook, coping skills, resilience, spirituality, maturity, and maintaining interests or hobbies outside medicine.

Fatigue and Exhausation

Aspects of residents’ work that contribute to fatigue and exhaustion also contribute to burnout: Long hours, the need to come into work early, and limited time off preclude protective behaviors such as exercise, sleep, and work-life balance. Heavy workloads result in an erosion of boundaries between work and home and interrupt educational activities. Faculty acknowledged that residents receive mixed messages about whether to prioritize educational activities or patient care.

Time spent at work is stressful because of time constraints and the urgent nature of tasks. This contributes to negative thoughts and feelings about not making progress and never having done enough. “One of the reasons you get so burn[ed] out is … you don’t even feel like you’re provid[ing] good care (R4).” A sense of urgency was also seen as detracting from learning: “Just the pure pressure and constancy of that urgency … there’s no time to reflect or think about your patients (F4).” The demanding nature of work also makes it challenging for residents to pursue self-care: “It’s easy to get caught up in the flow...
Residents cited the high stakes of the job as being emotionally taxing: “These are people's lives in our hands (R7).” Residents described difficulty establishing appropriate boundaries with patients, at times becoming too emotionally involved and using desensitization as a self-protective mechanism: “You have to find ways of coping … like callous humor or minimizing things … because if you didn’t, then it would weigh pretty heavily on you (R5).” Spending time away from work to reset and rejuvenate, obtaining adequate sleep, engaging in exercise and hobbies, maintaining a life outside work, and stress management are factors cited as helping to prevent exhaustion.

Cultural Values of Medicine
Participants reported that cultural values in medicine contribute to burnout, including stigma of burnout and expectations that physicians be “superhuman (R2).” “Residency in general has a culture of [having] to pretend you're okay (R2).” Reaching out to colleagues for help is difficult because of these cultural beliefs: “You don’t want to complain to your colleagues because it’s … admitting to your inability to keep up (R6).”

Being burned out is sometimes normalized, for example, “I don't think anybody gets through residency without being burned out at some point. (F3)” Alternatively, burnout is seen as an impossible problem to resolve without major structural changes, which participants thought were unlikely to occur: “It doesn’t always seem like there are viable alternatives … [Are you gonna work less (R6)?]” The need for, and futility in pursuing, system-level changes as a solution was emphasized: The necessity of residents to do the main work of the hospital is inherent in residency, and so there’s no way to support us in some of the stuff that leads us to exhaustion and hopelessness, without the hospital taking a huge financial and workload hit (R4).”

Other shared cultural beliefs support prioritizing work over personal time and self-care. Residents described feeling guilty about taking time off: “I feel like I'm never sick enough to prove I'm sick (R2).” Organizational messages also signal that residents should prioritize patients' needs over their own: “You're always being told the patient comes first (R4).”

Faculty acknowledged poor self-care themselves, making it challenging for them to be role models for residents: “I could teach you a differential, but if I don’t know self-care, how am I gonna teach you that (F6)?” Some faculty expressed beliefs about the current generation of residents (the Millennials, or Generation Y) as being less tolerant than previous generations. In several faculty focus groups, participants described residents as more prone to complain, sensitive to negative feedback, and having unrealistic expectations.

Residents are familiar with these faculty beliefs, viewing them as unfair and lacking acknowledgment of major changes that have occurred in medicine: “I am covering over 100 patients at a time and [don’t] feel like I’m doing meaningful work bedside with the patient. … [T]he work has changed so much that I think we are having higher levels of burnout because the work we do is less fulfilling (R4).” Residents sometimes feel shut down by faculty comments about generational differences that marginalize their experiences.

Steep Learning Curve
Transitioning from medical school to residency involves a steep and inherently stressful learning curve, with a tremendous amount of information to absorb and increased responsibilities: “One minute ago you didn’t have any responsibility, and now you’re in charge and you have to make decisions and it affects people’s lives (F6).” During this transition, residents struggle with feelings of self-doubt and insecurity. Frequent performance feedback, typically highlighting weaknesses and areas for improvement, exacerbates these feelings. Faculty acknowledged that residents receive an excessive amount of feedback, which is not always delivered in an optimal fashion or time. However, they commented that current residents seem to have a particularly hard time accepting feedback, which they attributed to generational differences: “They want to be perfect. They want you to tell them all the things they did great (F7).”

Residents acknowledged that having unrealistic expectations of themselves was a challenge and assumed that faculty share their high expectations. Poorly communicated faculty expectations, and uncertainty regarding whether they are being met, contribute to residents’ stress and anxiety.

Residents’ steep learning curve extended to facing a realistic understanding about what their career as a physician involves. Faculty noted that residents often romanticize their chosen profession and are disappointed when reality doesn’t match these expectations: “Medicine isn’t glamorous (F7).”

Social Relationships
With limited time to spend with family and friends, and a demanding job that is difficult for those outside the profession to understand, residents feel isolated from their usual sources of social support. Many residents are juggling multiple roles and responsibilities, including marriages, children, and aging parents, which exacerbates stress levels. Tense and hostile interpersonal interactions at work or challenging interactions with patients, families, ancillary staff, and faculty are sources of stress. Residents feel disrespected and unappreciated when told they are “just a resident” or when dedicated educational time is interrupted for nonurgent matters. Both residents and faculty also acknowledged faculty burnout as a problem and noted that faculty sometimes modeled “bad behaviors” or foster a “culture of complaining.”

Strong social support at home and at work protect residents from burnout, and the importance of peer support was emphasized. Several residents commented on positive experiences having seniors or chief residents reach out when they had been struggling: “When I was an intern … they really took care of me even on wards and I try to pay it forward (R5).” The importance of social support from peers is the ability to relate: “A lot of peole don’t understand what you’re going through except the people going through it (R7).” Informal opportunities to get together with other residents promotes connection and allows residents to process stressful experiences. Supportive and engaged faculty were also protective: “Sometimes you’ll have an attending who really cares about you, wants to teach, is invested in you. You don’t feel like you’re getting in the way (R1).”
Recommendations to Address Resident Burnout

Participants identified strategies to help prevent and mitigate the effects of burnout. These strategies targeted 3 levels (Table 1).

**Individual-Level Strategies**

Participants recommended educating residents and faculty on the signs and symptoms of burnout, making support available to those experiencing symptoms, and additional education about resources available to residents. Faculty recommended educating residents on stress management techniques and coping skills, as well as strategies to find meaning and purpose in their work and establishing more realistic expectations. Some faculty also proposed screening for resilience during recruitment to identify candidates who may be less prone to burnout.

**Social Network Strategies**

Suggestions addressing the social network included peer-centered strategies: "Peer to peer is probably the most valuable. ... They're going to respect ... the person next to [them] ... going through the exact same challenges more than a person of designated authority (F6)." Social activities, team building, peer-to-peer mentoring, confidential discussions, and training residents to look for burnout in each other were all mentioned as opportunities for fostering connection.

Both residents and faculty mentioned the importance of addressing burnout in the faculty and recommended restructuring attitudes that stigmatize burnout or attribute it to generational differences. They also suggested intentional role modeling by faculty: "Being an example as to how you as a faculty member aren't burned out, how you as a faculty member get day-to-day joy out of your practice, how you've found ways to get through your day and find meaning (F6)."

**Learning and Work Environment Strategies**

Some participants viewed systems factors as the most critical target for interventions, rather than individual strategies, such as relaxation techniques: "We've had Tai Chi people and yoga people and all those things, but I don't think that is the solution. We're not gonna yoga our way out of this. [Burnout] is literally a system issue (R4)." Participants suggested restructuring work to make it more meaningful for residents, increasing awareness and recognition of positive work outcomes, and providing opportunities to pursue personal interests through electives, teaching, and research.

Other areas identified as targets for interventions included the high workload, limited time off, and lack of control. Specific suggestions included dedicated time off for self-care, allowing residents to have greater control over their schedules, and creating an anonymous and confidential forum where residents could voice their concerns and see them addressed: "Not only a place to talk and be able to be heard, but also action is taken upon those things (R2)."

Changing the cultural environment to reduce the stigma of burnout and encourage and support wellness and self-care is also important to residents and faculty: "Making an environment where people feel like they can ask for help (R3)." Having faculty openly and frequently discuss burnout was recommended as a strategy to reduce stigma. Other recommendations included reducing conflict among the faculty, ensuring supportive leadership, and promoting faculty who are compassionate and reach out to residents: "Building a culture of wellness ... a mindset of being intentional towards caring about residents? Do we reach out and say 'hey, how are you doing today?' or 'is there anything we can do to help support you more' (F1)?"

Residents and faculty also expressed the need for the integration of a proactive system to identify and support residents with burnout symptoms, such as conducting routine surveys, incorporating discussions of burnout into routine resident check-in meetings, standardizing a process for addressing burned-out residents, and hiring a mental health professional into the Graduate Medical Education Department.

**DISCUSSION**

Intervention strategies to address resident burnout are limited, and identification of new approaches to prevent and alleviate burnout is a priority. However, consensus regarding the critical issues...
that interventions should address, and the level at which they should be targeted is lacking. Sponsoring institutions and residency programs are confronted with an overwhelming number of potential resident wellness interventions that they might consider implementing. Our study sought to determine what residents and faculty, who have direct experiences with resident burnout, view as both contributing and protective factors, as well as how best they think burnout might be addressed. Our findings provide insights that may help focus future prevention efforts.

Although we expected to find differences between residents and faculty, these groups shared perspectives on both the contributing and protective factors of resident burnout, as well as potential interventions. Both groups viewed resident burnout as a problem with varied causes and recommended solutions targeting multiple levels: Individual residents, residents’ social networks, and the learning and work environment. Nevertheless, most factors identified as contributing to resident burnout were related to the learning and work environment. This finding is in accordance with previous research and theory, which characterizes burnout as a problem arising from the social environments in which people work, and not as a problem caused by the people working in those environments.

Despite this, intervention approaches for physician burnout have predominantly focused on individuals, and not on work environments. An exception is the handful of studies that assessed how duty-hour restrictions affect resident burnout. A recent review concluded that restricting work hours reduced residents’ emotional exhaustion but did not have an impact on the other 2 domains of burnout: Depersonalization and low personal accomplishment. Various authors have called for additional interventions to address burnout that target residents’ learning and work environment.

Our research yields insights about possible targets for interventions at the level of the learning and work environment. Our findings support Maslach and Leiter’s areas of work life framework, which identifies 6 domains of organizational factors as predictors of burnout: 1) workload, 2) control, 3) rewards, 4) community, 5) fairness, and 6) values. Residents and faculty in our focus groups connected all these factors to burnout. For example, the chronically unmanageable workload and excessive physical and emotional demands of the work were cited as contributing factors.

Residents’ lack of control and autonomy was reported as a major source of stress. Residents also stated that a lack of reward for their work, both financial and nonfinancial, resulted in feeling unappreciated and that their work lacked meaning.

Residents also described feeling they were treated unfairly or disrespectfully because of their low status as a trainee. Conflicts between personal values and work also emerged, with residents reporting they thought their performance was suboptimal because of lack of time, support, or preparation. They also perceived the administrative tasks they spent a large amount of time on were not meaningful or educationally valuable, and at times they did not see their work as having clear benefits for patient welfare. A community of supportive peers and faculty was a protective element, as other studies have found.

Improving the fit between residents and job conditions in any of these 6 domains is likely to improve residents’ work engagement and reduce burnout. Some work domains may be more easily transformed than others, and this framework provides multiple focal points to be leveraged for improvements. Many of the participants recommended for intervention strategies were well aligned with this framework. Decreasing administrative work and improving systems for time off to support rest, recovery, and self-care will target workload. Posing a culture of appreciation and recognition targets rewards. Allowing for more choice in work and vacation schedules, increasing electives, and creating a forum where residents can voice concerns targets autonomy. Increasing the amount of time residents spend on direct patient care vs administrative tasks targets personal values. Scheduled retreats and social activities, formal mentoring programs, and teamwork target community. There are various possibilities for how specific interventions can be designed to target these domains.

Our study results also confirm that there are social and cultural norms in medicine that stigmatize burnout and make self-care a challenge for physicians. Cultural changes are needed to support healthier behaviors. Faculty served as role models for residents and can demonstrate healthy and productive attitudes and behaviors but can also reinforce existing cultural norms and stigma. Faculty members were at times burned out themselves, not surprising given their exposure to the same work environment as residents. Both residents and faculty commented that addressing faculty burnout was critical for addressing resident burnout.

Faculty beliefs about generational differences emerged as a salient theme in the focus groups. Some faculty acknowledged beliefs about Generation Y (the Millennial generation), to which most current residents belong, as being less motivated to work, more prone to complain, and having unrealistic expectations. These beliefs affected how faculty perceived residents and presented challenges for faculty in responding to residents’ distress. Residents reported direct exposure to these beliefs and thought that their experiences were at times discounted and not taken seriously by faculty.

Although most research on generational differences has occurred in industries outside health care, the literature has found real and measurable disparities, which should be acknowledged and addressed to create the most effective educational and clinical practice environments for everyone. Like what we heard in our focus groups, previous research has found...
that the Millennial generation places higher value on work-life integration, working in teams, receiving clear communication and frequent feedback, and having a close mentorship relationship with someone who can foster both professional and personal development.\(^{20,21}\) Additionally, the Millennial generation wants to believe their work has meaning, be acknowledged for their efforts, and feel valued for their contribution.\(^{22,23}\)

Faculty development to support working with and teaching millennials may be beneficial.\(^{24}\) However, additional studies of generational differences (real and perceived) and their impact on faculty and residents in the health care industry are warranted.

Given the continued stigma associated with burnout, formal curriculum on burnout and wellness for residents and faculty is essential to provide accurate information on burnout prevalence, signs and symptoms, coping and self-care, and to make confidential support available. This may prove helpful for residents in identifying and supporting peers. So that the importance of the content is not undermined, this education should be incorporated into regularly scheduled didactics, and not as an add-on or optional curriculum. The stigma and normalization of burnout symptoms also underscore the importance of proactive systems to identify individuals experiencing burnout. Faculty reported a need for a clear protocol outlining how residents with burnout symptoms should be supported vs leaving this up to program discretion.

Residents and faculty identified the need for interventions targeted at individuals. One suggestion included fostering opportunities for residents to reflect on and connect with what brings meaning to their work. Job-related sources of gratitude and physician self-awareness are factors that have been reported by physicians as helping to promote resilience,\(^{25}\) and interventions to enhance these factors have demonstrated effectiveness.\(^{26}\) Another recommendation pertained to helping residents with setting realistic expectations. The transition from medical school to residency involves a steep learning curve, which is stressful and challenging for a resident’s perceived competence.\(^{5,18}\) This adjustment may also involve the reconciliation of idealized views of medicine with reality.\(^{18}\) Strategies to help residents establish realistic expectations during this inherently stressful transition, and to reinforce their competence, might be useful to enhance their well-being.\(^{25}\) Having faculty provide frequent positive feedback and explicit information on performance expectations may be an area of intervention related to these points. Clear benchmarks for performance could reduce anxiety associated with unclear expectations and would allow residents to evaluate their own performance against a standard. Positive feedback could bolster residents’ sense of confidence by reinforcing existing areas of competence. Formal mentoring programs might also help residents in establishing appropriate expectations.

Although we recruited participants from 2 medical centers in different cities in Southern California, our research is limited by the fact that residents were recruited from a single institution. It is possible that the views expressed by the participants in this study do not reflect the views of other residents and faculty in different training programs or settings. Given the sensitive nature of the topic, we made efforts to help residents feel comfortable by holding separate groups by program, and by having a focus group moderator who was not directly affiliated with any of the residency programs. Despite our efforts to promote frank and open discussion, it is possible that some participants felt reluctant to express their honest views. Additionally, the resident focus groups were held with residents across training years. It is possible that participants’ views regarding factors contributing to burnout or interventions vary by training year,\(^{16}\) but this was not something explored in our research. Although our study identified many areas of focus for future interventions, additional research is needed to evaluate the effectiveness of these approaches.

**CONCLUSION**

Given the diverse factors that contribute to resident burnout, a silver bullet intervention is unlikely. Our results highlight potential focus areas for future burnout interventions and point to the importance of interventions targeted at the social environments in which residents work and learn. Other residency programs and sponsoring institutions may wish to consider implementing a similar effort to engage residents and faculty in understanding causes of burnout and recommended interventions. This will aid in identification of locally relevant solutions and may foster a greater sense of ownership in whatever strategies are ultimately implemented.  

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**Disclosure Statement**

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

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**References**


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Developing the Mind

One of the chief defects in our plan of education in this country is that we give too much attention to developing the memory and too little to developing the mind; we lay too much stress on acquiring knowledge and too little on the wide application of knowledge.

— William J Mayo, MD, 1861-1939, American physician and surgeon, cofounder of the Mayo Clinic
Hypocalcemia after Total Thyroidectomy in Graves Disease

Malak Al Qubaisi1; Philip I Haigh, MD, MSc, FRCSC, FACS2

ABSTRACT

Context: Total thyroidectomy has been shown to provide a cost-effective and efficient method of permanently treating Graves disease; however, hypocalcemia can be a common complication.

Objective: To evaluate the risk of hypocalcemia after total thyroidectomy in patients with vs without Graves disease.

Design: The 2016 American College of Surgeons National Surgical Quality Improvement Program participant use data files for procedure-targeted thyroidectomy and from 5871 patients were merged. This study included any patient who underwent total thyroidectomy.

Main Outcome Measures: Whether symptomatic hypocalcemia developed anytime within 30 days after the thyroidectomy. A clinically severe hypocalcemic event was also evaluated as a secondary outcome measure.

Results: Of the 2143 patients who underwent total thyroidectomy, 222 patients experienced hypocalcemia after surgery, 124 of whom had symptomatic hypocalcemia postoperatively. Among patients with hypocalcemia, 16.3% had Graves disease, whereas only 9.4% of patients without Graves disease experienced significant hypocalcemia. Multivariable logistic regression analysis revealed that women (odds ratio = 1.79; 95% confidence interval = 1.16-2.76; p = 0.009) and patients who underwent parathyroid autotransplantation (odds ratio = 1.91; 95% confidence interval = 1.30-2.81; p = 0.001) were at greater risk of development of hypocalcemia. Older patients were less likely to experience hypocalcemia postoperatively (odds ratio = 0.586; 95% confidence interval = 0.44-0.79; p = 0.0001).

Conclusion: Patients with Graves disease are about twice as likely to experience hypocalcemia or clinically severe hypocalcemia postoperatively than are patients without the disease.

INTRODUCTION

Graves disease is the most common autoimmune disorder in the US and the most common cause of hyperthyroidism.1 Although the initial treatment may be antithyroid medications or radioactive iodine, surgery is an excellent definitive treatment and may be indicated because of goiter, local compressive symptoms, or nodules that may harbor malignancy.2 Likewise, patients may prefer surgery to avoid radioactive iodine therapy and the potential adverse effects of antithyroid medication. However, there are complications associated with surgery, including hematoma, recurrent laryngeal nerve palsy, and most commonly, hypoparathyroidism.3-4 Up to 50% of patients who undergo total thyroidectomy may experience hypoparathyroidism.1,3,4 Patients with Graves disease are apparently more prone to tetany developing after total thyroidectomy than any other patients who do not have Graves disease.5-12 Most studies are smaller case series, and to our knowledge, no population-based studies to date have compared patients with and without Graves disease after total thyroidectomy.

The objective of this study was to use the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database to evaluate the risk of hypocalcemia after total thyroidectomy in patients with Graves disease compared with those without Graves disease.

METHODS

Data Sources and Study Subjects

The 2016 NSQIP participant use data files for procedure-targeted thyroidectomy were merged with 2016 NSQIP participant use files into a file that contained data for 5871 patients. Any patient who underwent a total thyroidectomy was then identified from this group using Current Procedural Terminology (CPT) codes 60240 or 60271. Those patients who underwent synchronous parathyroidectomy (CPT code 60500) were excluded. Patients who underwent a neck dissection—either limited or modified radical or radical—or any other surgical procedure were also excluded.

Perioperative Variables

Patient demographic variables that were collected included age (< 50 years old vs ≥ 50 years), sex, body mass index (BMI), and presence or absence of Graves disease. Status of parathyroid autotransplantation was also collected.

Outcomes

The main outcome measure was whether patients experienced symptomatic hypocalcemia anytime within 30 days after the thyroidectomy. As a secondary outcome measure, clinically severe hypocalcemic event was evaluated, and it was defined by NSQIP as: “emergent evaluation in clinical office/Emergency Department,” and/or “readmitted for low calcium, and/or “IV [intravenous] calcium supplementation.”

Statistical Analysis

Categorical predictor variables were compared between the 2 age groups using the χ² test. The likelihood of hypocalcemia within 30 days and a clinically severe hypocalcemic event was estimated using multivariable logistic regression models adjusting for age (< 50 years old vs ≥ 50 years), sex, BMI, Graves disease (yes, no), and parathyroid autotransplantation. Odds
ratios (ORs) with 95% confidence intervals (CIs) were calculated. All p values were 2-tailed, and p < 0.05 was the criterion for statistical significance on final multiple regression models. All analyses were performed using statistical software (SPSS Version 25, IBM, Armonk, NY).

RESULTS

Patient Demographics

There were 2143 patients who underwent total thyroidectomy, and of these, 294 had Graves disease. A total of 915 patients (42.7%) were younger than age 50 years (Table 1). Most patients (81.2%) were women. There were 218 patients (10.8%) who required autotransplantation (Table 1).

Patients were similar in most characteristics when evaluated by Graves disease status; however, patients with Graves disease were younger, with 71.1% less than age 50 years (Table 1).

Symptomatic Hypocalcemia within 30 Days after Thyroidectomy

Of the 2143 patients who underwent total thyroidectomy, 222 patients (10.4%) experienced symptomatic hypocalcemia. By Graves disease status, 48 (16.3%) of 294 patients with Graves disease had hypocalcemia compared with 174 (9.4%) of the 1849 patients in the non-Graves disease group (p = 0.001). We evaluated the following risk factors and analyzed their independent effect on symptomatic hypocalcemia: Age, BMI, Graves vs non-Graves disease, and parathyroid autotransplantation. Women were independently at greater risk of hypocalcemia compared with men (OR = 1.79; 95% CI = 1.16–2.76; p = 0.009), as were patients with Graves disease (OR = 1.57; 95% CI = 1.09–2.25; p = 0.015) and those who had parathyroid autotransplantation (OR = 1.91; 95% CI = 1.30–2.81; p = 0.001; Table 2). The older group of patients in the study were less likely to experience hypocalcemia (OR = 0.586; 95% CI = 0.44–0.79; p = 0.0001). The BMI had no significance on whether a patient would be more prone to development of hypocalcemia (OR = 0.99; 95% CI = 0.97–1.01; p = 0.194).

Clinically Severe Hypocalcemia Event within 30 Days after Thyroidectomy

Of the 222 patients who had hypocalcemia, 124 had clinically severe hypocalcemic-related events. A clinically severe hypocalcemic event occurred in 29 (9.9%) of the patients with Graves disease vs 95 patients without Graves disease (5.1%). Graves disease was an independent predictor of clinically severe hypocalcemic event (OR = 1.69; 95% CI = 1.07–2.66; p = 0.024, Table 3). Likewise, women were at a greater risk of hypocalcemia development compared with men (OR = 2.10; 95% CI = 1.14–3.87; p = 0.017). The older patients were less likely to experience a clinically severe hypocalcemic event (OR = 0.62; 95% CI = 0.43–0.91; p = 0.014). The BMI (OR = 0.98; 95% CI = 0.95–1.00; p = 0.090) had no significance on whether a patient would be more prone to experiencing significant hypocalcemia. Interestingly, parathyroid autotransplantation increased the risk for this outcome, but the difference was not statistically significant (OR = 1.56; 95% CI = 0.93–2.61; p = 0.092).

DISCUSSION

Results of this study confirm that patients with Graves disease have a higher likelihood of hypocalcemia developing within 30 days after total thyroidectomy compared with those without Graves disease. Other factors such as age, sex, and parathyroid autotransplantation are associated with significant hypocalcemia, independent of Graves disease.

The preoperative state of the patient with Graves disease plays a pivotal role in causing postoperative tetany. Before the surgery, in patients with Graves disease receiving antithyroid drugs, “hungry bone syndrome” can develop, in which bone restoration depletes the calcium and vitamin D reservoirs and causes a calcium and vitamin D deficiency. This condition leads to secondary hyperparathyroidism, which causes hypocalcemia postoperatively. High levels of parathyroid hormone (PTH) circulating for prolonged periods preoperatively decrease the organ sensitivity to calcium and induce downregulation of PTH.
receptors peripherally.\textsuperscript{15} Secondary hyperparathyroidism further increases vitamin D deficiency by producing 1,25-dihydroxyvitamin D that converts vitamin D in the liver to its inactive form that goes on to be excreted in the bile.\textsuperscript{6}

Multiple risk factors have been shown to contribute to the hypocalcemic outcome after thyroidectomy in patients with Graves disease. Erbil et al\textsuperscript{9} stated that vitamin D deficiency had the greatest contribution to causing hypocalcemia after surgery. Factors such as sex, the degree of parathyroid gland manipulation at the time of surgery, and the size of goiter may also be responsible.\textsuperscript{1,14,19} Our data also showed that younger patients are more prone to experiencing significant hypocalcemia and clinically severe hypocalcemic events postoperatively compared with older patients. Aging can cause vitamin D deficiency and decreased intestinal calcium absorption and thus contributes to the hypocalcemic outcome.\textsuperscript{9,11,14,20}

Our study results have shown that women are at higher risk of development of both significant hypocalcemia and a clinically severe hypocalcemic event postoperatively than men. The mechanism as to why women are more prone to hypocalcemia development after total thyroidectomy has been disputed.\textsuperscript{16} One reason may be that women are at a higher risk of vitamin D deficiency.\textsuperscript{9} A second reason may be a drop in the level of calcitriol in menopausal women.\textsuperscript{16} Third, multiple regulatory genes in men have been found that heighten the parathyroid gland’s ability to undergo mitosis to maintain calcium homeostasis when demands for calcium increase.\textsuperscript{24} Fourth, genetic differences may be responsible for vulnerability to hypocalcemia in women.\textsuperscript{25} Finally, parathyroid glands in women are smaller and differ in parenchymal and stromal fat composition compared with those in men, which may have contributed to women having a higher percentage of inadvertent parathyroidectomy during a total thyroidectomy.\textsuperscript{21}

It is interesting to note that parathyroid autotransplantation played a significant role in causing hypocalcemia postoperatively. Parathyroid autotransplantation during thyroidectomy is the placement of morcellated parathyroid tissue from a parathyroid gland that has been inadvertently removed or devascularized back into the patient, usually in an intramuscular pocket in the neck. Studies have shown that undergoing parathyroid autotransplantation puts patients at greater risk of transient hypocalcemia developing postoperatively\textsuperscript{12,16}; however, permanent hypocalcemia is less likely to develop in these patients over time.\textsuperscript{12,22-24} Because the ACS NSQIP collected data for only 30 days after the surgery, we were unable to assess whether parathyroid autotransplantation caused permanent hypocalcemia. The role of parathyroid autotransplantation has been debated, as it has also been shown to provide no benefit or to actually increase the risk of permanent hypocalcemia postoperatively.\textsuperscript{20,25} We still believe that autotransplantation acts as insurance in salvaging functional parathyroid tissue; however, there has yet to be a study comparing autotransplantation with leaving a devascularized parathyroid gland in situ.

Surgeons can prepare for hypocalcemia in patients with Graves disease by recognizing the predictors of hypocalcemia. Before surgery, serum calcium and PTH levels, vitamin D concentrations, and alkaline phosphatase levels should be measured and adjustments should be made accordingly by using calcium and vitamin D supplements.\textsuperscript{8} Postoperatively, calcium and PTH levels should be monitored closely in these patients. Low levels of calcium and PTH are highly predictive of postoperative hypocalcemia.\textsuperscript{49} For example, patients who had their PTH levels measured after surgery and had low levels (< 6–35 pg/mL) 30 minutes to 5 days after total thyroidectomy were prone to development of transient hypocalcemia.\textsuperscript{99} In a study that focused on PTH levels postoperatively, PTH levels less than 10 pg/mL increased the risk of tetany 23-fold higher.\textsuperscript{6} It would be prudent to follow-up patients with Graves disease more closely than the routine testing that is normally done.

Indocyanine green florescence has recently been used to assess blood perfusion in the parathyroid glands.\textsuperscript{26,27} Studies have shown that by using indocyanine green fluorescence angiography, surgeons can avoid postoperative hypocalcemia by ensuring at least one well-perfused parathyroid gland.\textsuperscript{26,27} This has removed the necessity to measure PTH and calcium levels intraoperatively to determine whether hypocalcemia occurs postoperatively and has provided an alternative method to measure hypoparathyroidism immediately after thyroid excision.\textsuperscript{26,27} Lang et al\textsuperscript{27} developed a system that measures the numeric value of the blood perfusion of the parathyroid gland. This may potentially be useful in patients with Graves disease, if not used routinely, to try to reduce the risk of hypocalcemia in this disease.

Although this study has the potential to alter certain aspects of clinical management when it comes to treating patients with Graves disease, it does come with some limitations. The database we used did not provide calcium, vitamin D, and PTH levels of the patients with Graves disease preoperatively, intraoperatively, and postoperatively. Moreover, the severity of the Graves disease was not recorded. It was also unknown whether patients were taking antithyroidal medication. Our data also state that certain subjects had a clinically severe hypocalcemic event, but it is not noted exactly how long after surgery it occurred.
Hypocalcemia after Total Thyroidectomy in Graves Disease

CONCLUSION
Our study findings have shown that patients with Graves disease are almost twice as likely to experience transient hypocalcemia and clinically severe hypocalcemic events after total thyroidectomy than patients without Graves disease. Age, parathyroid autotransplantation, and sex all are important risk factors in causing transient hypocalcemia postoperatively. Surgeons may adjust their routine biochemical follow-up after total thyroidectomy and follow-up patients with Graves disease more closely.

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

Acknowledgments
The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) and the hospitals participating in the ACS NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

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References
Dr Kern reports: "This photograph was taken in the Oneonta Gorge of the Columbia River near Portland, OR. The winter landscape, recent rainfall, and wood barricade came together nicely and helped form this image."

Dr Kern is a Urology Resident at the Los Angeles Medical Center in California.
Effect of *Helicobacter pylori* Treatment on Unexplained Iron Deficiency Anemia

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ABSTRACT

**Background:** A large number of patients with iron deficiency anemia have no known cause of their anemia despite a full evaluation. Optimal management and follow-up for this issue is unclear. Results of previous studies have implicated *Helicobacter pylori* infection as a potential cause of iron deficiency anemia.

**Objectives:** To investigate whether *H pylori* infection could be a cause of unexplained iron deficiency anemia.

**Methods:** All adult patients with both unexplained iron deficiency anemia and *H pylori* infection diagnosed between January 1, 2008 and April 30, 2015 were identified from Kaiser Permanente Northern California’s electronic medical records database and were followed-up for up to 2 years. We employed bivariate statistics to analyze demographic and clinical characteristics between *H pylori* treatment groups (treated and untreated). Multivariable logistic regression was used to assess the odds of continued presence of anemia at follow-up.

**Results:** Of 508 subjects who fit our inclusion criteria, 408 subjects were treated for *H pylori*. The median initial level of hemoglobin was 10.5 g/dL and ferritin was 7.0 ng/mL. No difference existed in the continued presence of iron deficiency anemia at follow-up between those treated for *H pylori* and those not treated (24.3% vs 26.5%, p = 0.71). Both groups had improved levels of hemoglobin (25.4% mean increase in treated vs 27.5% mean increase in untreated) at follow-up.

**Conclusion:** In contrast to the findings of previous studies, we found no evidence that *H pylori* is involved in causing iron deficiency anemia. Iron deficiency anemia resolved in most subjects regardless of *H pylori* treatment status.

INTRODUCTION

Iron deficiency is the most common nutritional disorder in the world, and it is estimated that at least 500 million people have iron deficiency anemia (IDA) worldwide. Iron deficiency anemia can develop from poor iron intake, chronic blood loss, or impaired iron absorption. Additionally, in women of reproductive age, IDA is commonly attributed to increased blood loss from menstruation. Standard care for adults with IDA includes a complete evaluation of the gastrointestinal tract to exclude an abnormality. However, even after a full investigation, approximately 30% of IDA cases remain without a clear cause. Many of these patients undergo repeated rounds of invasive and expensive gastrointestinal procedures and testing. *Helicobacter pylori* is a common infection worldwide. It is estimated that 30% to 40% of the US population are infected with *H pylori*. Most of those infected with *H pylori* are clinically asymptomatic; however, *H pylori* infection is associated with several important upper gastrointestinal tract conditions, including chronic gastritis, peptic ulcer disease (PUD), and gastric malignancy. Established indications for *H pylori* testing and treatment include PUD, gastric mucosa-associated lymphoid tissue lymphoma, gastric cancer, and uninvestigated dyspepsia. Current treatment regimens for *H pylori* infection involve an antisecretory agent combined with antimicrobials. Cure rates of 80% to 90% have been attained with these regimens.

Multiple studies have implicated an association between *H pylori* infection and IDA. Lesions from PUD or gastric cancer can bleed and eventually lead to IDA. More commonly, however, *H pylori* infection causes chronic gastritis without overt symptoms. Several theories have been put forward as to how *H pylori* infection can lead to IDA, including impairing iron absorption, competing with the host for uptake of iron, or elevating the pH and reducing vitamin C concentration. The American College of Gastroenterology has called for further studies to assess whether *H pylori* eradication offers benefit to patients with unexplained IDA, and several guidelines now recommend *H pylori* eradication in these patients. We therefore conducted a retrospective cohort study of patients with a diagnosis of unexplained IDA and the presence of *H pylori* to determine whether treatment of *H pylori* infection leads to significant improvement of IDA.

METHODS

**Setting**

This study was conducted in Kaiser Permanente Northern California (KPNC), an integrated health care delivery organization serving approximately 3.85 million patients as of 2016, across 18 medical centers covering urban, suburban, and semirural areas. The KPNC member population approximates the socially and racially/ethnically diverse general population of Northern California.

**Study Design**

Data such as diagnosis codes and procedure codes; laboratory tests and results; vital signs; and physician notes from outpatient, inpatient, and Emergency Department visits are recorded and maintained in KPNC electronic medical records. In this retrospective cohort study, International Classification of Diseases,
Ninth Revision codes (280.9, 281.8, 281.9, 285.9, 280.0, 280.1, and 280.8) were used to identify patients between age 18 and 89 years who had a diagnosis of anemia coded from January 1, 2008, to April 30, 2015. IDA was defined as having iron deficiency and a low hemoglobin value. We used normal hemoglobin parameters adjusted for sex and age using data derived from the second National Health and Nutrition Examination Survey (NHANES II). Serum ferritin is the most sensitive and specific test used for the identification of iron deficiency. Other commonly used laboratory tests provide little diagnostic value over ferritin. For this study, we relied on expert recommendations to determine a serum ferritin level less than 30 ng/mL as iron deficient, providing a sensitivity of 92% and specificity of 98%. Subjects with low serum ferritin and hemoglobin values within 2 months of a coded diagnosis of anemia were considered to have IDA.

Data on endoscopic procedures were obtained and manually reviewed. Only those patients with a documented "negative" workup—results that did not yield a cause of their anemia—were included in the cohort. A negative workup was defined as a normal esophagogastroduodenoscopy (EGD) and colonoscopy within 6 months after an IDA diagnosis. We considered the date of the first endoscopic procedure as the index date for the purposes of the study. If a capsule endoscopy was performed, the results were examined, and only those patients whose capsule endoscopy results did not reveal the cause of anemia were included in the study. Clinically significant gastrointestinal findings included masses, ulcerations, villous blunting of the small bowel mucosa suggestive of celiac disease, colitis, vascular ectasia or arteriovenous malformation, inflammatory polyps, or large bleeding hemorrhoids. Nonspecific descriptive findings such as inflammation or mucosal erythema of the gastric mucosa were not excluded.

We identified _H. pylori_ infection by a biopsy with histopathologic evidence of _H. pylori_, a stool antigen positive for _H. pylori_, a urea breath test positive for _H. pylori_, or positive serum anti- _H. pylori_ antibody obtained within 6 months of the endoscopic procedures. Those patients who did not have a positive or abnormal _H. pylori_ result were excluded.

We further excluded those with a previous history of _H. pylori_ infection, malignancy, anemia of other cause, inflammatory bowel disease, gastrointestinal hemorrhage, chronic kidney disease, PUD, celiac disease, presence of arteriovenous malformation, pregnancy within 9 months of the endoscopic procedures (before or after), or history of gastrointestinal surgery.

Treatment of _H. pylori_ was extracted from pharmacy records. The cohort was divided into those who were treated and those who were not treated for _H. pylori_ infection. At follow-up closest to 24 months, the groups were evaluated for continued presence of IDA, the presence of anemia without iron deficiency, and the change in ferritin level.

We gathered information on demographic factors, including age, sex, and race/ethnicity. Socioeconomic status was obtained measuring census block-level median family income and median education levels. Comorbid conditions were measured with the Charlson Comorbidity Index. Pharmacy data were collected with respect to the medical regimens used to eliminate _H. pylori_. For 2 years from the index date (date of the first endoscopic procedure), information on treatment with medications that could affect bleeding tendencies or treat gastrointestinal tract conditions (eg, histamine 2 [H2] blockers, proton-pump inhibitors [PPIs], nonsteroidal anti-inflammatory drugs [NSAIDs], antplatelet agents, and anticoagulants) was extracted electronically, as well as by manual chart review because these medications are also available in over-the-counter forms. Because PPI use is included in the treatment regimen for _H. pylori_, we were unable to separate PPI use for other indications. As iron supplements can improve ferritin and hemoglobin levels, manual and electronic chart review was once more employed to search for use of oral or intravenous iron.

This study was approved with a waiver of consent by the Kaiser Foundation Institute’s institutional review board.

**Statistical Analysis**

We employed bivariate statistics to analyze demographic and clinical characteristics between _H. pylori_ treatment groups. The association between _H. pylori_...
treatment and continued presence of IDA was examined. Bivariate comparisons on categorical variables, such as study group and the patient’s sex, race/ethnicity, median education level (census-block level), Charlson comorbidity score, test used for diagnosis of H pylori, and medication use were made using the χ² test and Fisher exact test. The Student t-test was used for comparison of means for age, which was a normally distributed continuous variable. Other continuous variables, including baseline hemoglobin level, baseline ferritin level, and family income (census-block level), were found to be nonnormally distributed; they were reported using medians and interquartile ranges and were compared using the Wilcoxon rank sum (Mann-Whitney) nonparametric test.

We performed multivariable logistic regression to assess the odds of continued presence of anemia at follow-up in subjects in the treated group compared

### Table 1. Baseline characteristics of patients with unexplained iron deficiency anemia and history of Helicobacter pylori infection at Kaiser Permanente Northern California

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patient total (N = 508)</th>
<th>H pylori treatment status</th>
<th>p value (χ²)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Yes (n = 408)</td>
<td>No (n = 100)</td>
</tr>
<tr>
<td>Sex, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>317 (62.4)</td>
<td>243 (59.6)</td>
<td>74 (74.0)</td>
</tr>
<tr>
<td>Men</td>
<td>191 (37.6)</td>
<td>165 (40.4)</td>
<td>26 (26.0)</td>
</tr>
<tr>
<td>Mean age (SD), y</td>
<td>58.2 (15.1)</td>
<td>58.3 (13.0)</td>
<td>57.7 (13.4)</td>
</tr>
<tr>
<td>Age group, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-45</td>
<td>86 (16.9)</td>
<td>68 (16.7)</td>
<td>18 (18.0)</td>
</tr>
<tr>
<td>46-55</td>
<td>159 (31.3)</td>
<td>125 (30.6)</td>
<td>34 (34.0)</td>
</tr>
<tr>
<td>56-65</td>
<td>103 (20.3)</td>
<td>82 (20.1)</td>
<td>21 (21.0)</td>
</tr>
<tr>
<td>66-75</td>
<td>101 (19.9)</td>
<td>86 (21.1)</td>
<td>15 (15.0)</td>
</tr>
<tr>
<td>&gt; 75</td>
<td>59 (11.6)</td>
<td>47 (11.5)</td>
<td>12 (12.0)</td>
</tr>
<tr>
<td>Median baseline Hb, g/dL (IQR)</td>
<td>10.5 (9.5-11.3)</td>
<td>10.5 (9.5-11.3)</td>
<td>10.4 (8.7-11.3)</td>
</tr>
<tr>
<td>Median baseline ferritin, ng/mL (IQR)</td>
<td>7.0 (4.9-11.0)</td>
<td>7.0 (4.9-11.5)</td>
<td>7.0 (4.9-10.0)</td>
</tr>
<tr>
<td>Race/ethnicity, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>137 (27.0)</td>
<td>108 (26.5)</td>
<td>29 (29.0)</td>
</tr>
<tr>
<td>Black</td>
<td>48 (9.5)</td>
<td>42 (10.3)</td>
<td>6 (6.0)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>172 (33.9)</td>
<td>130 (31.9)</td>
<td>42 (42.0)</td>
</tr>
<tr>
<td>Asian</td>
<td>111 (21.9)</td>
<td>94 (23.0)</td>
<td>17 (17.0)</td>
</tr>
<tr>
<td>Other/missing</td>
<td>40 (7.9)</td>
<td>34 (8.3)</td>
<td>6 (6.0)</td>
</tr>
<tr>
<td>Median family income, $US (IQR)*</td>
<td>83,266 (60,949-107,375)</td>
<td>85,213 (63,210-108,269)</td>
<td>73,259 (54,888-94,787)</td>
</tr>
<tr>
<td>Median education level, no. (%)*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school or below</td>
<td>87 (17.1)</td>
<td>67 (16.4)</td>
<td>20 (20.0)</td>
</tr>
<tr>
<td>Some college or above</td>
<td>421 (82.9)</td>
<td>341 (83.6)</td>
<td>80 (80.0)</td>
</tr>
<tr>
<td>Charlson Comorbidity Index score, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>269 (52.9)</td>
<td>213 (52.2)</td>
<td>56 (56.0)</td>
</tr>
<tr>
<td>≥ 1</td>
<td>239 (47.1)</td>
<td>195 (47.8)</td>
<td>44 (44.0)</td>
</tr>
<tr>
<td>Medication use, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iron, documented</td>
<td>340 (66.9)</td>
<td>270 (66.2)</td>
<td>70 (70.0)</td>
</tr>
<tr>
<td>PPI</td>
<td>388 (76.4)</td>
<td>329 (80.6)</td>
<td>59 (59.0)</td>
</tr>
<tr>
<td>H₂ blocker</td>
<td>124 (24.4)</td>
<td>107 (26.2)</td>
<td>17 (17.0)</td>
</tr>
<tr>
<td>NSAID</td>
<td>335 (65.9)</td>
<td>268 (65.7)</td>
<td>67 (67.0)</td>
</tr>
<tr>
<td>Antiplatelet agent</td>
<td>14 (2.8)</td>
<td>11 (2.7)</td>
<td>3 (3.0)</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>29 (5.7)</td>
<td>26 (6.4)</td>
<td>3 (3.0)</td>
</tr>
<tr>
<td>Test used for diagnosis, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serologic analysis</td>
<td>111 (21.9)</td>
<td>80 (19.6)</td>
<td>31 (31.0)</td>
</tr>
<tr>
<td>Biopsy on endoscopy</td>
<td>355 (69.9)</td>
<td>293 (71.8)</td>
<td>62 (62.0)</td>
</tr>
<tr>
<td>Stool antigen</td>
<td>3 (0.6)</td>
<td>3 (0.7)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Urease breath test</td>
<td>39 (7.7)</td>
<td>32 (7.8)</td>
<td>7 (7.0)</td>
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</tbody>
</table>

* p value for comparison calculated by Student t-test.
* p value for comparison calculated by Wilcoxon rank sum test.
* Family income and education level are on the census block level.
* p value for comparison calculated by Fisher exact test.

Hb = hemoglobin; H₂ = Histamine 2; IQR = interquartile range; NSAID = nonsteroidal anti-inflammatory drug; PPI = proton-pump inhibitor; SD = standard deviation.
with the untreated group. Multivariable analyses were adjusted for the covariates: Age, sex, race and ethnicity, comorbid conditions, censusblock level median income, census-block level median education level, medication use, and test used to detect *H pylori* infection. All data management and analyses were performed using statistical software (SAS Version 9.3, SAS Institute, Cary, NC). A *p* value of < 0.05 was considered significant.

### Results

A total of 446,938 subjects had a coded diagnosis of anemia between January 1, 2008, and April 30, 2015. After we applied preliminary exclusions on active malignancy and age, 54,205 subjects had laboratory evidence of IDA (defined as low ferritin and low hemoglobin results within 2 months of coded anemia diagnosis). Further exclusions ultimately yielded 730 subjects with positive *H pylori* tests within 6 months of their EGD/colonoscopy procedure. After additional exclusionary criteria were applied (history of *H pylori* treatment, the cause found for anemia on EGD/colonoscopy, or no follow-up laboratory testing), the final cohort included 508 subjects. Of these, 408 were treated for *H pylori* infection (Figure 1).

Results for demographic and clinical characteristics between subjects treated for *H pylori* and those not treated are shown in Table 1. Overall, the median age of the cohort was 58 years, and most patients were women (62.4%), possibly because women of menstruating age were included. At baseline, the median hemoglobin level for the entire cohort was 10.5 and median ferritin level was 7.0 ng/mL (interquartile range = 4.9-11.0 ng/mL). There was a diverse range of ethnicities represented. Median family income for the entire cohort was $83,266 but was significantly lower in the untreated group than in the treated group (*p* = 0.02). The Charlson comorbidity score and the test used for diagnosis were similar between the treated and untreated groups. Medication use was also similar between the 2 groups except for significantly higher use of PPIs in the treated group (*p* < 0.001; Table 1). Of the 508 subjects in our cohort, only 25 (4.9%) had capsule endoscopies performed. Among 408 subjects treated for *H pylori*, most (84.6%, *n* = 345) were treated with 10- or 14-day courses of amoxicillin, clarithromycin, and omeprazole. The remainder (15.4%, *n* = 63) were treated with omeprazole and metronidazole combined with clarithromycin or amoxicillin.

Table 2 displays the continued presence of anemia and IDA at the time of follow-up overall as well as by treatment group. There were 172 subjects with no follow-up ferritin results, so their iron deficiency status at follow-up could not be assessed. No significant difference existed in the continued presence of IDA at follow-up between those treated for *H pylori* and those not treated (24.3% vs 26.5%, *p* = 0.71). The mean (standard deviation) time for follow-up hemoglobin results for untreated patients was 21.7 (6.4) months compared with 22.7 (6.0) months for treated subjects. For ferritin, the mean (standard deviation) time for follow-up was 19.4 (9.4) months in the untreated group, whereas for those treated it was 18.6 (8.9) months.

Laboratory values, including hemoglobin and ferritin, at baseline and at

<table>
<thead>
<tr>
<th>Laboratory test</th>
<th>Treated for <em>H pylori</em></th>
<th>Untreated for <em>H pylori</em></th>
<th><em>p</em> value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin, mean (SD), g/dL</td>
<td>At baseline</td>
<td>At follow-up</td>
<td>Absolute difference</td>
</tr>
<tr>
<td>Overall</td>
<td>10.29 (1.58)</td>
<td>12.90 (1.89)</td>
<td>2.61 (2.31)</td>
</tr>
<tr>
<td>Women</td>
<td>9.98 (1.35)</td>
<td>12.31 (1.67)</td>
<td>2.33 (2.21)</td>
</tr>
<tr>
<td>Men</td>
<td>10.75 (1.77)</td>
<td>13.77 (1.86)</td>
<td>3.02 (2.40)</td>
</tr>
<tr>
<td>Ferritin, mean (SD), ng/mL</td>
<td>At baseline</td>
<td>At follow-up</td>
<td>Absolute difference</td>
</tr>
<tr>
<td>Overall</td>
<td>8.86 (5.61)</td>
<td>47.28 (64.61)</td>
<td>38.43 (64.26)</td>
</tr>
<tr>
<td>Women</td>
<td>8.08 (5.44)</td>
<td>40.28 (58.97)</td>
<td>32.22 (59.15)</td>
</tr>
<tr>
<td>Men</td>
<td>10.0 (5.67)</td>
<td>60.67 (72.69)</td>
<td>50.31 (71.91)</td>
</tr>
</tbody>
</table>

* *p* value for comparison calculated by Student t-test. 
* A total of 140 subjects were missing serum ferritin results. 
* A total of 32 subjects were missing ferritin results. 
* *p* value for comparison calculated by Wilcoxon rank sum test. 
* A total of 67 subjects were missing ferritin results. 
* A total of 25 subjects were missing ferritin results. 
* A total of 73 subjects were missing ferritin results. 
* Seven subjects were missing ferritin results. 
* SD = standard deviation.
follow-up are described in Table 3. Overall, both groups had improved levels of hemoglobin (25.4% increase in those treated vs 27.5% increase in those untreated; p = 0.64). The improvements were similar for both men and women. Unfortunately, our results for ferritin were limited because a large number of subjects did not have follow-up ferritin tests performed. Predictably, the ferritin levels also improved, by an average of 38.43 ng/mL for treated and an average of 32.78 ng/mL for those untreated for H pylori infection (p = 0.85). Interestingly, men had a much greater improvement in ferritin levels in the treated group, but the results were not significant (follow-up ferritin of 60.67 ng/mL vs 38.00 ng/mL, p = 0.57; Table 3). Because of concerns that menstruating women may have different causes for IDA, subanalyses were performed excluding women younger than age 50 years, excluding women younger than age 55 years, or just involving women younger than age 50 years. There were 107 women younger than age 50 years and 171 younger than age 55 years. No significant differences were found between treated and untreated groups in any of the subgroups.

After adjusting for demographic, socioeconomic, and clinical characteristics in multivariable logistic regression, treatment of H pylori was not a significant predictor of continued presence of anemia (adjusted odds ratio [OR] = 1.25, 95% confidence interval [CI] = 0.72-2.17; Table 4).

**DISCUSSION**

The presence of IDA with normal upper endoscopy and colonoscopy findings continues to present a diagnostic dilemma for primary care physicians and gastroenterologists. Experts have recommended screening for celiac disease, autoimmune gastritis, H pylori, and hereditary forms of IDA. If the IDA is still unexplained, options for management of these cases include examination of the small intestine through capsule endoscopy, imaging studies, repeated endoscopic studies, double balloon enteroscopy, or simply supportive monitoring of anemia status with iron supplementation over time. An investigation into capsule endoscopy showed a low diagnostic yield of 25.7%, with capsule endoscopy results not altering management in most patients and the conclusion that the utility of this technique is limited.

Previous studies have implicated H pylori infection as a cause of IDA. Most are epidemiologic surveys in developing countries or involve children. Cardenas et al found that among more than 8000 adults and children in an Alaska population, H pylori infection was associated with an increased risk of IDA (OR = 2.6, 95% CI = 1.5-4.6), with the chance of infection more common in immigrants, poor individuals, and nonbreastfed children. A meta-analysis on the role of H pylori infection in IDA found a relationship between H pylori and IDA (OR = 2.22, 95% CI = 1.52-3.324, p < 0.0001). Other studies have examined whether treatment of H pylori infection can resolve anemia. For example, Monzon et al prospectively evaluated 89 patients with refractory IDA and with H pylori infection, who had normal EGD and colonoscopy results. Resolution of IDA after treatment of H pylori was found in 80% of men (8 of 10), 71%

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**Table 4. Multivariate analysis of continued presence of anemia in treated group compared with untreated group at follow-up**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Adjusted odds ratio</th>
<th>95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-45</td>
<td>0.92</td>
<td>0.50-1.71</td>
</tr>
<tr>
<td>46-55 (reference)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>56-65</td>
<td>0.77</td>
<td>0.41-1.42</td>
</tr>
<tr>
<td>66-75</td>
<td>0.87</td>
<td>0.47-1.62</td>
</tr>
<tr>
<td>&gt; 75</td>
<td>0.48</td>
<td>0.22-1.04</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men (reference)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>1.29</td>
<td>0.83-2.03</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White (reference)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>0.55</td>
<td>0.28-1.10</td>
</tr>
<tr>
<td>Black</td>
<td>2.24</td>
<td>1.07-4.73</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1.45</td>
<td>0.83-2.55</td>
</tr>
<tr>
<td>Other</td>
<td>1.75</td>
<td>0.78-3.92</td>
</tr>
<tr>
<td>Charlson Comorbidity Index score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 (reference)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 1</td>
<td>1.09</td>
<td>0.70-1.69</td>
</tr>
<tr>
<td>Helicobacter pylori</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Untreated (reference)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treated</td>
<td>1.25</td>
<td>0.72-2.17</td>
</tr>
<tr>
<td>Medication use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PPI</td>
<td>0.87</td>
<td>0.54-1.41</td>
</tr>
<tr>
<td>H₂ blocker</td>
<td>1.40</td>
<td>0.87-2.26</td>
</tr>
<tr>
<td>NSAID</td>
<td>1.28</td>
<td>0.82-2.02</td>
</tr>
<tr>
<td>Iron</td>
<td>0.73</td>
<td>0.47-1.14</td>
</tr>
<tr>
<td>Test used to detect infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serologic analysis</td>
<td>0.79</td>
<td>0.46-1.34</td>
</tr>
<tr>
<td>Biopsy on endoscopy (reference)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stool antigen or urease breath test</td>
<td>0.80</td>
<td>0.38-1.72</td>
</tr>
<tr>
<td>Median income (per $10,000)</td>
<td>1.01</td>
<td>0.95-1.08</td>
</tr>
<tr>
<td>Median education level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school or less (reference)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some college or above</td>
<td>0.91</td>
<td>0.51-1.66</td>
</tr>
</tbody>
</table>

H₂ = histamine 2; NSAID = nonsteroidal anti-inflammatory drug; PPI = proton-pump inhibitor.
of postmenopausal women (10 of 14), but only 23% of premenopausal women (14 of 60).24 Similarly, a case series of 30 patients with IDA, H pylori-associated gastritis, and negative workup were followed after treatment of H pylori infection and discontinuation of iron therapy for 12 months.25 At 6 months, 74% of patients had recovered from anemia, and 91.7% had recovered at 12 months.25

In contrast, our study does not show any difference in improvement of IDA after treatment of H pylori when followed-up for up to 2 years compared with those who were not treated. More specifically, even though studies have found that IDA resolves with treatment of H pylori, our findings show that anemia resolves in most patients regardless of whether the infection was treated or not. It was reassuring that even though the cause of IDA was unknown in these cases, the anemia resolved in all but 27.2% of our population. This finding suggests that the initial cause of the anemia may have been self-limited and did not require specific treatment; however, that leaves almost 30% of our patients with persistent, unexplained anemia.

It was interesting to see the marked improvement, although not statistically significant, in ferritin levels in the treatment group among men. Additional studies with a larger cohort may be helpful in determining if there are significant differences in iron levels by sex over time.

Because of the retrospective design, limitations of our study include selection bias and being confined to the data available in existing databases. The latter limitation is evident in the use of nonprescription medications such as NSAIDs and iron because of the reliance on patient self-report for medical documentation. However, any major NSAID-related cause of gastrointestinal hemorrhage and IDA would likely be diagnosed through endoscopic evaluation. There was also a substantial loss to follow-up and lack of follow-up laboratory studies performed. This was most noticeable in the deficiency of follow-up ferritin levels that were available. Furthermore, we were unable to measure or ensure compliance with treatment or document eradication of H pylori infection in all patients. Tracking nonprescription medications was limited by the accuracy of written electronic documentation. Because of differences in physician practice patterns, the outcome measures in this study were not standardized, with variability of laboratory testing at different time points.

To the best of our knowledge, our study is the first to assess the impact of H pylori treatment on IDA in a large population-based setting. The study shows the importance of having an appropriate comparison group when examining causation. Our use of an untreated H pylori group, in contrast to previous studies on this subject, could explain the reason for our disparate results. Although most prior studies were conducted in developing countries where poverty and malnutrition are common, our study population represents a racially, ethnically, and socioeconomically diverse population in the US. Thus, it is possible that the underlying causes of IDA in our population are different than those seen in the study populations of previous studies.

CONCLUSION

We found no evidence that the treatment of H pylori has an effect on resolving unexplained IDA in insured adults in an industrialized country. Our findings call into question the importance of having an appropriate comparison group when examining causation. The use of an untreated H pylori group, in contrast to previous studies on this subject, could explain the reason for our disparate results. Although most prior studies were conducted in developing countries where poverty and malnutrition are common, our study population represents a racially, ethnically, and socioeconomically diverse population in the US. Thus, it is possible that the underlying causes of IDA in our population are different than those seen in the study populations of previous studies.

Disclosure Statement

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

References


Acknowledgments

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How to Cite This Article

Effect of Helicobacter pylori Treatment on Unexplained Iron Deficiency Anemia


The White Jaundice

There is a Malady which is called, The White Jaundice, as well as, The Green Sickness. … And beholding thy Natural Face in a glass; beholding how pale, how wan, how like a ghost it looks.

— Cotton Mather, 1663-1782, socially and politically influential New England Puritan minister, prolific author, and pamphleteer
The Annual Kaiser Permanente (KP) Los Angeles Research Week is culminated by the highly anticipated oral abstract competition. This research competition is often described by the house staff as the highlight of the academic year with its competitive intensity, celebratory aura, and even drama. The work is often a product of effort spanning the entire duration of training. The judges for this prestigious competition are a diverse group representing research, operations, clinical medicine, and medical education.

Several days before the competition, the Medical Center hosted the annual research abstract poster session of original research, quality and patient outcomes, operational research, and case reports. The set of 40 papers in the linked-bibliography came from different medical subspecialties and from different health fields, including pharmacy and nursing.

Throughout the years, KP research has provided insights and helped shape medicine in many ways. In 1969, Irving Rasgon, MD, published a study on colon cancer screening in the journal *CA: A Cancer Journal for Clinicians*, and in 1977, Harry Ziel, MD, with Gordon et al, published a study on estrogens causing endometrial cancer in the *New England Journal of Medicine*. In 1981, Peter Maher, MD, with Eshoo, published his study of the safety of same-day cardiac catheterization in *Catheterization and Cardiovascular Diagnosis*. More recent examples include identifying major adverse risk with common drugs such as COX 2 inhibitors, questioning the overall benefit vs risk of routine colonoscopy in the elderly population, and informing people of the risks associated with beta blockers in pregnancy. In addition, we have dispelled myths about porcelain gallbladder, described unlikely benefits of cannabis, and helped establish guidelines for care such as with hematuria. We have helped provide insights on comparative outcomes for...
management strategies for many different diseases including cancer, and continue to describe and share our success rates for chronic disease management programs and innovations in care delivery for such conditions as hypertension, diabetes, and heart failure, to name a few.10,11 KP has become a source for health information not just on its members, but on its medical residents as well. A recent qualitative study gathered the perspectives of both residents and faculty across multiple disciplines on the causal and protective factors for burnout in residency. The results have been presented locally, as well as nationally, and are being used to develop prevention and intervention strategies across the region.9

Research is a standard for the KP community and now part of its DNA. The history of the Los Angeles Medical Center Research Week (see Sidebar: History Highlights: Los Angeles Medical Center Research Week) has reflected a changing culture where recognition, emphasis, and support of research continues to increase in the organization and training programs. If physicians are asked to change and improve on the ways they practice medicine, the evidence must be there. This has led to the fostering and growth of research as well as the recruitment and attraction of talented research-minded physicians to KP. This year’s work, like others in the past, will affect future care within KP and elsewhere.

KP medicine strives to continually transform and improve upon itself because of its introspective approach and willingness to study what we do from all perspectives. Thus, research is embedded in so much of how we operate. With research as a priority, we hope to continue to challenge and advance the field of medicine. Finally, the basis for why we deliver high-quality and efficient care largely lies within the information that we obtain from our own clinical practice and experience, which is based entirely on our members. For this we are infinitely grateful to the members of KP. They are truly the reason we do research and the reason we can do research. 

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

How to Cite this Article

References

Research
Research, untrammeled by near reference to practical ends, will go on in every properly organized medical school; its critical method will dominate all teaching whatsoever.

— Abraham Flexner, 1866-1959, American educator, reformer of medical and higher education in the US and Canada
The Kaiser Permanente Los Angeles Annual Research Week Abstract Summaries

TOP 5 FROM THE HOUSE STAFF ORAL ABSTRACT COMPETITION

First Place
Maternal Glycemic Control and Risk of Fetal Congenital Heart Disease in a Multi-Ethnic Cohort of Women with Diabetes
Marwan Qattan, MD; Lewei Duan, MS; Avetis Hekimian, MD; Ming-Sum Lee, MD, PhD
This study investigated singleton births among pregnant women with diabetes mellitus. They found that poor maternal glycemic control was associated with greater risk of fetal congenital heart disease.

Second Place
Hypothyroidism: A Potential Modifiable Risk Factor for Chronic Kidney Disease?
Cheng-Wei Huang, MD; Bonnie Li, MS; Connie Rhee, MD; John J Sim, MD
Hypothyroidism and chronic kidney disease (CKD) are both highly prevalent conditions. Whether hypothyroidism is a modifiable risk factor to CKD is unknown, although animal studies suggest a plausible mechanism for a causal relationship. This study evaluated whether hypothyroidism and different levels of hypothyroidism are associated with CKD.

Third Place
Gallbladder Polyps: Real or Imagined?
Yiping, Li, MD; Talar Tejirian, MD, FACS; J Craig Collins, MD, MBA, FACS
The finding of gallbladder polyps on imaging studies usually prompts further workup and often concern for cancer leads to surgery. Imaging results may not always correlate with final pathology. This study compared polypoid lesions of the gallbladder found on preoperative ultrasonography with final pathologic diagnosis after cholecystectomy to refine estimates of clinical risk and thus, to guide decision making.

Effects of Nonsteroidal Anti-inflammatory Drugs on Complications and Postoperative Pancreatic Fistula in Patients Undergoing Pancreatectomy
Louis Andrew DiFronzo, MD; Azure Adkins, MD; Jennifer Lee, MD; Stefanie Sueda, MD; Mayo Hotta, MD; Mohammed Al-Temimi, MD
The effect of nonsteroidal anti-inflammatory drugs (NSAIDs) on complications following pancreatic resection is important because of high postoperative morbidity and significant patient and economic costs. This study compared the rate of postoperative pancreatic fistula and other 30-day morbidity in patients who did and did not receive NSAIDs after pancreatectomy.

Clinician Prescribing Practices Associated with Antidepressant Medication Adherence—A Retrospective HMO Database Study
Rohan Hattiangadi, MD; Ellen Lorange, DO, MPH
Perceptions of weight gain among users of hormonal long-acting reversible contraception have led to early discontinuation. This study evaluated the magnitude of weight gain in reproductive-age women using either the 52-mg levonorgestrel intrauterine system, etonogestrel subdermal implant, or copper intrauterine device during 12-, 36-, and 60-month periods.

POSTER AWARDS—ORIGINAL RESEARCH

First Place: Sports Medicine
Nonsteroidal Anti-Inflammatory Drug Use, Sex, and Functional Outcomes after Achilles Tendon Rupture
Vanessa Franco, MD, PhD; Marissa Vasquez, MD; Michael Fong, MD

Second Place: Cardiology
Maternal and Fetal Outcomes in Pregnant Women with Heart Failure—A Population-Based Study
Angie Ng, MD; Lewei Duan, MS; Theresa Win, MD; Albert Y-J Shen, MD; Ming-Sum Lee, MD, PhD

Honorable Mention: Surgery
Comparing Aesthesia Modalities in Endovascular Aneurysm Repair
Michael Cheng, MD; Qiaoling Chen, MS; Linda Chun, MD; Wesley Lew, MD; Kevin Patel, MD, FACS

Honorable Mention: Allergy
Establishing the Safety and Efficacy of Higher Dose Starting Protocols for Patients with Aspirin Hypersensitivity and Coronary Artery Disease
Emily H Liang, MD; Cy Y Kim, MD; Shefali A Samant, MD; Javed Sheikh, MD
Honorable Mention: Internal Medicine
Identifying and Studying Rare Disease Using an Electronic Health Record and Machine Learning-Based Approach: The KPSC Membranous Glomerulonephritis Cohort
Amy Z Sun, MD; Yu-Hsiang Shu, PhD; Teresa N Harrison, SM; John J Sim, MD

POSTER AWARDS—CASE REPORT

First Place: Internal Medicine
Necrotizing Neutrophilic Dermatosis of the Dorsal Hands after IV Antibiotic Therapy
Osama Hashmi, MPH; Saad Ashraf, MD; Frances Hetherington, MD

Second Place: Family Practice
Elderly-Onset Gout
Humberto Avila, MD; Bruno J Lewin, MD, DTMH; Steve S Lee, DO, FACC

Honorable Mention: Rheumatology
Case Report of Neuropsychiatric Systemic Lupus Erythematosus with Ring-Enhancing Lesion on Magnetic Resonance Imaging
Raksha Pradhan, DO; Phot Luisiri, MD

POSTER AWARDS—QUALITY IMPROVEMENT

First Place: Internal Medicine
Multipronged Outpatient Influenza Vaccine Quality Improvement Initiative
Eric Ton, MD, MBA, MD; Christine M Panganiban MD, MS; James Evans, MD; Sangeeta Aggarwal, MD

Second Place: Family Practice
Homeless Health at Kaiser Permanente Los Angeles Medical Center
Helen Yu, MD; Jayanti Dasgupta, MD; Rima Shah, MD; Joanie Chung, MPH, MA; Neil Chawla, MD

Honorable Mention: Family Practice
Domestic Violence Screening by Ethnicity at Kaiser Permanente LAMC
Jayanti Dasgupta, MD; Chris Chung, MD; Su-Jau Yang, PhD; Tara Thacker, MD

POSTER AWARDS—SPECIAL REPORT

First Place: Internal Medicine
Once- Versus Twice-Daily Enoxaparin for Peri-Operative Bridging
Mane Keshishyan, PharmD; Derenik Gharibian, PharmD; Marlene Nashed, PharmD; Daniel Lang, MD

Second Place: Pharmacy
Evaluation of Renal Function in HIV-1 Patients after Switch from Tumor Degenerating Factor to Tumor Angiogenic Factor
Ruth Madievsky, PharmD; Derenik Gharibian, PharmD; Marlene Nashed, PharmD; Lindsay Gordon, PharmD; William Towner, MD

Honorable Mention: Pharmacy
Improving Efficiency and Safety of Patients during Transition from Door Time to Groin Puncture
Dinah Hernandez, MS Ed, PHN, BSN, RN, CRN; Joseph Villafuerte, MSN, BSN, RN; Miho Richmond, RN

POSTER AWARDS—CARDIOLOGY

Characteristics and Clinical Outcomes of Patients with Spontaneous Coronary Artery Dissection
Ryan Clare, MD; Lewei Duan, MS; Michael Jorgensen, MD; Anne Ichiuji, MD; Albert Y Shen, MD; Ming-Sum Lee, MD PhD

Statin Use is Associated with Reduced Mortality in Heart Failure Patients with Preserved but not Reduced Rejection-Fraction
Avetis Hekimian, MD; Ryan Clare, MD; Lewei Duan, MS; Wansu Chen, PhD; Ming-Sum Lee, MD, PhD

Dual Antiplatelet Therapy Before Cardiac Catheterization: To Pretreat or Not
Brandon Kai, MD; Somjot Brar, MD, MPH
A Case of Intravenous Methadone Used for the Treatment of Opioid-Induced Hyperalgesia in a Cancer Patient at the End of Life
Heather Bitar, DO; Andre Cipta, MD; Kuo-Wei Lee, MD; Wesley Woo, MD

Preventing Burnout: Perspectives of Residents and Faculty in Community-Based Training Programs
Davida Becker, PhD; Kristen Ironside, MA; Isabel Chen, MD; Adegbemisola Daniyan, MD; Ary Kian, MD; Neeta Saheba, MD; Felice Klein

Factors Pertaining to Statin Treatment Adherence during the First Year of Use: A Retrospective Study of a Southern California Cohort
Hardeep Aujla, MD; Edward Erlikh, MD; Arash Khalili, MD; Bradley Richie, MD

A Descriptive Study of Patients with Chronic Urticaria before and after Taking Omalizumab
Christine M Panganiban, MD, MS; Javed Sheikh, MD

Case Report of Neuropsychiatric Systemic Lupus Erythematosus with Ring-Enhancing Lesion on Magnetic Resonance Imaging
Raksha Pradhan, DO; Phot Luisiri, MD

Internal Medicine Multipronged Outpatient Influenza Vaccine Quality Improvement Initiative
Eric Ton, MD, MBA; Christine M Panganiban, MD, MS; James Evans, MD; Sangeeta Aggarwal, MD

Role of Serial Electroencephalograms during Initial Management of Childhood Absence Epilepsy in Defining Treatment Failure in Patients Started on Ethosuximide or Valproic Acid
Suresh Gurbanim, MD; Sirichai Chayasirisobhon, MD; Noriko McCall, MD; Aditya Gurbani, MD; Abel Wu, MD

The Use of an Alternative Measurement of Visceral Adiposity to Evaluate Endometrial Cancer Recurrence and Survival
Monica Avila, MD; Jared R Funston, MD; Allison E Axtell, MD; Scott E Lentz, MD

Racial Disparities in Knowledge of Urogynecologic Issues and Expectation of Treatment
Mabel Mora, MD; Atieh Novin, MD; Michael Weinberger, MD

Nonsurgical Patients with Advanced Gynecologic Cancer Discharged to Subacute Rehabilitation Centers Have Low Rates of Subsequent Chemotherapy
Nathan M Riley, MD; Camille L Clefton, MD; Guillermo Urzua, MD; Antonia Cotwright, DO; Christopher Bui, MD; Elena X Martinez, MD; Carolyn Lefkowits, MD

Nonmalignant Sequelae Following Unconfined Power Morcellation
Hao Mike Zhang, MD; Lee Ann Christianson, MD; Claire Templeman, MD; Scott Lentz, MD
### POSTER AWARDS—PEDIATRICS

<table>
<thead>
<tr>
<th>Title</th>
<th>Authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure to Angiotensin-Converting Enzyme Inhibitors in Pregnancy and the Risk of Low Birth Weight and Congenital Cardiac Malformation</td>
<td>Sneha Chintamaneni, MD; Lewei Duan, MS; Avetis Hekimian, MD; Marwan Qattan, MD; Ming-Sum Lee, MD, PhD</td>
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<tr>
<td>Food Allergy Screening: A Pilot Study Using an Electronic Medical Record to Identify Candidate Patients</td>
<td>Victoria Eng, MD; Michael Kaplan, MD; Shefali Samant, MD; Javed Sheikh, MD</td>
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<tr>
<td>Assessment of the Asthma Medication Ratio as an Asthma Control Predictor in the Pediatric Population</td>
<td>Janet Trang, MD; Scott Takahashi, PharmD; Kristen Ironside, MA; Jiaxiao Shi, PhD; Binh Do</td>
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### POSTER AWARDS—RADIATION/ONCOLOGY

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<tr>
<th>Title</th>
<th>Authors</th>
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<tr>
<td>Improving Efficiency and Safety of Patients during Transition from Door Time to Groin Puncture</td>
<td>Dinah Hernandez, MSN Ed, PHN, BSN, RN, CRN; Joseph Villafuerte, MSN, BSN, RN; Miho Richmond, RN</td>
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### POSTER AWARDS—SPORTS MEDICINE

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<tr>
<td>Appearance and Performance-Enhancing Drugs among Co-Ed College Athletes in the Los Angeles Metro Area: Evaluating Prevalence and Attitudes</td>
<td>Oluyemi Ajiotutu, MD; Branden Turner, MD; John K Su, MD, MPH</td>
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### POSTER AWARDS—SURGERY

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<tr>
<td>Aortic Dissection Causing Malperfusion from Stent Graft Collapse in a Patient with Previous Hybrid Repair of a Paravisceral Aortic Aneurysm: A Case Report</td>
<td>Marie S Tran-McCaslin, MD; Wesley K Lew, MD; Kaushal (Kevin) Patel, MD; Linda J Chun, MD</td>
</tr>
<tr>
<td>A National Review of ACGME General Surgery Resident Case Logs: Assessing the Impact of Minimally Invasive Surgery</td>
<td>Janice Verham, MD; Borna Mohabbatizadeh, MD; Kaushal (Kevin) Patel, MD</td>
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### POSTER AWARDS—UROLOGY

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<tr>
<td>Safety and Feasibility of Outpatient Robotic-Assisted Radical Prostatectomy</td>
<td>Peter Elliott, MD; Pooya Banapour, MD; Ashish Parekh, MD; Apurba Pathak, MD; Madhur Merchant, MD; Kirk Tamaddon, MD</td>
</tr>
<tr>
<td>Adoption of Robotic Partial Nephrectomy: Its Effect on Renal Cancer Surgery and Kaiser Permanente Southern California Practice Patterns</td>
<td>Ramzi Jabaji, MD; Heidi Fischer, PhD; Gary W Chien, MD</td>
</tr>
<tr>
<td>Prevalence of Urethral Stricture in Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis</td>
<td>Tyler Kern, MD; Daniel Artenstein, MD; Gil Weintraub MD; Polina Reyblat, MD; Christopher Tenggardjaja, MD</td>
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</table>
Hillary Mullan says: “I have the privilege of being exposed to the beauty of the human body regularly. I believe that art and creativity can play a unique role in the healing process, and use art as a means of processing the various and challenging experiences I have had in medical school. The hearts were cut out of colored cardstock with an X-Acto knife, assembled with foam tape, and mounted on larger sheets of cardstock. I chose the title ‘Spectrum’ because it is reflective of the many colors in the piece and because it also brings to mind the many forms of love we encounter throughout our lives.”

Hillary Mullan is a Medical Student at the University of Massachusetts in Worcester.
ABSTRACT

We suggest changes in the electronic health record (EHR) in hospitalized patients to increase EHR usability by optimizing the physician's ability to approach the patient in a problem-oriented fashion and by reducing physician data entry and chart navigation. The framework for these changes is a Physician's Daily Hospital Progress Note organized into 3 sections: Subjective, Objective, and a combined Assessment and Plan section, subdivided by problem titles. The EHR would consolidate information for each problem by: 1) juxtaposing to each problem title relevant medications, key durable results, and limitations; 2) entering in the running lists under Assessment and Plan the most relevant information for that day, including abbreviated versions of relevant reports; and 3) generating a flow sheet in a problem's progress note for any key results tracked daily. To reduce physician EHR navigation, the EHR would place in the Objective section abbreviated versions of notes of other physicians, nurses, and allied health professionals as well as recent orders. The physician would enter only the analysis and plan and new information not included in the EHR. The consolidation of information for each problem would facilitate physician communication at points of transition of care including generation of a problem-oriented discharge summary.

INTRODUCTION

In physician satisfaction surveys from around the world, most physicians are dissatisfied with their electronic health record (EHR). The percentage of dissatisfied physicians appears to be increasing. The degree of dissatisfaction is reflected in these phrases in the titles of recent publications: "Why aren't they happy;" "technology as friend or foe;" "hope, hype, and harm;" "time to re-engineer the clinical note;" "transitional chaos or enduring harm;" "an unfulfilled promise and a call to action;" "a bitter pill for many physicians;" and "failure or simply time to reboot."

Reasons for physician dissatisfaction with the EHR include the perception that the EHR increases physician workload, stress, fatigue, burnout, and cognitive burden; decreases physician productivity; impairs physician communication with patients and other physicians; may have unintended consequences that affect patient safety; and has not been convincingly demonstrated to improve the quality of care. On the other hand, a new industry formed in response to physician EHR dissatisfaction (medical scribes) has been reported to increase physician and patient satisfaction.

Problems with EHR utility and usability are the primary factors that determine physician dissatisfaction with the EHR. Utility is the existence of a system feature necessary to perform a task. Utility problems include those of system functionality (eg, search capabilities, system interoperability). Usability is most simply defined as the ease with which a system allows a user to perform a task. Problems with physician EHR usability are most commonly caused by poor organization and display of information, interference with practice workflow, increased physician cognitive burden, or poor system function design.

Some problems attributed to EHR usability are actually caused by physician misuse of the EHR (eg, cloned or bloated notes).

Our focus in this article is on improving physician EHR usability in hospitalized patients. There is an extensive literature (primarily in outpatients) on EHR usability's definitions, principles, metrics, and methods of measurement. Recommendations on EHR usability have been made by the American Medical Association, the American Medical Informatics Association, and the US Office of the National Coordinator of Health Information Technology.

We improve physician EHR usability, primarily by optimizing the EHR's ability to help the physician approach the patient in a problem-oriented fashion. The rationale for this is as follows: 1) usability is the ease with which a system allows a user to perform a task; 2) the physician's main task is to diagnose and treat each patient problem; 3) therefore, if the EHR increases the physician's ability to diagnose and treat each patient's problem this should increase physician EHR usability.

We increase the physician's ability to approach the patient in a problem-oriented fashion by having the EHR provide a consolidated display of information for each patient problem. In the Physician's Daily Hospital Progress Note the most important information for each problem will be displayed together on the same page as the one on which the physician is entering the note. The Agency for Healthcare Research and Quality report: EHR Usability Toolkit—A Background Report on Usability and Electronic Health Records states that physician problem solving would benefit from a succinct summarization of complex clinical data.

Such a problem-oriented information display would reduce the physician's cognitive burden because as the progress note is being composed less information would require retention in working memory. If the amount and complexity of information...
The framework for our proposed EHR modifications is Lawrence Weed’s problem-oriented medical record in which the approach to each patient problem is organized as Subjective, Objective, Assessment, Plan (SOAP). We use a variant of this in which the physician’s progress note rather than the approach to each problem is so organized. We further modify this variant by combining Assessment and Plan into one section, subdivided by problem title. Under each problem title there is a running list of a physician’s daily comments.

To this framework we add EHR modifications to achieve our main goals of problem-oriented information display and reduced physician clerical burden. We have added our EHR modifications primarily in the Assessment and Plan section, but there is marked variability in physicians’ use of the EHR to view data and document findings.

Several EHRs that extensively use problem-orientation are already available, but none go to the extent that we have gone to achieve problem-orientation. Because our EHR modifications are not available in our current EHR, the authors, to varying degrees, manually add them in our hospital progress notes.

Because our key EHR modification is the running list under each problem in the Assessment and Plan section we first discuss the running lists in this section before discussing the relatively minor modifications in the Objective and the Subjective sections. We will end with some projections on the effects of these modifications on physician time spent with the EHR. The Sidebar: Increasing Physician Electronic Record Usability describes the mechanisms by which the proposed EHR modifications would increase physician EHR usability. The Sidebar: Running Lists in the Assessment and Plan Section of the Physician’s Daily Hospital Progress Note is an example of the running lists for each problem in the Assessment and Plan section of the Physician’s Daily Hospital.

### MODIFICATIONS IN THE ASSESSMENT AND PLAN SECTION

**Daily Running List for Each Problem**

Because the vast majority of the information that the physician needs to incorporate into the note is already stored in the EHR, it should not be the physician but the EHR that finds, organizes, and enters the relevant information for each problem in the Physician’s Daily Hospital Progress Note. The physician would enter only the analysis and plan as well as any relevant information not already in the EHR such as changes in the physical findings or recent conversations with other caregivers. These notes are in reverse chronologic order so that the problem’s current note is adjacent to the problem title and information juxtaposed to the problem title.

These running lists would be particularly useful when a physician assumes care of a new patient, especially multiple new patients. For example, the first day that Physician A rounds on a patient seen the previous day by Physician B, the course of each problem could be reviewed simply by scrolling from one problem to another in the last note of Physician B. This review would also be problem-oriented. If Physician A so chooses, the prior day’s note in the Assessment and Plan section of Physician B could be carried forward, and new comments could be added.

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### Increasing Physician Electronic Record Usability

<table>
<thead>
<tr>
<th>Consolidation of a problem’s important information in Assessment and Plan</th>
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<tbody>
<tr>
<td>• Juxtaposition to problem titles of relevant medications, durable results, major risk factors, limitations of treatment</td>
</tr>
<tr>
<td>• All of a problem’s notes in its running list would be viewable on one screen</td>
</tr>
<tr>
<td>• Each note would contain all of that problem’s relevant information for that day including concise reports (e.g., Radiology, Pathology)</td>
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<tr>
<th>Reduced physician chart navigation</th>
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<tbody>
<tr>
<td>• Subjective section—Contains concise versions of notes of nurses and allied health professionals so the physician would not have to navigate to each to read</td>
</tr>
<tr>
<td>• Objective section—Contains significant events, critical laboratory results, and concise versions of other physicians’ notes so one would not have to navigate to each to read</td>
</tr>
<tr>
<td>• Assessment and Plan section—All of the modifications in the section above would also reduce physician chart navigation</td>
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<tr>
<th>Increased electronic health record chronologic functionality and ability to interrelate problems by generation of running lists for:</th>
</tr>
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<tbody>
<tr>
<td>• Each active problem title’s assessment and plan</td>
</tr>
<tr>
<td>• Indications for each hospital admission</td>
</tr>
<tr>
<td>• A patient’s daily chief complaint</td>
</tr>
<tr>
<td>• The current hospitalization’s major procedures, new diagnoses, significant events</td>
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<th>Improved communication</th>
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<tr>
<td>• Embedding concise notes of nurses, pharmacists, allied health professionals, and other physicians in the physician’s progress note reduces barriers to their being read</td>
</tr>
<tr>
<td>• Improved display of significant events and critical laboratory would facilitate physician notification of same</td>
</tr>
<tr>
<td>• Running lists in Assessment and Plan facilitate physician communication at points of transition of care</td>
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</table>
A Daily Hospital Progress Note that Increases Physician Usability of the Electronic Health Record by Facilitating a Problem-Oriented Approach to the Patient and Reducing Physician Clerical Burden

The author of each entry would be identified. Carrying forward patient information in this manner would facilitate the continuity of care and not be thoughtless and potentially dangerous cloning. The running lists would also be useful at other points of transition of care such as evening handoffs, consultations, and hospital discharges.

Entry of Key Daily Results into the Running Lists

If a problem has 1 or several key results followed daily (eg, laboratory data, input and output) that were entered by the EHR in that problem’s running list adjacent to the date, this would build a flow sheet for those results in the progress note. The physician, via a macro, and/or the EHR could determine which result or results to associate with each problem. Buchanan describes an EHR in which a committee of experts systematically determining which results the EHR should associate with each problem.

Entry of Other Important Information into the Running Lists

Inserting concise impressions of a problem’s major procedures, radiology reports, and pathology reports in each problem’s running list in the Assessment and Plan section would help consolidate the important information for each problem for the duration of the hospital stay. If these impressions were highlighted, they could be viewed “at a glance.” Alternatively, if the information warrants a change in a problem title that could be done.

MODIFICATIONS IN PROBLEM TITLES

Accurate Problem Titles

Accurate problem lists are an EHR modification only in that they are present in a minority of hospital charts. If the physician or the EHR could update the problem titles in Assessment and Plan during the course of the admission, it would better direct hospital care. Automated problem list generation by the EHR has recently been described using natural language processing and machine learning-based Watson method models.

Juxtaposition of Relevant Medications to Problem Titles

With juxtaposition to the problem title of the medications being given to treat that problem that day, the physician during that problem’s note entry would no longer need to recall the medication list or navigate back to it. Such juxtaposition would also help identify those medications that should be administered for a problem and are not. Medication details would be in the medication list. Relevant maintenance intravenous fluids could be treated as a medication and be similarly displayed (eg, hypotension—normal saline at 200 mL/h).

Displaying a complete medication list in a separate window on the same screen as the one on which the physician is entering the progress note would be another option. A complete list would facilitate the physician’s ability to determine if the patient was receiving any medications contraindicated for that problem. However, in patients with many problems this may require repeated views of a long medication list (unless that problem’s relevant medications in the complete list were highlighted).

Running Lists in the Assessment and Plan Section of the Physician’s Daily Hospital Progress Note

<table>
<thead>
<tr>
<th>ASSESSMENT and PLAN</th>
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<tbody>
<tr>
<td>MYOCARDIAL INFARCTION (aspirin, metoprolol, clopidogrel)</td>
</tr>
<tr>
<td>5/8/2017 - 4-vessel coronary artery bypass grafts, tolerated well. J Smith</td>
</tr>
<tr>
<td>5/7/2017 - troponin T 40 ng/mL, chest pain persists, Thoracic Surgery has seen. J Smith</td>
</tr>
<tr>
<td>5/6/2017 - troponin T 25 ng/mL, recurrence of chest pain at rest. J Paul</td>
</tr>
<tr>
<td>5/5/2017 - several 10-beat runs of symptomatic ventricular tachycardia. J Paul</td>
</tr>
<tr>
<td>5/3/2017 - troponin T 10 ng/mL, no chest pain, heart catheterization in AM. J Smith</td>
</tr>
<tr>
<td>5/2/2017 - troponin T 15 ng/mL, heart rate 35 beats per minute, temporary pacemaker placed. J Smith</td>
</tr>
<tr>
<td>5/1/2017 - troponin T 35 ng/mL, new onset of chest pain with ST elevation in a patient who had angioplasty in obtuse marginal 9 months ago. Aspirin and metoprolol started. J Smith</td>
</tr>
</tbody>
</table>

| ACUTE KIDNEY INJURY (prednisone) |
| 5/7/2017 - creatinine 5.9 mg/dL, hemodialysis started. J Smith |
| 5/6/2017 - creatinine 4.6 mg/dL, acute interstitial nephritis found on renal biopsy, steroids started. J Paul |
| 5/5/2017 - creatinine 3.4 mg/dL, input 2000 mL, output 500 mL, nausea and vomiting worse. J Paul |
| 5/4/2017 - creatinine 2.4 mg/dL, input 2000 mL, output 600 mL, renal biopsy. J Smith |
| 5/3/2017 - creatinine 1.8 mg/dL, input 2000 mL, output 600 mL, no response to volume. J Smith |
| 5/2/2017 - creatinine 1.6 mg/dL, input 1000 mL, output 400 mL, volume depleted? Will give normal saline. Renal ultrasound: Normal renal size, no obstruction. J Smith |

| HYPERTENSION (lisinopril, chlorothalidone, metoprolol) normal renal angiogram 2013 |
| 5/4/2017 - blood pressure 185/96 mmHg, intravenous antihypertensives stopped. J Smith |
| 5/3/2017 - blood pressure 200/99 mmHg, now having headaches and new leg edema probably due to amlopidine so will stop amlopidine and add metoprolol 50 mg/d. J Smith |
| 5/2/2017 - blood pressure 205/105 mmHg, no symptoms, chlorothalidone 25 mg/d added. J Smith |
| 5/1/2017 - blood pressure 210/125 mmHg, not taking any blood pressure medications at home for months, no papilledema, started on amlopidine 10 mg/d and lisinopril 20 mg/d, will give intravenous hydralazine for systolic BP >200 mmHg as needed. J Smith |
Juxtaposition of Limitations or Durable Results to Problem Titles

Some information may be so important to be kept in mind as a problem is being addressed each day that the physician may choose to juxtapose that information to the problem title. In some cases, the EHR may be able to make this association. Examples are as follows: Atrial fibrillation—no anticoagulants because of fall risk; gastrointestinal hemorrhage—no transfusions, is a Jehovah’s Witness; refractory hypertension—normal aldosterone/renin ratio; metabolic encephalopathy—normal cranial computed tomography scan results; chronic kidney disease—avoid angiotensin-converting enzyme inhibitors (angioneurotic edema).

MODIFICATIONS IN THE OBJECTIVE SECTION

Running Lists in the Objective Section

With a problem-oriented medical record it can be difficult to interrelate a patient’s many problems. Running lists that would help interrelate problems could include: 1) A list of dates of clinically significant events, major procedures, and consultations. This would form a timeline of the hospital course. It would probably benefit from, not just EHR, but also physician input; and 2) A list of the dates of each hospital admission and the principle indication for each admission. This is available in many EHRs, but is not commonly displayed in the physician’s hospital progress note.

Abbreviated Versions of Consultant Notes and Recent Orders

The EHR could further reduce physician chart navigation if abbreviated versions of consultant notes and recent orders were available in the Objective section. For consultant notes, other options would not be just the note of one day but for each day (a running list) or putting the notes in the Assessment and Plan section under the appropriate problem title (so they would be problem oriented).

Significant Events or Critical Laboratory Test Results

Significant events (eg, seizures, severe hypoglycemic reaction) or critical laboratory test results can fail to be communicated to the physician even though there are several mechanisms to do so within and without the EHR.44,53 Reporting and highlighting such information as a subsection in the Objective section would reduce the likelihood of the information being missed and require less physician navigation. Alternatively, if the information was added to a new or already active problem title in the Assessment and Plan section it would facilitate the physician being able to document a response.

MODIFICATIONS IN THE SUBJECTIVE SECTION

Addition of Running Lists of a Patient’s Daily Chief Complaint

A running list of a patient’s daily complaints to the physician could help track a patient’s hospital course and help interrelate problems.

Addition of the Notes of Nurses and Allied Health Professionals

Because notes from nursing and affiliated health care professionals tie in well with the patient’s chief complaint, it would be reasonable to display them in subsections adjacent to the patient’s daily chief complaint as listed above. These notes would need to be very concise and not duplicative for the writer. That hospital notes are commonly read only by the author may contribute to the often poor collaboration between physicians, nurses, and allied health professionals.39,66,56 Just adding a link to such notes would not reduce physician chart navigation. The physician may be more likely to view a note that is not daily and not filled with documentation requirements, but is as needed and succinctly expresses important observations.

MODIFICATIONS IN COMPUTERIZED PHYSICIAN ORDER ENTRY

This article addresses computerized physician data entry (CPOE) only to point out the redundancy of the physician documenting in the progress note that a medication change is going to be made and the rationale, and to also enter the medication name into CPOE. One could easily forget to make this second entry, especially if the physician’s workflow is to enter orders only after all the progress notes have been entered. Seamless integration of the medication name from the progress note into CPOE would prevent this potential error and any quality and cost consequences. In physician satisfaction surveys, if questions on CPOE are excluded from those on other EHR components, the correlation between physician burnout and the EHR is no longer evident.59

EFFECTS ON BUILDING A PROBLEM-ORIENTED DISCHARGE SUMMARY

A daily running list under each problem in Assessment and Plan that consolidates all the relevant information for each problem could facilitate a problem-oriented discharge summary (and problem-oriented outpatient care) in several ways: 1) It could simplify dictation of a discharge summary because all the relevant information for each problem should already be in each problem’s running list. 2) The running list for each problem could actually be the hospital course segment of the discharge summary. If so, the physician’s final entry for each problem could be a brief overview (details are in the running lists). 3) If an electronic discharge summary template were used, the hospital course segment could be autopopulated with the running list for each problem. 4) If on the day of discharge the physician does not have time to compose a high-quality discharge summary, as an interim measure, the running list for each problem and the reconciled discharge medication list could be sent.57,59 Many hospitalists believe they do not have sufficient time on the day of discharge to perform a discharge summary.59 Delayed transmission of discharge summaries to the outpatient physician has been associated with increased 30-day readmission rates.60

EFFECTS ON NOTE LENGTH VS PHYSICIAN ELECTRONIC HEALTH RECORD TIME

For those entering notes into the chart, EHR navigation and data entry would be reduced because the EHR enters the problem title, date of note entry, physician identifier, and all other relevant information (including a mini flow sheet in the progress note for key daily results). If the EHR entered in the Physician’s Daily Hospital Progress Note all the relevant data for each problem,
the physician would click the mouse once to enter the analysis and plan for the first problem and not need to click again until finished with the last problem (unless orders were entered after each problem). In a study comparing a conventional EHR with one in which the information display for each problem could be determined by the user, the data acquisition time was markedly reduced in the experimental EHR. For those reading the progress notes, duplicate entry of some key information would increase note length, but the problem-oriented information display should reduce physician navigation time. The time required to read a progress note would also be reduced if the EHR and/or the physician could delete inactive problems or remote entries and the EHR could identify which problems include an entry that day. The progress note reader’s time would also be reduced by the increased ability to detect note cloning (if the progress notes in the Assessment and Plan section are in a running list format, the physician’s daily notes would be adjacent to each other).

CONCLUSION

The EHR and the problem-oriented medical record have each been paradigm shifts in medical care, but physicians rarely use the complete problem-oriented medical record and are becoming increasingly dissatisfied with the EHR. Used together in hospitalized patients, their synergistic effects may facilitate the physician’s ability to diagnose and treat each patient problem, thereby enhancing EHR usability and physician satisfaction with the EHR. Any benefits of their combined use would require EHR implementation and testing of those modifications so chosen.

Disclosure Statement

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

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How to Cite this Article


References

SPECIAL REPORT


Minuteness

In writing the history of a disease, every philosophical hypothesis whatsoever, that has previously occupied the mind of the author, should lie in abeyance. … the clear and natural phenomena of the disease should be noted—these, and these only. They should be noted accurately, and in all their minuteness …

— Thomas Sydenham, 1624-1689, English physician, known as "The English Hippocrates"
Self-Management of Depression: Beyond the Medical Model

Harpreet S Duggal, MD, FAPA

ABSTRACT
Self-management is increasingly becoming the standard of care among people with chronic medical conditions. Its application to depression is mostly extrapolated from the paradigms used for nonpsychiatric medical illnesses. Such an approach falls short in addressing strength-based interventions that foster recovery in individuals with depression. This article describes a new paradigm of self-management, which is in line with the recovery model, is patient-centered, and goes beyond amelioration of clinical symptoms.

INTRODUCTION
During the last 2 decades, as chronic diseases have increased owing to an aging population, health care delivery systems have developed evidence-based self-management programs to cater to these needs. Most of these programs have involved patients with medical conditions such as hypertension, congestive heart failure, diabetes, arthritis, and asthma. Self-management programs for these medical illnesses have been extensively studied and transformed into best practices, but self-management for depression has still lagged behind. Most self-management strategies currently being used in depression are an extrapolation of the Chronic Disease Self-Management Program (CDSMP). Although 25% of individuals with chronic illnesses may have concurrent depression, most self-management medical programs give mental health only a superficial treatment under the rubric of “dealing with psychological issues.” However, depression, with its myriad presentations, cannot be treated by such one-size-fits-all programs, which, although moving away from a paternalistic health care model, are still mostly prescriptive in nature.

When I see patients seeking help for depression, more often than not, their primary reason for seeing me is, “Doc, I want to be happy,” or “I want to be able to enjoy life.” Being trained as a physician, I practice the medical model, which emphasizes finding what is not working and fixing it. Thus, when my patients ask me how they can feel happy again, I find myself redirecting the conversation to why they are feeling depressed. Regrettably, the focus of traditional psychotherapies and self-management programs has been on mitigating deficits, disorders, symptoms, syndromes, weaknesses, and vulnerabilities. This is not surprising given the fact that negatives are more pervasive and potent than positives and for 1 positive emotional term, there are 10 negatives. However, this deficit-based medical model has 3 major shortcomings:
1. It incorrectly assumes that only “symptoms” must be treated, and any positives are byproducts of treating the negatives.
2. It fosters labeling of psychological distress into discrete disorders, which is not undesirable but robs an individual of his/her rich complexity.
3. It does not necessarily enhance well-being or happiness. Research has shown that absence of psychological distress is not equivalent to presence of well-being.

I have faced these shortcomings of the medical model when helping individuals with depression. I use medications and evidence-based psychotherapies such as cognitive behavioral therapy (CBT) to treat depression. These treatments are successful in ameliorating depression in most of my patients. However, I still grapple with the question, “Are these individuals happy or, as one would say in the positive psychology lingo, flourishing?” Put in real-life terms, not having clinical depression does not automatically guarantee that one is having a meaningful life along with the ability to enjoy things and have positive relationships. This is where evidence-based self-management strategies based on a person’s preferences and values provide a useful adjunct to traditional treatments.

Self-management of mental illnesses in the context of recovery is a recent paradigm shift, which differentiates this approach from the traditional medicalized self-management paradigm. This approach is the focus of this article.

WHAT IS SELF-MANAGEMENT?
Before we delve into what self-management in the context of recovery looks like, it is prudent to first review what self-management actually means. Self-management refers to the use of self-regulation skills to manage chronic conditions or risk factors for these conditions. The processes involved in self-management generally include tasks such as goal setting, self-monitoring, decision making, problem solving, planning for and engaging in specific behaviors, self-evaluation, and management of physical, emotional, and cognitive responses associated with health behavior change. The goals of self-management are to have individuals with chronic illnesses recognize the signs of deteriorating health status, plan actions to take when they see signs of relapse, and know what resources are available and how to access them.

When it comes to self-management of depression, the grim reality is that most of the evidence-based treatments still focus on treating acute episodes of depression, either with medications or with individual and/or group psychotherapy. This “self-help” approach runs contrary to the current conceptualization of depression being a chronic illness, with up to 35% of people with depression having a chronic long-term course. According to a study that followed individuals with depression over 25 years, more than 80% of individuals experienced recurrent depression. The high rates of relapse and/or chronicity in many individuals with depression has led to recommendations for maintenance treatment of 2 or more years for chronic depression.

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Keywords: behavioral health, depression, lifestyle medicine, mental illness management
A distinction must be drawn between self-help and self-management. Most of the self-help approaches for treating depression are repackaging of techniques based on CBT and are geared toward treating acute symptoms of depression. In contrast, self-management involves learning new ways to manage an illness during a longer period. Lorig and colleagues further elaborate on self-management: It is a “management style” wherein one is a positive self-manager who not only uses the best treatments provided by health care professionals but also approaches one’s illness in a proactive manner on a daily basis, leading to a healthier life. Self-management teaches skills that continue to work above and beyond the short-term relief that may be gained from self-help strategies. To illustrate this, let us consider diabetes as an example. Good self-managers of diabetes, besides taking medications, educate themselves about diabetes, learn to recognize symptoms of low or high blood glucose (sugar), monitor their blood sugar levels regularly, eat healthy and avoid foods that may destabilize their diabetes, exercise to maintain their weight, and seek professional help if their blood sugar levels are staying above or below the normal range. People with diabetes, heart disease, emphysema, asthma, and other long-standing medical conditions have successfully used self-management to live a healthy life. Unfortunately, the treatment of depression is still catching up with incorporating the concept of self-management, even though approximately 1 in 3 people with depression have a chronic course.

Key components of self-management are highlighted in Table 1, although the list is not exhaustive. As can be gleaned from this list, most of the prevalent paradigms of treating depression are devoid of a majority of these components of self-management. Being able to self-manage depression, a disease that can make one feel powerless, fosters a sense of empowerment, enhances confidence, and gives one a sense of control in dealing with one’s illness. Enhancing self-efficacy, that is, the ability to successfully perform a task or specific behavior or change one’s state of mind, is the driving force behind the self-management construct.

### NEED FOR SELF-MANAGEMENT IN DEPRESSION

Our current understanding of depression is that it results from a complex interplay of biological and environmental risk factors. Unfortunately, the modern conceptualization of depression has been skewed by popular media into making people believe that it is purely a “chemical imbalance” that must be fixed by taking medications that “restore the imbalance.” This has led to a misperception that antidepressants are the be-all and end-all of depression treatment. Here is a fact check. The response rate of antidepressants (eg, 50% decrease in depressive symptoms compared with baseline) is approximately 54%, and that for a placebo is around 37%. The remission rate, which is now considered the goal for antidepressants, also presents a sobering picture, with only 37% individuals with depression remitting after the first trial of an antidepressant and subsequent rates of remission being lower with later treatment steps. Evidence-based psychotherapies for depression such as CBT are as efficacious as medications for treating depression, but this efficacy also depends on the adequacy of therapy implementation and the competence of the therapist. This is not to suggest that antidepressant medication or CBT is not an effective way to treat depression and that people quit taking antidepressants or stop seeing their therapist. It does, however, indicate that antidepressants and existing depression-focused psychotherapies are far from being the optimal treatment of depression. This is where self-management strategies complement the existing approaches to treat depression by boosting an individual’s sense of well-being.

### Table 1. Components of self-management of depression

<table>
<thead>
<tr>
<th>Component</th>
<th>Tasks</th>
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<tbody>
<tr>
<td>Information</td>
<td>Educating self and family members/friends about depression</td>
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<tr>
<td>Medication management</td>
<td>Taking medications as recommended by one’s health care provider</td>
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<td></td>
<td>Overcoming barriers to adherence to medications</td>
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<tr>
<td>Symptom management</td>
<td>Using various strategies to manage symptoms of depression</td>
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<td></td>
<td>Self-monitoring of symptoms</td>
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<tr>
<td></td>
<td>Managing concurrent symptoms of anxiety and/or substance use</td>
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<td></td>
<td>Using techniques to deal with frustration, fatigue, and isolation</td>
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<tr>
<td></td>
<td>Managing sleep</td>
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<tr>
<td></td>
<td>Managing symptoms of medical conditions associated with depression</td>
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<tr>
<td></td>
<td>Relaxation</td>
</tr>
<tr>
<td></td>
<td>Using strategies for preventing relapse of depression</td>
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<tr>
<td>Lifestyle</td>
<td>Exercise</td>
</tr>
<tr>
<td></td>
<td>Overcoming barriers to exercise adherence</td>
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<tr>
<td></td>
<td>Vacations</td>
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<tr>
<td></td>
<td>Leisure activities</td>
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<tr>
<td></td>
<td>Healthy nutrition and diet</td>
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<tr>
<td>Social support</td>
<td>Family support</td>
</tr>
<tr>
<td>Communication</td>
<td>Relationships with peers and friends</td>
</tr>
<tr>
<td></td>
<td>Assertiveness</td>
</tr>
<tr>
<td>Others</td>
<td>Accessing support services</td>
</tr>
<tr>
<td></td>
<td>Creating action plans</td>
</tr>
<tr>
<td></td>
<td>Decision making</td>
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<tr>
<td></td>
<td>Goal setting</td>
</tr>
<tr>
<td></td>
<td>Problem solving</td>
</tr>
<tr>
<td></td>
<td>Career planning</td>
</tr>
<tr>
<td></td>
<td>Spirituality</td>
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</table>

*Adapted from: Barlow et al and Duggal.*
Depression differs from other chronic illnesses because of the associated social stigma and its effect on one’s self-esteem and identity. Core symptoms in depression include loss of interest, low motivation, and low energy levels, which are more pronounced compared with other medical conditions. Thus, whether general interventions of self-management like those used in the CDSMP are applicable to depression, is questionable. Evidence also shows that given a choice between antidepressants and psychotherapy, people with depression prefer psychotherapy because they assume that it provides them with an opportunity for personal exchange and to solve the problem underlying the depression. Self-management also assumes importance in the context of recovery. The concept of recovery in mental health has expanded beyond the narrow definition of absence of clinical symptoms to include the following:

- hope for the future
- reestablishment of a positive identity
- establishment of personal meaningful goals
- taking responsibility for one’s life
- feeling included and connected to others
- feeling empowered
- contributing to community life.

Established treatments of depression may help an individual meet the clinical cutoff for remission from depression on rating scales, but recovery still remains a person-centered paradigm. This is where self-management techniques complement the traditional medical model of treating depression. Finally, self-management could be used as a prophylactic strategy in individuals with a high risk of developing depression or those who have had previous episodes of depression to prevent onset, recurrence, or relapse of depression.

**Effectiveness of Self-Management in Depression**

Depression has been a late entrant in the field of self-management. Most of the initial studies on self-management focused on medical illnesses and, interestingly, studied depression as an outcome measure under the general rubric of psychological well-being. A landmark study on the CDSMP showed that although the program was successful in increasing healthful behaviors, maintaining or improving health status, and decreasing rates of hospitalization, a noteworthy negative finding was that there was no change in psychological well-being compared with the control group. A later study with a pre-post longitudinal design and lacking a control group documented the CDSMP being effective in decreasing depression when individuals were reassessed after 6 months. A review of the literature on self-management for people with chronic conditions reported that it is effective in managing depression, but the review included only 1 study on depression. A meta-analysis of “disease management programs” for depression demonstrated decrease in severity of depression, better adherence with treatment, and greater provider and patient satisfaction compared with usual primary care.

Self-management is one of the core components of the collaborative Chronic Care Model (CCM), and CCM has been studied in people with depression. Several meta-analyses have shown CCM to be an effective intervention in improving depression outcomes across a wide variety of settings, with an effect size ranging from 0.25 to 0.31. The benefit of this intervention, in some studies, lasted up to 5 years. To put this in perspective, the effect size of antidepressants in reducing depressive symptoms compared with placebo is 0.32. A notable finding that emerged from 1 of the meta-analyses was that CCM may benefit people with moderate to severe depression more compared with those with mild depression. When it comes to individuals with depression with comorbid chronic physical conditions, CCM is as effective in these individuals as in those without comorbid physical conditions. This has put an end to the speculation that self-management strategies based on the CCM model are more effective when used for treating depression in the context of chronic medical illnesses in a primary care setting.

Besides programs that are facilitated by mental health professionals, there is an increasing impetus on trained peer specialists co-leading self-management programs. Compared with a professionally led group, a peer-led group is more likely to enhance an individual’s sense of self-efficacy. A randomized controlled trial studying individuals with chronic depression demonstrated that a self-management program co-led by peer specialists resulted in decreased depression and higher recovery scores. Contemporary research shows that peer support increases an individual’s engagement in nonacute and less costly care; activates them for self-care; decreases substance use, unmet needs, and demoralization; and increases hope, empowerment, social functioning, quality of life, and satisfaction with life.

Although research has historically focused on self-management of depression from a chronic medical disease perspective, there are self-management programs that address depression per se outside a medical context. One such program is the Depression Self-Management Workshop, a community-based group program with 10 weekly sessions that are nonprescriptive in nature and emphasize participants’ own strengths in their own recovery. In a pre-post design study without a control group, the Depression Self-Management Workshop significantly decreased depressive symptoms and improved self-efficacy and self-management behaviors in individuals with depression. An important finding from this study was that most participants in this study were already being treated with antidepressants and had a history of having more than 1 episode of depression. This finding makes this intervention a viable option as an adjunct to antidepressants in individuals with recurrent depression.

Whereas most evidence points toward the effectiveness of self-management in improving outcomes in depression, some studies have not shown such positive results. These, however, were pilot studies with small sample sizes.

**Factors Influencing Self-Management**

On the basis of structured models of self-management such as the CDSMP, it
is tempting to think that such programs are homogenous and would benefit anyone with depression. Research shows otherwise. Self-management is not a one-size-fits-all intervention, and its effectiveness depends of several variables. Some of the key variables are listed in Table 2.⁴⁻⁶⁻⁻ Implicit in these factors are also the potential barriers to self-management, including at the patient, provider, and organizational levels. Also, it would be prudent to list factors that do not influence outcomes of a self-management program. The prominent ones in this category include system and clinic setting, disorder/diagnosis (depression vs other chronic medical illnesses), age, sex, minority status, and country where self-management is practiced.⁴⁻⁷ This suggests that self-management is not only an evidence-based but also a population-based intervention with broader public health implications.

**SELF-MANAGEMENT IN CONTEXT OF RECOVERY**

**What is Recovery?**

Now more than ever, a multifaceted humanistic approach to recovery is front and center of patient-centered treatment in mental health. Recovery is not an elusive feel-good concept, as some skeptics might claim. Researchers have broken down recovery into 5 broad dimensions:⁸⁻⁻⁻ 1. **Clinical** recovery: This includes symptom management, medical care, medication management, and psychotherapy
2. **Existential** recovery: This includes religion and spirituality, self-efficacy, personal goals and hope, and personal empowerment
3. **Functional** recovery: The 3 main components of functional recovery are employment, housing, and education
4. **Physical** recovery: Physical recovery refers to positive improvement in physical health and well-being. It is known that depression is associated with an increased risk of metabolic syndrome, which in part, may be related to unhealthy diet and lack of physical activity.⁹ In addition, physical recovery also involves recovering from the physical ill effects of any comorbid substance use disorders
5. **Social** recovery: Recovery from depression is incomplete without recovery in the interpersonal and community arena. Social recovery involves establishing and maintaining rewarding relationships with family, friends, peers, and significant others. It also involves engaging in rewarding social activities (eg, sports), actual and felt community integration, and active citizenship.

Clearly, recovery is more than just swallowing pills and changing one’s biochemistry. It is changing one’s life and requires hard work, strong will, vision, hope, courage, imagination, commitment, and resilience.

**Self-Management and Dimensions of Recovery**

In their quest to align self-management strategies to the currently prevailing concept of recovery, some investigators have identified individual strategies that target each of the 5 dimensions of recovery.⁹⁻⁻ Although listing all these techniques would be beyond the scope of this article, some key interventions are highlighted in Table 3. A review of various self-management strategies used by people with depression identified that the most helpful strategies

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**Table 2. Factors influencing self-management**

<table>
<thead>
<tr>
<th>Domain</th>
<th>Factors</th>
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<tbody>
<tr>
<td><strong>Personal/lifestyle</strong></td>
<td>Individual’s level of knowledge about his/her health condition, symptom management, medication management, and alternative therapy</td>
</tr>
<tr>
<td>characteristics</td>
<td>Health and cultural beliefs</td>
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<tr>
<td></td>
<td>Perception of stigma related to mental health issues</td>
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<td></td>
<td>Level of self-efficacy and hope to self-manage</td>
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<td></td>
<td>Availability of time to use self-management skills</td>
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<td></td>
<td>Prior experience with self-management</td>
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<tr>
<td></td>
<td>Ability to integrate lifestyle and treatment-related behaviors into everyday life</td>
</tr>
<tr>
<td><strong>Health status</strong></td>
<td>Comorbid conditions (eg, anxiety, substance use, personality disorders, chronic medical conditions)</td>
</tr>
<tr>
<td></td>
<td>Severity of depression</td>
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<td></td>
<td>History of prior good or poor response or adverse effects with interventions</td>
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<td>Cognitive ability to problem-solve</td>
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<tr>
<td><strong>Resources</strong></td>
<td>Financial (eg, funding for self-management programs, insurance coverage for self-management programs)</td>
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<tr>
<td></td>
<td>Psychosocial (eg, perceived support or lack thereof from family, friends, or peers and access to support or peer groups)</td>
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<td></td>
<td>Internet-based resources (eg, online peer support groups)</td>
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<tr>
<td><strong>Environmental</strong></td>
<td>Conditions at home (eg, perception of family members about an individual’s mental illness, health problems of other family members)</td>
</tr>
<tr>
<td>characteristics</td>
<td>Conditions at work (eg, support of employers and coworkers, time and schedule constraints imposed by work)</td>
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<tr>
<td></td>
<td>Community (eg, transportation, social stigma, access to places that facilitate self-management such as a gym)</td>
</tr>
<tr>
<td><strong>Health care system</strong></td>
<td>Access to a health care system that promotes self-management</td>
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<td></td>
<td>Time constraints for providers to use self-management tools</td>
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<tr>
<td></td>
<td>Availability of trained staff to run the self-management programs</td>
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<tr>
<td></td>
<td>Ease of navigating the health care system (eg, long wait times, confusing communication with staff)</td>
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<tr>
<td></td>
<td>Relationship with providers (eg, collaborative approach with shared decision making)</td>
</tr>
</tbody>
</table>
### Table 3. Self-management strategies in recovery

<table>
<thead>
<tr>
<th>Domain</th>
<th>Goals</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social</td>
<td>Surround yourself with people who make you feel better</td>
<td>Get support from friends, family, and people with a similar illness&lt;br&gt;Engage in activities with others&lt;br&gt;Choose the people with whom you can discuss problems&lt;br&gt;Avoid negative people or unhealthy relationships</td>
</tr>
<tr>
<td></td>
<td>Take care of others</td>
<td>Serve as a role model for friends and family&lt;br&gt;Recognize the support received&lt;br&gt;Serve others</td>
</tr>
<tr>
<td>Existential</td>
<td>Have a positive outlook</td>
<td>Take inspiration from someone who has recovered&lt;br&gt;Take stock of your own progress with recovery&lt;br&gt;Use downward social comparison&lt;br&gt;Reminisce about times of wellness&lt;br&gt;Use humor&lt;br&gt;Have spiritual beliefs&lt;br&gt;See the illness as an opportunity to make some changes&lt;br&gt;Read or post inspiring thoughts/images&lt;br&gt;Appreciate positive aspects of your life</td>
</tr>
<tr>
<td></td>
<td>Develop a balanced sense of self</td>
<td>Recognize and value strengths/achievements&lt;br&gt;Accept the illness&lt;br&gt;See mental illness as equivalent to a physical illness&lt;br&gt;Accept your limitations/weaknesses</td>
</tr>
<tr>
<td></td>
<td>Empower oneself</td>
<td>Realize the efforts required to recover&lt;br&gt;Find the motivation needed to recover&lt;br&gt;Be more assertive about your needs and expectations</td>
</tr>
<tr>
<td></td>
<td>Find meaning</td>
<td>Have realistic expectations about recovery&lt;br&gt;Pursue goals that promote autonomy, competence, and relatedness&lt;br&gt;Find meaning in life by clarifying your values&lt;br&gt;Find meaning even in adversity and suffering</td>
</tr>
<tr>
<td>Functional</td>
<td>Create a routine</td>
<td>Follow a schedule or a daily maintenance plan&lt;br&gt;Perform daily personal care tasks</td>
</tr>
<tr>
<td></td>
<td>Take action</td>
<td>Engage in activities that increase pleasure or sense of mastery&lt;br&gt;Create an action plan on the basis of realistic, relevant, and measurable goals&lt;br&gt;Adopt an important role in society&lt;br&gt;Respect your own rhythm as you take action</td>
</tr>
<tr>
<td>Physical</td>
<td>Maintain a healthy lifestyle</td>
<td>Be physically active/exercise&lt;br&gt;Adopt a good sleep pattern&lt;br&gt;Eat well&lt;br&gt;Reduce consumption of alcohol&lt;br&gt;Stop smoking</td>
</tr>
<tr>
<td></td>
<td>Manage one’s energy levels</td>
<td>Avoid stimulating or stressful situations&lt;br&gt;Engage in relaxation/breathing exercises&lt;br&gt;Reduce hours of work</td>
</tr>
<tr>
<td>Clinical</td>
<td>Seek formal professional help</td>
<td>Take your medication and/or continue psychotherapy&lt;br&gt;Receive help from a mental health organization&lt;br&gt;Seek prompt help in times of crisis&lt;br&gt;Receive an alternative treatment</td>
</tr>
<tr>
<td></td>
<td>Develop a better understanding of your illness</td>
<td>Investigate the causes of your illness&lt;br&gt;Attend conferences/workshops&lt;br&gt;Find information on mental illness&lt;br&gt;Learn about available resources</td>
</tr>
<tr>
<td></td>
<td>Manage daily symptoms</td>
<td>Analyze and change your thoughts/emotions/behavior&lt;br&gt;Challenge your fears&lt;br&gt;Gain some perspective on situations&lt;br&gt;Problem-solve</td>
</tr>
<tr>
<td></td>
<td>Prevent relapse</td>
<td>Remain vigilant to signs of a relapse/monitor your moods&lt;br&gt;Develop a relapse prevention plan</td>
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The concept of recovery shifts a clinician's attention away from the disease processes and onto the whole person in the life context. Although a provider still pays attention to the pathologic processes, it is hoped that a recovery-driven intervention will foster a mindset that goes beyond the traditional “fix-what’s-wrong” approach to “build-what’s-strong” approach. The first and foremost strategy to encourage self-management is for the clinicians to change their practice and accept advantages of transferring control to people with depression—a patient-centered approach that incorporates their preferences.

Ask Appropriate Questions
A simple yet effective way by which providers can facilitate self-management in people with depression is to ask appropriate questions. Activation Questions
Inherent in depression are fatigue, low energy, loss of interest, and lack of motivation that lead to avoidance and procrastination. This avoidance and procrastination fuels a sense of guilt, which then exacerbates depression. Behavioral activation is an evidence-based strategy that works to break this vicious cycle in depression. This entails having people with depression engage in activities that increase either their sense of pleasure or their feeling of mastery. The following are several questions that will help an individual with depression explore some of these activities:
• “What will you be doing differently when you are happy?”
• “Supposing you wake up on a Saturday morning and look back at your week and say, ‘Wow, that was a great week.’ During a great week, what do you suppose you would be doing?”
These questions help direct a depressed person to switch from negatively stated action-oriented goals. The Motivation Question
The motivation question goes like this: “Suppose one night, while you are asleep, you don’t know that the miracle has already happened. When you wake up in the morning and look back at your week and say, ‘Wow, that was a great week.’ During a great week, what do you suppose you would be doing?”

The Miracle Question
The miracle question helps the patient hone in on the solutions of a problem rather than getting stuck with the assumption that the solution is somehow connected with understanding and eliminating the problem. After the patient responds to the miracle question, you can ask, “What part of the miracle is already happening?”

Scaling Questions
“On a scale of 0 to 10, with 0 being no progress and 10 being that you have met your goal, how would you rate your progress in accomplishing your goal?” If the patient scores more than 0, ask, “How did you get up to this number from 0?” or “How is your score different from 0?” or “What makes your score not lower?” or “How will you know when you move just 1 number higher on this scale?”

The purpose of scaling questions is to amplify strengths, positive differences, and successes, which people with depression tend to disqualify. Doing scaling questions with a patient on an erasable whiteboard in your office and having that person circle the number s/he thinks s/he is at puts the patient in the driver’s seat for self-management.

Coping Questions
When bogged down with a problem, people tend to ignore their strengths and the coping skills that they may have used to deal with a similar problem in the past. Ask the patient, “What would your loved ones see you doing now that would tell them that you are being strong and successfully handling this situation?”

The Miracle Question
“Are you willing to do whatever it takes to make things better for you/solve this problem/achieve your goals?” You can also have the patient rate his/her motivation using the aforementioned scaling questions. Exception Questions
When facing a problem or a difficult situation, it is not uncommon for people to make global statements, and depression makes this worse because of irrational thought patterns, such as all-or-none thinking. For example, an individual may say, “I am angry all the time,” “I am totally stressed,” or “He is never at home.” These global statements reflect an inner state...
of feeling hopeless and out of control. However, no one stays angry 100% of the time, for they would surely be exhausted! In other words, every problem or difficult situation has some exceptions, but one has to look for those exceptions. Ask the patient, “Have there been occasions in the past when you didn’t face this problem/felt angry (or any other emotion)?” “What did you do differently at that time?” “Why were you not feeling angry (or any other emotion)?”

The purpose of finding exceptions is to help an individual do more of what has worked well for that person in the past when s/he was not facing a particular problem. This strategy allows patients to build on their strengths rather than inventing new strategies and also gives them a sense that they are in control more often than they think. Often, counting the minutes, hours, or days when a problem is not happening, makes the problem seem more solvable and less intrusive in life. For example, if a person feels depressed 3 days in a week and for 4 hours each day, it means that only 12 of 168 hours are “depression hours.” This gives patients more sense of control over their depression.

Problem Solving

Problem solving is one of the core components of self-management and is also an effective treatment of depression, especially in older adults. The problem-solving steps for the patient are described next.

1. Define the problem in clear and specific behavioral terms, that is, what specific behavior needs to be addressed or changed. One is able to generate better solutions for a specific problem such as, “I have been postponing paying my bills for last 2 weeks and feel overwhelmed whenever I try to do that” vs the vague problem, “I cannot get anything done.” To get the specifics of a problem, describe it in terms of Who? What? Where? When? Why? and How?
2. Define your goals in addressing the problem. “What is your desired outcome?” “Goals are often stated beginning with the phrase, “How can I …?”
3. Brainstorm possible solutions to the problem. When brainstorming solutions, generate as many solutions as possible, do not analyze or judge the possible solutions at this stage, and think in terms of both broad strategies and focused tactics. However, be aware that when one is feeling depressed, it is a challenge not to prematurely judge a solution negatively because of underlying negative irrational thoughts (eg, “This is never going to work,” or “Yes, but …” rejection of a solution). Also, a judgmental stance engendered by depression curbs creative thinking. If the patient is drawing a blank, use the following strategies to stimulate the brain into thinking about more solutions:
   a. “Think about an individual you know personally whom you admire and respect or someone from the world of movies, books, or current events. Next, ask yourself, ‘How would he or she approach this problem? What actions would this person take if faced with the same problem?’
   b. “Close your eyes and imagine yourself in the problematic situation. Imagine yourself successfully coping with the problem. Think of what you would say and do to deal effectively with the situation.”

4. Weigh pros and cons for each solution: “How likely is it that this solution would help you reach your goal?” “What bad things could happen if you pick this solution?” “What is the likelihood that you can implement this solution in its optimal form?”
5. Pick 1 solution and implement it. Sometimes, however, a combination of solutions may work better because they complement each other.
6. Evaluate the effectiveness of your approach and make changes if needed.
7. If the problem is not resolved, use 1 of the following troubleshooting strategies:
   a. Reset your goals because they may not be realistic
   b. Break the problem down into smaller chunks
   c. Think of more possible solutions
   d. Seek help from someone who is more knowledgeable or trained to deal with your situation.

Creating an Action Plan

A well-written action plan is key to the success of any self-management program and will help an individual to move from planning to action phase. A template for an action plan is illustrated as follows:

- **Goal:** SMART goal: Specific, Measurable, Attainable, Relevant, and Time-bound.
- **Action steps:** What steps must be taken to implement the goal?
- **Resources:** What specific supports are needed to implement the action steps?
- **Potential barriers:** What problems would one run into with the action steps (time, cost, scope)?
- **Measures of implementation:** How would a person know that s/he has succeeded in his/her action steps?
- **Deadline:** By when will an individual complete the action steps?

Gratitude Journal

For 1 or 2 nights a week, write down 3 things that went well that day and their causes. Gratitude is one of the most commonly used evidence-based positive psychology practices for treating depression. Interestingly, individuals with chronic medical conditions who are more likely to express gratitude show lower levels of depressive symptoms compared with those who are less likely to express gratitude.

Exploring Your Core Values

Psychologist Russ Harris describes values as our heart’s deepest desires for the way we want to interact with the world, other people, and ourselves. They are what we want to stand for in life, how we want to behave, what sort of person we want to be, and what sort of strengths and qualities we want to develop. Values are subjective; what one may consider as a value (eg, being famous) may be considered as being cocky by another person. Below are some questions that you may ask a patient to evaluate his/her values:

- “What do you care most about in life?”
- “What matters most to you?”
- “How do you hope your life will be different a few years from now?”
- “What are the rules you live by?”
people with severe mental illness across community mental health centers, its use in primary care settings for depression needs more research. ♦

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References
Never Despair

It may be hard to cure, but not impossible for him that is most grievously affected, if he be but willing to be helped.

— Robert Burton, 1577-1640, English scholar, author of The Anatomy of Melancholy
From Dr. Lippert: "I snapped this picture while at Venice Beach earlier this year with my children. My teenage son has a better picture of the approaching storm, but I still thought mine was lovely enough to share."

Originally from California, Dr. Lippert currently hails from Portland, OR, where she works as a Mental Health Therapist at the East Interstate Clinic and as a Child Interviewer on a child abuse evaluation team at Child Abuse Response and Evaluation Services (CARES) Northwest, a collaboration involving Kaiser Permanente and 3 other leading health systems. During her spare time, she loves to write even more than she loves to take pictures. Her latest publication is a children’s book titled Goodbye, School.

More work by Dr. Lippert can be seen on page 89.
Successful outcomes of airway emergencies (AEs) in the hospital depend on rapid recognition and intervention before patients become unstable. We describe our medical center's experience with a coordinated rapid response to AEs, including an illustrative case. This approach emphasizes early recognition of impending AEs and instantaneous activation of a team of specialists and operating room personnel to rapidly respond to AEs anywhere in our medical center. The literature on critical response teams for AEs is reviewed.

**CASE EXAMPLE**

A 46-year-old woman with lupus receiving long-term immunosuppressive therapy was brought to the Emergency Department (ED) with a fever, hypotension, and altered mental status. She had retrognathia and a short thyromental distance. Two experienced providers attempted orotracheal intubation for airway protection but could not place the endotracheal tube. Airway edema ensued, further making intubation difficult. The responding intensivist placed a laryngeal mask airway, but adequate positive pressure ventilation and tidal volumes could not be maintained. An airway emergency (AE) (“Condition A”) was declared, the critical response team was mobilized, and the patient was evaluated quickly by the responding on-call anesthesiologist and otolaryngologist. The patient was transported to the operating room for further airway management, including a possible tracheostomy. She was successfully intubated by the otolaryngologist through the laryngeal mask airway using an Aintree intubation catheter over an intubating bronchoscope. A 6.0-mm endotracheal tube was passed over the catheter, and the airway was secured. The patient remained intubated for several days and was extubated uneventfully. She recovered fully and was discharged home without sequelae.

**INTRODUCTION**

AEs are critical events that can occur at any time in the hospital or clinic. First responders often vary in their level of expertise and confidence in managing AEs. Ideally, rapid assessment and intubation of the airway will occur while the patient is still cooperative and breathing spontaneously. At times, a surgical airway must be obtained when other means fail. Inexperience, inadequate equipment, and a lack of trained support staff can complicate an already tenuous situation. Time is probably the most crucial factor that must be managed to resolve an AE successfully. When time is squandered, options rapidly diminish, and the risk of a poor outcome rises. The morbidity associated with unplanned procedures is well known.3,4 Mortality is especially high if the patient is in cardiopulmonary arrest at the time the emergent surgical airway is attempted.2,4,5

This article describes our medical center’s approach toward a coordinated response to AEs. The emphasis of this approach is on early recognition of impending AEs and instantaneous activation of a team of specialists and operating room personnel to rapidly respond to them anywhere in our medical center. Early recognition is reinforced through education and periodic drills. Confidence is encouraged through an expansion of privileges. Sequential improvement is maintained through structured debriefings. Any medical center can benefit from such a program, especially smaller hospitals and those without dedicated in-house resident support. The challenges in those facilities of handling low-frequency, high-acuity events make the implementation of such a program even more appropriate.

**CRITICAL RESPONSE TEAM AND “CONDITION A”**

The Kaiser Permanente Fresno Medical Center is a 169-bed, not-for-profit community hospital with maternity, emergency, intensive care, outpatient, radiology, laboratory, pharmacy, and health education services. Located in the San Joaquin Valley of California, the medical center supports 3 additional outpatient satellite facilities in Selma, Oakhurst, and Clovis with a total member service population of approximately 145,000. Level 1 trauma is managed by other area hospitals, and there are no surgical residents or critical care fellows in the facility. Head and neck surgeons do not take “in-house call.”

In 2010, a group of medical center leaders met to review and improve the management of AEs. The impetus for this work was a conference from the prior year addressing hospitalwide safety. A near-miss that occurred in the ED illustrated the need for a more coordinated response in our facility to AEs, a process we named Condition A. In 2012, the Medical Executive Committee approved a policy creating a critical response team for AEs. This policy is reviewed every 3 years and requires ongoing approval by the committee. On average, approximately 4 Condition As are called per year in our facility. This situation does not include stat anesthesia calls, awake tracheostomies, or fiberoptic intubations that may occur outside the scope of a Condition A call.

When an impending or actual AE is identified, the page operator is notified and broadcasts an alert (“Condition A”) on the overhead paging system throughout the medical center. In addition, pages are sent to the members of the AE critical response team (Table 1). Their respective roles have been clarified formally in the policy and are reinforced through mock drills and real-life emergencies.
On activation, the team converges on the location of the AE prepared to assist in intubation of the patient or to perform a surgical airway if needed. If the AE occurs in the ED or Intensive Care Unit (ICU), the physician in charge of the patient activates the Condition A and directs care until the critical response team assembles. These physicians are skilled at noninvasive airway management but may be called on to obtain a surgical airway if a head and neck surgeon is not immediately available. If the AE occurs in the hospital floor or clinic, the initiating responder evaluates and treats the patient until more experienced help arrives.

To enhance their confidence and skills with performing surgical airways, the clinical privileges of ED and ICU physicians have been expanded to include assisting head and neck surgeons in the operating room on elective tracheostomies. Although cricothyrotomies are more likely to be done by nonsurgeons, it is believed that mastery of the technique of tracheostomy provides adequate training for both procedures.

In the ED and ICU, all the equipment necessary for oral or nasal intubation, as well as emergent surgical airway intervention, is maintained in those departments. Each setting has its own intubating bronchoscopes with video monitors, portable videolaryngoscopes (GlideScope, Verathon Inc, Bothell, WA), and jet ventilators. Elsewhere in the hospital, this equipment is brought via cart to the bedside by the respiratory therapist on duty. Figures 1 and 2 depict the cart in detail, and Table 2 lists the standardized equipment carried in each cart. Fiberoptic intubations are typically carried out by Anesthesiology Department staff or a head and neck surgeon.

Both physician and nonphysician health care providers may call a Condition A. Respiratory distress resulting from angioedema, deep neck space infection, tumor, active bleeding, and recognized anatomical factors that lead to a “cannot intubate, cannot ventilate” scenario are all reasons to initiate a Condition A (Table 3). However, it is recognized that a Condition A may also evolve out of these other calls in conjunction with the emergency being treated. Other authors have published similar criteria for activating rapid response teams. To differentiate them, we have encouraged staff to identify those patients with anticipated or evolving airway distress combined with risk factors for a difficult airway (Table 3). However, it is recognized that a Condition A may also evolve out of these other calls in conjunction with the emergency being treated. Other authors have published similar criteria for activating their critical incident response teams.

If time allows, AE cases are typically managed in the operating room where lighting, equipment, and trained personnel are optimal. Transportation occurs via gurney with monitoring, anesthesia staff, the surgeon, and a respiratory therapist usually in attendance. Culturally, there is a strong tradition of teamwork among operating room staff and providers that is enhanced through a TeamSTEPPS (Team Strategies & Tools to Enhance Performance and Patient Safety) approach to communication. TeamSTEPPS is an evidence-based teamwork system to

<table>
<thead>
<tr>
<th>Team member</th>
<th>Roles/responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesiologist on-call</td>
<td>Arrives prepared to intubate the patient nasotracheally or orotracheally.</td>
</tr>
<tr>
<td>CCU RN</td>
<td>Assists in the AE anywhere in the hospital, including the ED, OR, and floor.</td>
</tr>
<tr>
<td>Head and neck surgeon on-call</td>
<td>Directs the surgical team and either performs or assists qualified personnel in performing intubation, cricothyroidotomy, or tracheostomy.</td>
</tr>
<tr>
<td>Nursing supervisor</td>
<td>Presents to the area of the AE. Assists in coordination of care. Assumes OR charge nurse responsibilities after hours.</td>
</tr>
<tr>
<td>OR charge nurse</td>
<td>Coordinates activities in the OR to secure a room, team, and equipment for the impending arrival of a critical airway patient.</td>
</tr>
<tr>
<td>Respiratory technician</td>
<td>Transports difficult airway cart from the CCU to the location paged (OR and ED have their own staff for this). Checks equipment, sets up intubating bronchoscope or videolaryngoscope (GlideScope, Verathon Inc, Bothell, WA), and assists with intubation and ventilation. Prepares and administers topical airway medications if ordered by the physician.</td>
</tr>
</tbody>
</table>

Table 1. Critical response team personnel and responsibilities

*Not in-house after hours.

AE = airway emergency; CCU = Critical Care Unit; ED = Emergency Department; OR = operating room; RN = registered nurse.

Figure 1. Six-drawer airway cart with attached cabinet at right (and in Figure 2) for 2 intubating bronchoscopes. Note Aintree catheters (Cook Medical) hanging from the cabinet on frontal view.

Figure 2. Cabinet attached to airway cart with 2 intubating bronchoscopes.


**Table 2. Contents of difficult airway cart**

<table>
<thead>
<tr>
<th>Drawer</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Skin preparations, scalpels, sutures, syringes</td>
</tr>
<tr>
<td>2</td>
<td>Bronchoscopy valves, slip tip syringes, suction catheters, Lukens mucus traps</td>
</tr>
<tr>
<td>3</td>
<td>Laryngoscopes, bite blocks, atomizers, green catheter guide airway</td>
</tr>
<tr>
<td>4</td>
<td>Tracheostomy tubes, LMA’s, lubricant</td>
</tr>
<tr>
<td>5</td>
<td>Oral and nasal ET tubes, tube exchangers, intubating stylets</td>
</tr>
<tr>
<td></td>
<td>Oral airways and nasal trumpets: MLT tube, cuffed 5.0 mm;</td>
</tr>
<tr>
<td></td>
<td>MLT tube, cuffed 6.0 mm</td>
</tr>
<tr>
<td>6</td>
<td>Tracheostomy tray</td>
</tr>
<tr>
<td></td>
<td>Cricothyroidotomy set</td>
</tr>
<tr>
<td></td>
<td>Transtracheal ventilation needles</td>
</tr>
<tr>
<td></td>
<td>Jet ventilator</td>
</tr>
<tr>
<td></td>
<td>Bronchoscopy kit</td>
</tr>
</tbody>
</table>

* Videolaryngoscopes are kept in the Emergency Department, Intensive Care Unit, and operating room and are brought to the bedside separately from the airway cart. 

**Table 3. Factors suggestive of difficult orotracheal intubation**

<table>
<thead>
<tr>
<th>Pediatric risk factors</th>
<th>Adult risk factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airway foreign body</td>
<td>Airway bleeding*</td>
</tr>
<tr>
<td>Airway malformation (malacia, stenosis)</td>
<td>Angioedema (opharyngeal and supraglottic)*</td>
</tr>
<tr>
<td>Ankylosis</td>
<td>Anterior larynx</td>
</tr>
<tr>
<td>Congenital disorders of the upper aerodigestive tract (Pierre Robin syndrome, Treacher Collins syndrome, trisomy 18 syndrome, Down syndrome, Klippel-Feil syndrome, CHARGE syndrome)</td>
<td>Cardiac arrest</td>
</tr>
<tr>
<td>Cormack-Lehane Grades 3 and 4</td>
<td>Deep neck space infection</td>
</tr>
<tr>
<td>Deep neck space infection</td>
<td>Difficult intubation history*</td>
</tr>
<tr>
<td>Difficult intubation history</td>
<td>Difficult mask ventilation</td>
</tr>
<tr>
<td>Difficult laryngoscopy</td>
<td>Head and neck tumor/cancer*</td>
</tr>
<tr>
<td>Neck mobility limitation/cervical spine fusion</td>
<td>Inhalation injury</td>
</tr>
<tr>
<td>Trismus</td>
<td>MacroGLOSSIA</td>
</tr>
<tr>
<td>MacroGLOSSIA</td>
<td>Male sex</td>
</tr>
<tr>
<td>Mandibular hypoplasia</td>
<td>Mallampati oropharyngeal classification (high)</td>
</tr>
<tr>
<td>Micrognathia/retronathia</td>
<td>Maxillomandibular fixation</td>
</tr>
<tr>
<td>Postsurgical airway edema</td>
<td>Limited mouth opening/trismus</td>
</tr>
<tr>
<td></td>
<td>Obesity*</td>
</tr>
<tr>
<td></td>
<td>Neck mobility limitation/cervical spine fusion*</td>
</tr>
<tr>
<td></td>
<td>Presence of a tracheostomy</td>
</tr>
<tr>
<td></td>
<td>Prominent maxillary incisors</td>
</tr>
<tr>
<td></td>
<td>Presence in the ED</td>
</tr>
<tr>
<td></td>
<td>Recent neck surgery</td>
</tr>
<tr>
<td></td>
<td>Reduced sternomental distance</td>
</tr>
<tr>
<td></td>
<td>Reduced thyromental distance</td>
</tr>
<tr>
<td></td>
<td>Retronathia</td>
</tr>
<tr>
<td></td>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td></td>
<td>Subcutaneous emphysema</td>
</tr>
<tr>
<td></td>
<td>Trauma (facial, cervical, laryngeal)</td>
</tr>
<tr>
<td></td>
<td>Tracheal stenosis/stent</td>
</tr>
<tr>
<td></td>
<td>Wilson risk score (high)</td>
</tr>
</tbody>
</table>

* Items in boldface were found to be most predictive in the study by Hillel et al.7

**CHALLENGES OF IMPLEMENTATION**

Implementation of the Condition A policy was not without challenges. Engaging the principal stakeholders was an early barrier, but this was overcome by emphasizing the critical lifesaving work of the initiative. The respective roles and skill sets of the involved providers were already established, albeit their execution in the event of a true AE could be uncoordinated and inconsistent. Bringing organization to these efforts through a coherent policy with clearly defined roles helped overcome this problem. Equipment was already in place and was of high quality to begin with, so no additional expenditures were needed in this area. Expansion of privileges to allow ED and ICU physicians to accompany head and neck surgeons to the operating room required revision of existing privileges through our Credentials and Privileges Committee.

Education and standardization of practice has been slow but steady and relies on periodic drills, presentations of the Condition A initiative at departmental meetings, and sharing of lessons learned from each Condition A occurrence. A homepage on the medical center Intranet was created that outlines the goals of the Condition A policy, identifies medical center leaders, and has an online feedback form to submit after each event. An ongoing barrier has been maintaining awareness among new physicians, nurses, and ancillary staff as they onboard into our medical center. Incorporating this information into the
onboarding process has not been done but is certainly a worthwhile endeavor that we continue to explore.

EXPERIENCE SINCE IMPLEMENTATION

Since this policy was adopted in our medical center in 2012, we have had 24 Condition A calls, or 4 on average per year. The numbers of calls per year ranged from 1 (in 2014) to 7 (in 2017). Patient demographic characteristics were not routinely collected on these patients, which limits our analysis. However, 54% of patients came from the ED; 29%, from the ICU; and 17%, from the wards. None came from the clinics. All were adults. Of the 24 Condition A calls, 13 (54%) occurred from 7 am to 7 pm and 11 (46%) occurred from 7 pm to 7 am, which is consistent with what other authors report.15 Angioedema and deep neck space infections accounted for most of these cases, which is seen in other studies.13 Excluded from these numbers are patients who may have been brought directly to the operating room for airway intervention by the attending otolaryngologist. These calls would not necessarily have triggered a Condition A call if the patients were stable and breathing on their own. Examples include patients seen in the clinic for routine cancer follow-up only to be found to have stridor caused by an obstructing tumor or patients in the ED with deep neck space infections (eg, Ludwig angina) but without increased work of breathing.

There has been one death after a Condition A was called because of an inability to secure the airway. This patient had been electively decannulated after tracheostomy. The patient experienced cardiac arrest secondary to respiratory failure and could not be intubated. An emergent surgical airway was attempted but could not be obtained.

All other cases of AEs managed with the new critical response team had good outcomes, including the illustrative case presented in the abstract. Consistent with the experience of other groups,7,16 it is our perception that the need for emergent surgical intervention has decreased. Those surgical airways that have been obtained have not resulted in substantial morbidity or mortality.

DISCUSSION

Review of Literature

AEs are infrequent but life-threatening events that can occur without warning at any time in the hospital. Nearly all these events will occur in relatively resource-rich areas such as the ED, ICU, or Pediatric ICU. Concentrating equipment, training, and personnel in these areas will address most AEs. However, a sizable minority can occur in more isolated areas of a hospital.12 In a study by Hillel et al,7 39% of AEs occurred on the hospital wards and only 5% were from the ED. In our experience, 17% of AEs occurred on the wards. This necessitates a mobile team capable of responding in a timely manner to any area in the facility.

Risk factors for a difficult intubation have been reported by many authors.6-11 When known in advance, detailed plans can be made for successful airway management. Dissemination of this information early and widely in a patient's hospitalization may involve numerous approaches (see Sidebar: Communication Enhancers for Use with Difficult Airway Cases). There are various screening approaches to attempt to identify potential difficult intubations, such as the Mallampati oropharyngeal classification or the Wilson risk score, but these suffer from poor to moderate diagnostic accuracy.17 Furthermore, a large number of patients may have no identifiable risk factors. For this reason, the ability of a critical incident response team to assemble and intervene quickly at the patient’s bedside to stabilize the airway becomes essential.

Common features of most critical airway response teams include: 1) a dedicated multidisciplinary team with defined roles for each team member; 2) involvement of anesthesiology, surgery, critical care, respiratory therapy, and nursing; 3) activation of the team through a centralized paging system; 4) ability of the team to respond anywhere in the hospital; 5) equipment for airway management that is brought directly to the patient’s bedside; and 6) education for physicians and staff on AE recognition and how/when to activate the critical response team. Furthermore, critical airway teams must be skilled in all aspects of airway management (Table 4). Most team members become proficient in these skills by the end of their residencies. However, specialty courses dedicated to management of the difficult airway are offered by many leading institutions and through specialty-specific boards.

The most comprehensive examples of critical airway teams have been reported by authors from large Level I trauma centers with academic affiliations.6,8,10,11,13,18,19 These institutions may have an oversight committee responsible for data acquisition, quality improvement, training, and education. In addition to physician representatives, membership may also include personnel as diverse as human factors engineers, Lean Six Sigma experts, safety officers, and risk management specialists. The core critical response team

<table>
<thead>
<tr>
<th>Table 4. Skill sets required of a critical airway team</th>
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<tbody>
<tr>
<td><strong>Type of skill set</strong></td>
</tr>
<tr>
<td>Intubation</td>
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<td> </td>
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<tr>
<td> </td>
</tr>
<tr>
<td>Laryngoscopy</td>
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<td> </td>
</tr>
<tr>
<td>Placement of supraglottic airway device</td>
</tr>
<tr>
<td>Surgical airway management</td>
</tr>
<tr>
<td> </td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td> </td>
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</tbody>
</table>
The Critical Response Team in Airway Emergencies

is responsible for direct patient care and may be composed of numerous medical and surgical disciplines with support from nurses, respiratory therapists, pharmacists, radiologists, and even chaplains. In addition to active intervention in an emergency, these teams may offer in-depth consultation services. Nykiel-Bailey and colleagues\(^\text{13}\) have reported on their Difficult Airway Service with an emphasis on advanced identification and planning for difficult airways. Their average daily census at Washington University in St Louis, MO, was 9 patients per day. The chief role is to review patient airway status, communicate recommendations to the consulting service, round daily, and maintain an accurate inpatient census list. They then assist the primary team in airway management as needed.

Medical centers specializing in pediatric care have benefited from critical airway teams. Congenital abnormalities of the upper aerodigestive tract and trachea can make intubation/extubation uniquely challenging. Pediatric patients may desaturate quickly and are more prone to respiratory arrest than are adults. Furthermore, most algorithms for managing the difficult airway focus on adults rather than pediatric patients.\(^\text{10,11}\) Although the reported mortality for adults after the implementation of critical response teams has generally been very low in most institutions, the findings of Sterrett et al\(^\text{11}\) indicate that mortality in pediatric AEs can still be substantial. Compared with other studies of similar size, they reported a mortality rate of 6% (10 patients of 162 activations) related to the AE itself. In a study by Mark et al,\(^\text{3,13,18}\) surgical airway rescue was less common in children than in adults (4 vs 29) and was related to high mortality (75%), possibly because it was performed too late in the critical airway event and/or after respiratory arrest had already ensued. The authors suggested that earlier surgical airway intervention may be an opportunity for improvement.

In these institutions, the benefit of a prospective consultation service has been demonstrated. The Difficult Airway Service at Washington University in St Louis, MO, may be consulted regarding patients who present with risk factors for difficult intubation.\(^\text{10}\) A plan for airway management is formulated in advance, and the patients are followed-up through their hospitalization. If intubation is required, this service may be directly involved and will also help outline a plan for safe extubation.

The presence of a head and neck surgeon on the critical airway response team has been reported to reduce the need for emergent surgical interventions\(^\text{4,11}\) and has resulted in decreased morbidity and mortality.\(^\text{7}\) In the study by Hillel et al,\(^\text{7}\) the percentage of cricothyrotomies performed decreased by 71%, perhaps because of increased comfort by the team with fiberoptic nasal intubation.

In the work by Sterrett and colleagues,\(^\text{11}\) head and neck surgeons managed most AEs in children through intubation with the assistance of laryngoscopy (rigid and flexible). Only a small number needed a surgical airway. Having a member skilled in the surgical airway may help move teams faster along the difficult airway algorithm, with less wasted time on redundant and ineffective steps. Timely surgical intervention has been shown to reduce mortality and morbidity. However, once cardiopulmonary arrest has occurred, the mortality rate rises significantly.\(^\text{3,11,18}\)

Mark and colleagues\(^\text{13}\) have argued persuasively for the implementation of a critical airway team. Death and anoxic brain injuries arising from AEs constitute a large proportion of malpractice claims inside and outside the operating room. Having a reliable and robust response system in place to deal with low-frequency but high-acuity events is important for maintaining good quality outcomes. Survival from cardiac arrest has also been shown to improve with the presence of a dedicated airway team.\(^\text{18}\)

### Project Strengths and Limitations

This article reviews the development of a specialized critical airway response team in a small hospital where surgical expertise is not in-house, events are few, and there are no residents. Our critical response team has several strengths. The development of our team did not require additional capital expenditures on any equipment or personnel. Instead, existing resources were reorganized via a coherent policy so that lifesaving interventions are completed parallel rather than sequentially. This team encompasses the use of an otolaryngologist, which has been

![Existing resources were reorganized via a coherent policy so that lifesaving interventions are completed in parallel rather than sequentially.](image-url)

### Communication Enhancers for Use with Difficult Airway Cases\(^\text{5,13,14,18}\)

**Electronic medical record enhancers:**
- Active problem list to include “difficult intubation”
- Hospital census updated daily to reflect all known patients at risk of difficult intubation
- Prominent banner/header in the electronic medical record denoting difficult intubation
- A hard stop warning when the chart is opened that requires the user to acknowledge the presence of a difficult intubation in the problem list
- Easily identified notes in the medical record from a difficult airway service

**Direct patient care enhancers:**
- Dedicated consultative service responsible for daily rounds on patients when required
- Easily visible signage at the patient’s bedside with specific instructions for managing the airway
- Special wristbands worn by patients on admission that identify them as a potential difficult intubation
- Protocols that activate the critical airway team directly for intubation and extubation of identified patients

**Patient education enhancer:**
- Educational materials provided to the patient about a difficult airway and the potential role of tracheostomy in its management.
Initiation of a critical response team in our medical center has been viewed as a marked improvement in patient care. The need for emergent surgical intervention appears to have decreased, and surgical airways that were obtained have not resulted in substantial morbidity or mortality. However, opportunities for improvement exist, including better identification of AE risk factors, acquisition of specific patient data, and a more robust training program.

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

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How to Cite This Article

CONCLUSION
AEs are life-threatening events that are infrequent and often unpredictable. When an AE is managed poorly, the consequences can be devastating for the patient and the hospital. Larger, academically affiliated, Level I trauma centers encounter these events more frequently and tend to be better equipped with more in-house staff to respond. Smaller community hospitals generally have fewer resources and personnel. Ensuring that providers maintain optimal performance levels is a challenge in both settings and mandates the development of specialized critical incident response teams.

References
How to Determine Whether Our Patients Can Function in the Workplace: A Missed Opportunity in Medical Training Programs

Edward C Alvino, MD1; Taha Mansoor Ahmad, MD, MPH2

E-pub: 05/20/2019

ABSTRACT
Patients often hand their physicians disability forms, and physicians too often struggle to complete them. Many physicians lack the training to complete these forms. This article aims to provide a clear understanding of impairment, limitations, restrictions, and disability. It explains how physicians can use skills they already possess to appropriately assess limitations, restrictions, and functional capacity, and it explains why accurate determinations are a vital part of good patient care.

INTRODUCTION
A 41-year-old warehouse worker arrives in your office with a complaint of chronic low back pain and requests that you complete a disability form.

Three open questions are posed to all practicing physicians and to physicians in training:
1. How comfortable are you addressing medical questions in the assessment of disability of your patients?
2. Have you had, or are you receiving, the appropriate medical training to adequately address medical questions on the limitations and/or restrictions that your patients may have because of their medical conditions?
3. Do you see this type of medical assessment as more of a nuisance that takes you away from providing your patients with the level of care that they need; or do you see this as an important part of the medical care that you provide for your patients?

It is not surprising that many physicians feel uncomfortable addressing medical questions in the assessment of disability for their patients. Physicians want their patients to be pleased with their care, they work to avoid discord with their patients; and they view themselves as advocates for their patients. But does being an advocate for your patient mean doing what your patient wants, or does it mean doing what is medically best for your patient?

DEFINING DISABILITY
The terms used in making a disability determination are impairment, limitations, restrictions, and disability. Impairment is the loss of structure or function, physically or mentally, because of disease or injury. A limitation is an activity that a person would be physically or mentally incapable of performing, even if s/he wanted to perform it, because of an impairment. A restriction is an activity that you would not allow a patient to perform, even if that patient were capable of performing it, because of an unacceptable risk resulting from that patient’s impairment. The same restrictions should apply to all individuals with the same level of impairment.1 For example, during a grand mal seizure, a patient would also be restricted from driving until seizure free for a time interval according to state law.

Disability is a determination usually made with medical, vocational, and legal input. For physicians to be comfortable and confident in their assessment of disability, they must focus on their medical assessment of impairment, limitations, and restrictions—what we term the medical aspects of disability—and avoid involving themselves in the vocational or legal aspects of disability.

The definition of disability depends on the organization defining it. The World Health Organization, the United Nations, the Americans with Disabilities Act, the Social Security Administration, and private insurance companies may all define disability differently. For private disability companies, the definition of disability may vary among insurers and may even vary between policies issued by the same insurer.

If the practicing physician stays within the role of addressing functional ability by accurately describing limitations and/or restrictions, it should not matter (to the physician) who is defining disability. If the medical record documents the appropriate limitations and/or restrictions that a patient needs to follow because of their medical conditions, it should not matter (to the physician) who is defining disability. If the medical record documents the appropriate limitations and restrictions, it should not matter (to the physician) who is defining disability. If the medical record documents the appropriate limitations and/or restrictions—what we term the medical aspects of disability—and avoid involving themselves in the vocational or legal aspects of disability.

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GAPS IN TRAINING
A review of the literature reveals a paucity of studies as to whether medical training programs in the US provide structured training for residents and fellows on the medical aspects of disability. We have encountered widespread physician discomfort and inconsistent training when it comes to disability applications and assessing patients’ functional ability. Many physicians view completing disability forms for private insurance companies or the Social Security Administration as a tedious exercise. In the absence of effective training, physicians may not view medical assessments of disability as their role and may fail to appreciate why such assessments are an important part of their patients’ medical care.

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Keywords: disability definition, functional ability, functional ability medical aspects of disability, unemployment, iatrogenic disability, medical assessment of disability, medical training to address limitations and restrictions, risk factors for poor health
Determing Function

An accurate medical determination of functional ability is essential for the physical and mental well-being of our patients and should be considered an aspect of high-quality health care. There is considerable literature demonstrating the association of adverse health outcomes with unemployment, the increased risk of death with unemployment, and that unemployment is a risk factor for poor health. Such studies accentuate the need for physicians to make accurate determinations when assessing functional ability in the presence of an impairment, and when assessing limitations and restrictions for patients with impairments.

This can be accomplished only by taking an accurate medical history, conducting an adequate physical examination, appropriately interpreting test results, and recognizing the consistencies and inconsistencies between what is reported and what is observed. Only then is the physician able to make determinations on limitations and restrictions that reflect reality. When a patient reports that chronic low back pain prevents adequate focus and concentration when sitting at work, a physician should question whether the patient is able to focus and concentrate when driving. When a patient reports that severe shoulder or arm pain has precluded the lifting of more than 5 lbs on a long-term basis, a physician should look for signs of atrophy on examination and observe how the patient moves his/her arm in the physician’s office.

Assessing Limitations and Restrictions as Part of Good Patient Care

Physicians must use the same skills in assessing limitations and restrictions that they use to make other accurate diagnoses: Correlating a patient’s symptoms with astute observations and examination findings, recognizing consistencies and inconsistencies, and formulating opinions that reflect sound medical reasoning. When individuals are symptomatic from impairments, they turn to their trusted physicians not only for evaluation and treatment but also for guidance on rest, activities, and any needed restrictions. Patients’ perceptions regarding recovery and coping with their impairments are influenced by their environment, including the workplace, family, and social networks. Patients can also be powerfully influenced by the attitude, approach, and style of the treating physician, especially in the early weeks and months of impairment.

A physician’s care should focus on maximizing the functional ability and resiliency of his/her patients while appropriately advising patients on avoiding activities that greatly compromise their safety and well-being. Just because a patient has an impairment does not mean that a patient is unable to work. A physician should not agree to support disability simply because the patient feels that s/he should not have to work with an impairment, and a physician should not document limitations or restrictions before determining consistency with the patient’s history, examination findings, test results, or activities observed by the physician.

Physicians should avoid inadvertently contributing to “iatrogenic disability.” Examples include 1) disability caused by the inappropriate use of medication resulting in greater restrictions or limitations than the condition being treated, such as long-term narcotic therapy for nonmalignant chronic pain syndromes, or 2) inappropriate medical advice that further compromises the patient’s well-being and functional ability, such as the inappropriate prescription of rest and inactivity for chronic lower back pain instead of a prescribed monitored graduated exercise program.

Recommendations

According to Talmage et al., “The American Medical Association encourages physicians everywhere to advise patients to return to work at the earliest date compatible with health and safety and recognizes that physicians can, through their care, facilitate patients’ return to work.” Have physicians received the training needed to ensure that they are able to provide their patients with both the advice and the care needed to make the appropriate medical determinations to successfully meet the American Medical Association’s recommendations? Do health care leaders and health care organizations have any interest in evaluating physician’s performance relevant to the medical aspects of disability?

Because unemployment and disability are linked to adverse health and well-being, a sound medical assessment of disability is part of good medical care, and an inappropriate medical assessment of disability represents a failure of good patient care. Organizations such as the National Committee for Quality Assurance that develop clinical metrics for quality should be encouraged to develop similar metrics to assess medical certification for disability. Medical schools and postgraduate training programs should take responsibility to provide training on the medical aspects of disability, and state medical boards should advocate for periodic continuing education on this topic.

In the name of good patient care, let the training begin.

Disclosure Statement

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

Acknowledgments

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How to Determine Whether Our Patients Can Function in the Workplace: A Missed Opportunity in Medical Training Programs

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Grappling

The problems of disease are more complicated and difficult than any others with which the trained mind has to grapple; the conditions in any given case may be unlike those in any other; each case, indeed may have its own problem.

— William Osler, MD, 1849-1919, physician, pathologist, teacher, diagnostician, bibliophile, historian, classicist, essayist, conservationalist, organizer, manager, and author
This picture was taken from an offshore cruise ship in the Pacific Ocean in July 2018. The Kilauea Volcano is located on the southeastern part of the island of Hawaii (the Big Island). The ship could only stay in the area a short period of time because of the extremely hot water from the volcano.

Dr. Jacobs is the President and Chief Executive Officer of Bethesda Referral and Teaching Hospital in Haiti and the Associate Editor-in-Chief of *The Permanente Journal*. 
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Percutaneous Endoscopic Necrosectomy of Complex Walled-Off Lateral Necrosis of the Pancreas with the Aid of Laparoscopic Babcock Forceps: A Case Report of an Endoscopic and Radiologic Team Approach

Andrew K Nguyen, MD, MBA; Andrew J Song; Tanya Swoipes, RN; Albert Ko, MD; Brian S Lim, MD, MCR

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CLINICAL MEDICINE

ABSTRACT

Introduction: The initial therapeutic intervention for infected necrotizing pancreatitis usually begins with endoscopic cystogastrostomy for drainage, followed by endoscopic necrosectomy. Endoscopic pancreatic necrosectomy is commonly performed transmurally through transgastric or transduodenal routes. This case describes necrosectomy via a transcutaneous route for laterally located walled-off pancreatic necrosis and the novel use of Babcock forceps for an obstructed fully covered metal stent.

Case Presentation: A 62-year-old woman presented with abdominal pain, nausea, and vomiting. After multiple admissions and repeated abdominal imaging, she was found to have laterally located, infected, walled-off pancreatic necrosis. Initially, a drainage catheter was placed by an interventional radiologist and was eventually upsized to a 28F catheter. Subsequently, a fully covered metal stent was placed in the gastroenterology suite under fluoroscopic guidance and was used to gain access for percutaneous sessions of necrosectomy. A percutaneous sinus tract endoscopic necrosectomy was performed under direct endoscopic view. However, difficulties occurred with removing necrotic debris even through this large covered stent. Thus, laparoscopic Babcock forceps were used under fluoroscopy to remove lodged debris from the midsten. Repeat abdominal computed tomography scan 3 days after necrosectomy showed near resolution of the walled-off pancreatic necrosis.

Discussion: This Babcock technique with endoscopic necrosectomy has not been previously described in the literature, to our knowledge. Babcock forceps were an ideal tool in our case because they were able to gain access to the obstruction in the stent, but the “teeth” are small and dull enough to prevent from catching onto the metal stent mesh.

INTRODUCTION

Necrotizing pancreatitis is a severe form of pancreatitis in which necrosis can occur in or around the pancreas, which leads to a substantial increase in morbidity and mortality. Walled-off pancreatic necrosis (WOPN) with encapsulated necrotic pancreatic and peripancreatic tissue usually develops 4 weeks after an acute pancreatic episode. Abdominal ultrasonography, computed tomography (CT), and magnetic resonance imaging have been used to differentiate WOPN from pancreatic pseudocyst, although contrast-enhanced CT remains the gold standard for imaging in severe acute pancreatitis. Endoscopic ultrasonography with fine-needle aspiration can aid in the diagnosis of WOPN by assessing the distinguishing features of the lesion, such as size and echogenicity.

Treatment strategies differ between sterile and infected necrosis. Sterile acute pancreatic necrosis does not warrant early intervention, but infected necrosis is one indication for intervention. Traditionally, treatment would be débridement or endoscopic necrosectomy, but some studies have shown antibiotics alone or antibiotic therapy with percutaneous drainage may also be effective. Surgical pancreatic débridement, although considered the definitive treatment, has been associated with mortality rates of up to 58%.

CASE PRESENTATION

Presenting Concerns

A 62-year-old woman with a medical history of diabetes mellitus type 2 with chronic kidney disease stage 3, hypertension, and hyperlipidemia arrived at the Emergency Department with abdominal pain, nausea, and vomiting. The pain was epigastric and radiated to the back. An abdominal CT scan showed evidence of necrotizing pancreatitis and gallstones. The patient improved clinically and was discharged home.

The patient was admitted several weeks later with increased abdominal pain, altered mental status, elevated lactate level (2.7 mmol/L, reference range = 0.5-1.9 mmol/L), and leukocytosis (leukocyte count of 13.7 × 10^9/L, reference range = 4.0-11.0 × 10^9/L). Infected WOPN was diagnosed (Figure 1). A gastroenterologist performed
endoscopic ultrasonography. However, it was determined that endoscopic cystogastrostomy would be unsafe and technically not feasible primarily because of a large intervening vessel in the trajectory of the needle. Instead, an interventional radiologist initially placed a 14F drainage catheter into the body of the large collection of necrosis to help remove the thick purulent discharge. Cytologic findings showed acute and chronic inflammation, but no malignant cells. Cultures yielded *Klebsiella*, and the patient was started on ertapenem therapy. The interventional radiologist upsized the drainage catheter to 28F percutaneously.

Given the patient’s worsening clinical status despite antibiotics and supportive care, a decision was made to perform transcutaneous endoscopic necrosectomy through the percutaneous tract. A guidewire with a hydrophilic tip was inserted into the cavity through the existing drainage catheter, over which the drain was removed. The wire tip location within the pancreatic necrotic cavity was confirmed on fluoroscopy. Over the wire, a 20-mm × 150-mm fully covered metal stent was placed under fluoroscopic guidance with the distal tip in the cavity and approximately 1 cm to 1.5 cm of stent protruding out at the skin level, which was sutured onto the skin to prevent migration. A 15-mm controlled radiation expansion balloon was placed over the wire to dilate the tract at 3 different locations throughout the newly created percutaneous tract.

Necrosectomy was performed under direct endoscopic visualization with different surgical accessories, including alligator forceps, rat-tooth forceps, net retriever, metal basket, and quadrapod forceps. A large amount of necrotic debris was able to be removed. At the end of the necrosectomy procedure, an interventional radiologist placed a stiff (floppy tip) wire into the cavity under fluoroscopic guidance, over which a 28F drainage catheter was placed.

### Table 1. Timeline of the Case

<table>
<thead>
<tr>
<th>Date</th>
<th>Summaries from initial and follow-up visits</th>
<th>Diagnostic testing</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/20/2017</td>
<td>Patient initially presented with abdominal pain, nausea, and vomiting. Pain was epigastric and radiated to the back.</td>
<td>Abdominal CT scan showed evidence of necrotizing pancreatitis and gallstones.</td>
<td>Patient improved with symptomatic treatment and was discharged home.</td>
</tr>
<tr>
<td>12/10/2017</td>
<td>3 months later, patient was admitted for increased abdominal pain and altered mental status.</td>
<td>Elevated lactate level (2.7 mmol/L, reference range = 0.5-1.9 mmol/L)</td>
<td>EUS performed. Interventional radiologist placed 14F drainage catheter. Cultures grew <em>Klebsiella</em> which was treated with ertapenem. Drainage catheter upsized to 28F.</td>
</tr>
<tr>
<td>12/23/2017</td>
<td>Patient declined clinically during admission.</td>
<td>Leukocytosis (leukocyte count of 13.7 × 10⁹/L, reference range = 4.0-11.0 × 10⁹/L)</td>
<td>Transcutaneous endoscopic necrosectomy performed.</td>
</tr>
<tr>
<td>12/24/2017</td>
<td>Patient had continued low-grade fevers and flank pain.</td>
<td></td>
<td>Repeated necrosectomy the next day. Babcock forceps used to relieve repeated obstruction of stent caused by large amount of necrotic debris.</td>
</tr>
<tr>
<td>12/27/2017</td>
<td>Results of repeated CT scan of the abdomen 3 days after the procedure showed near resolution of WOPN near the body and tail of the pancreas.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CT = computed tomography; EUS = endoscopic ultrasonography; WOPN = walled-off pancreatic necrosis.
was replaced through the existing metal stent for continuous drainage.

The patient continued to have low-grade fevers and flank pain, requiring further necrosectomy the next day. The existing drainage catheter was removed, and necrosectomy was performed with various endoscopic accessories that were used in the previous procedure. The necrotic debris became repeatedly lodged in the stent, which was difficult to extract with any accessories, making the procedure extremely prolonged. To overcome this difficulty, we used laparoscopic Babcock forceps under fluoroscopic guidance to pull out the lodged debris from the midstent (Figures 2A and 2B). This tool allowed for much easier removal of the debris out of the stent, shortening the duration of the procedure.

Results of repeated CT scan of the abdomen 3 days after the procedure showed near resolution of WOPN near the body and tail of the pancreas (Figure 3). The patient improved clinically and was discharged home shortly after the last necrosectomy procedure. Informed consent was obtained from the patient for publication of the case details. A timeline of the case appears in Table 1.

DISCUSSION

Necrotizing pancreatitis is a severe form of pancreatitis in which necrosis can occur in or around the pancreas. This pancreatic necrosis is associated with high morbidity and mortality of up to 10% to 40% and can lead to severe end-organ damage.7

The initial therapeutic intervention usually begins with endoscopic cystogastrostomy for drainage, followed by endoscopic necrosectomy. Endoscopic pancreatic necrosectomy is commonly performed transluminally through transgastric or transduodenal routes, but our case describes necrosectomy via a transcutaneous route for laterally located WOPN. The transluminal approach was not technically possible. Therefore, drainage placement by an interventional radiologist, percutaneous fully covered metal stent placement, and percutaneous necrosectomy were performed.

Percutaneous necrosectomy and sinus tract endoscopy performed in this manner have been successfully described in the literature previously.8,9 Initial results supported the advantage of percutaneous necrosectomy over open necrosectomy given the reduction in complications and death.8,10 Algorithm-based nonsurgical approaches have shown favorable outcomes compared with surgery, beginning with endoscopic drainage, followed by endoscopic necrosectomy as needed, and percutaneous catheter drainage/sinus tract endoscopic necrosectomy as an adjunctive therapy.8 In addition, there is substantial cost savings with minimally invasive intervention, as open necrosectomy can cost upward of $130,000 per patient.11

The continued clinical deterioration of our patient required additional necrosectomy with a considerable amount of necrotic debris removed through the fully covered metal stent nested in the transcutaneous tract. However, from our experience with this patient, we found that large necrotic debris can clog the stent in such cases, leading to prolonged procedures (Figure 4). Laparoscopic Babcock forceps traditionally used in laparoscopic surgeries can be used in these situations (Figure 5). The forceps were inserted into the fully covered metal stent (advanced only to the extent of the stent and not into the necrotic cavity) to grasp and remove the necrotic debris obstructing the stent (Figure 6). Babcock forceps were an ideal choice because they were able to gain access to the obstruction in the stent, but the “teeth” are small and dull enough to prevent the tip from being caught in the metal stent mesh during repeated debridement.

This Babcock technique with necrosectomy has not been previously described in the literature, to our knowledge. The technique helped lead to near resolution of WOPN on repeat CT scan just 3 days after the procedure and improved the patient’s overall clinical status, which allowed her to be discharged from the hospital shortly after the final necrosectomy. Although pancreaticocutaneous fistula can be a concern in transcutaneous endoscopic necrosectomy, especially with a large stent size such as in our case, our patient was...
not found to have a pancreaticocutaneous fistula in follow-up clinic visits.

CONCLUSION
This case describes necrosectomy via a transcutaneous route for laterally located WOPN resulting from severe necrotizing pancreatitis. Cases where the walled-off necrosis is laterally located can be challenging to access through the gastrointestinal lumen endoscopically as in this case and may require transtunaneous access. Necrosectomy with a substantial amount of necrotic debris removed can lead to the stent becoming obstructed repeatedly during the procedure. In our case, Babcock forceps were able to gain access and relieve the obstruction in the stent, facilitating the procedure without any additional complications.

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

Acknowledgments
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How to Cite this Article

References

Pancreatitis
Acute inflammation of the pancreas is both a well-characterized disease, and one which is much more frequent than is generally thought. ... It has been repeatedly confounded with acute intestinal obstruction, and has thus led, in several instances, to an ineffective laparotomy; an operation which, in the early stages of this disease, is extremely hazardous.

— Reginald Heber Fitz, MD, 1843-1913, American physician
ECG Diagnosis: Acute Myocardial Infarction in a Ventricular-Paced Rhythm

Ashley S Abraham; David R Vinson, MD, FACEP, FAAFP; Joel T Levis, MD, PhD, FACEP, FAAEM

INTRODUCTION
In the Emergency Department, the diagnosis of acute myocardial infarction (AMI) relies initially on a patient’s history and the 12-lead electrocardiogram (ECG). Establishing the diagnosis of AMI in the setting of a ventricular-paced rhythm (VPR) is difficult and can result in delay of definitive treatment. In 1996, Sgarbossa et al1 published a retrospective study comparing 17 ventricular-paced ECG controls with 17 ventricular-paced ECGs with AMI, confirmed by cardiac biomarkers. The authors found 3 ECG criteria to evaluate for AMI in patients with VPR: 1) ST-segment elevation (STE) greater than or equal to 1 mm for leads with a positive (concordant) QRS complex; 2) ST-segment depression (STD) greater than or equal to 1 mm in leads V1, V2, or V3; and 3) STE greater than or equal to 5 mm in leads with negative (discordant) QRS complexes. These criteria were identical to the criteria Sgarbossa developed to identify AMI in patients with left bundle branch block (LBBB), except the point scoring system was not used when the criteria were applied to patients with VPRs (Figure 1). Only 1 criterion had both relatively high specificity and statistical significance for the diagnosis of AMI at admission in patients with VPRs: STE greater than or equal to 5 mm in leads with a negative QRS complex. We report a case of an 81-year-old woman with a VPR who presented with chest pain, STE greater than or equal to 5 mm in leads with discordant QRS complexes, STE greater than or equal to 1 mm in a lead with concordant QRS complex, and was diagnosed with an AMI on cardiac catheterization. This case demonstrates the utility of Sgarbossa criteria for detecting AMI in patients with a VPR.

CASE PRESENTATION
An 81-year-old woman presented to the Emergency Department by emergency medical services, reporting left-sided chest pain and shortness of breath, which began 3 hours before arrival. She had a medical history significant for a dual-chamber pacemaker for symptomatic complete heart block. She also had chronic obstructive pulmonary disease, congestive heart failure, diabetes mellitus, coronary artery disease, and an STE myocardial infarction (STEMI) 2 weeks earlier, with cardiac stents to the proximal and mid-left anterior descending coronary artery. Her initial vital signs were: Oral temperature, 99 °F (37.2 °C); pulse, 105 beats/min; blood pressure, 189/111 mmHg; respirations, 30 breaths/min; and oxygen saturation, 93% on room air. Physical examination revealed an elderly woman in moderate distress with trace expiratory wheezing on lung examination, and a regular rate and rhythm without murmurs on cardiac examination. The patient was treated with aspirin and sublingual nitroglycerin, and a 12-lead ECG was obtained (Figure 2), which was compared with a previous ECG from this patient 2 weeks earlier following cardiac catheterization (Figure 3). The cardiologist was consulted, and the recommendation was to treat the patient with intravenous heparin and a nitroglycerin infusion. Laboratory test results were significant for troponin I, 0.43 ng/mL (normal range 0.00-0.04 ng/mL), and B-type natriuretic peptide.
Sgarbossa et al\(^1\) further applied their criteria to VPRs, as pacing of the ventricle results in an intraventricular conduction delay similar to that seen with LBBB. In the small study examining VPRs, several characteristics of the paced ECG were examined for findings that might predict AMI. The criteria have low sensitivities and cannot be applied to rule out an acute coronary event, but they do have potentially clinically useful specificities: 1) STE greater than or equal to 1 mm for leads with a predominantly positive QRS complex (sensitivity 18%, specificity 94%); 2) STD greater than or equal to 1 mm in leads \(V_1\), \(V_2\), or \(V_3\) (sensitivity 29%, specificity 82%); 3) STE greater than or equal to 5 mm in leads with negative (discordant) QRS complexes (sensitivity 55%, specificity 88%). In a more recent study by Maloy et al,\(^3\) 57 patients with ventricular-paced ECGs and an AMI diagnosed by elevated cardiac markers were identified retrospectively and compared with a control group of 99 patients with ventricular-paced ECGs and negative cardiac markers. For STE greater than or equal to 5 mm discordant with the QRS complex, the sensitivity for detecting AMI was 10% (95% confidence interval = 5%-21%), specificity 99% (95% confidence interval = 93%-99%), with a likelihood ratio of 5.2 (95% confidence interval = 1.3-21%).\(^3\) The authors concluded that the most specific Sgarbossa criterion in identifying AMI was STE greater than 5 mm discordant with the QRS complex.\(^3\)

Stent thrombosis occurs in 1% to 5% of patients, and is associated with medication discontinuation, undersizing of the coronary stent, present malignant disease, and intermediate coronary artery disease proximal to the lesion.\(^7\) A small late stent thrombosis risk remains 5 years after placement at less than 1% per year.\(^8\) Diabetes mellitus is an independent predictor of stent thrombosis within 30 days.\(^8\)

In our case, the patient presented with acute chest discomfort. She had an ECG with a VPR, discordant STE greater than 5 mm in 2 anterior leads (\(V_1\) and \(V_2\)), and concordant STE greater than 1 mm STE in \(V_4\) 2 weeks after stent placement. The application of Sgarbossa criteria to the ECG led to a timely diagnosis and prompt reperfusion treatment that might otherwise have been delayed. This case demonstrates the utility of Sgarbossa criteria in patients with VPRs presenting with chest pain or anginal-equivalent symptoms. The third Sgarbossa criterion depicted in Figure 1 (STE \(\geq 5\) mm discordant with the QRS complex) is the most useful to help rapidly identify Emergency Department patients with VPRs and AMI who may be eligible for early percutaneous coronary intervention.\(^9,10\) Although current guidelines for the diagnosis and treatment of STEMI do not specifically recognize these ECG findings in a VPR as a true STEMI equivalent,\(^11\) in such cases prompt consultation with the cardiologist is prudent to consider urgent cardiac catheterization.\(^*\)

**Disclosure Statement**

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

**How to Cite This Article**

CLINICAL MEDICINE

ECG Diagnosis: Acute Myocardial Infarction in a Ventricular-Paced Rhythm

References

Diagnosis

It is always necessary to speak first of the organ exhibiting a damaged function, then to search for the type of damage and whether the condition is persistent or still developing but will never remain stable; further, if it has already developed, whether the active cause of the disease remains attached to this organ or is transient.

— Galen of Pergamon, 130 AD-210 AD, prominent Greek physician, surgeon, and philosopher in the Roman Empire
CLINICAL MEDICINE

Image Diagnosis: Disappearing Digits: Metabolic Bone Disease in End-Stage Renal Disease

Shitij Arora, MD, FACP; Fathima Jahufar, MD

CASE PRESENTATION

A 32-year-old man with end-stage renal disease on hemodialysis since 2009 presented with reports of a “disappearing fingernail.” He denied bone pain and muscle weakness but confirmed dry skin and pruritus. He was noncompliant with his prescribed cinacalcet and sevelamer. On examination, he was noted to have loss of lunula in the left index finger with shortening of the distal phalanx (Figure 1). Laboratory test results showed a phosphorus level of 7.0 mg/dL and an intact parathyroid (PTH) level of 2380 pg/mL. Radiographic imaging of his hands showed severe generalized bone resorption (the left hand is shown in Figure 2). His PTH scan showed retention of Tc-99m methoxyisobutylisonitrile in the left lower pole and right upper pole, which was discordant with Tc-99m pertechnetate uptake. The scan findings were consistent with nodular PTH hyperplasia, and he was referred for parathyroidectomy.

DISCUSSION

Metabolic bone disease is a common complication in chronic kidney disease. In the past decade, a number of mechanisms for unchecked PTH level elevations have been identified. Low vitamin D levels, resistance of PTH-sensing receptors, and dysregulation of the fibroblast growth factor 23PTH axis can all lead to prolonged excessive synthesis and secretion of PTH, eventually leading to the development of metabolic bone disease.1,2 Current treatment options include correcting vitamin D deficiency, controlling dietary phosphorus intake, and prescribing phosphate binders and calcimimetics (cinacalcet). Recommendations include use of non-calcium-containing phosphate binders such as lanthanum and sevelamer.

The Kidney Disease Improving Global Outcomes guidelines recommend parathyroidectomy in patients with stage G5D with severe hyperparathyroidism who fail to respond to medical or pharmacological therapy (grade 2B). Historically, a PTH level greater than 800 pg/mL despite medical treatment would lead to a referral for parathyroidectomy (> 9 x the upper limit of a normal assay).3 There are data to suggest that hyperparathyroidism caused by nodular hyperplasia, along with cases where the ultrasonography of the PTH glands shows volume greater than 500 mm³ or the largest diameter is greater than 1 cm, may be resistant to medical treatment.4 There is a paucity of clinical trials comparing medical therapy with surgical parathyroidectomy in this patient population.

Cruzado et al5 studied the effect of cinacalcet and compared it with parathyroidectomy in renal transplant patients with a glomerular filtration rate greater than 30 mL/kg/min. Parathyroidectomy led to a statistically significant reduction in PTH levels starting at 3 months and the effect was even more pronounced at 12 months.6

Figure 1. Gross appearance of the left hand showing shortened finger length and loss of lunula in the left index finger.

Figure 2. Plain radiograph of the left hand showing near complete osteolysis of the distal phalanx of the index finger and similar changes involving nearly all bones of the hand.

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

How to Cite this Article

References
Dr Lippert relates: “After a long workday at Kaiser Permanente, I felt awe and
gratitude as I caught this sight from the top of the East Interstate parking lot.”

Originally from California, Dr Lippert currently hails from Portland, OR, where she works as a Mental
Health Therapist at the East Interstate Clinic and as a Child Interviewer on a child abuse evaluation
team at Child Abuse Response and Evaluation Services (CARES) Northwest, a collaboration involving
Kaiser Permanente and 3 other leading health systems. During her spare time, she loves to write even
more than she loves to take pictures. Her latest publication is a children’s book titled Goodbye, School.

More work by Dr Lippert can be seen on page 70.
Help Your Patients Stay Healthy on Their Cruise Vacation:
Suggestions for Primary Care Physicians from a Cruise Ship Physician

Lee Jacobs, MD
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E-pub: 06/21/2019

INTRODUCTION
During my 12 years of experience in caring for critically ill patients on cruise ships, I have learned that good advice and preparation by primary care physicians before sailing can prevent life-threatening situations from occurring when their patients are at sea.

Because cruise travel is a rapidly growing industry with estimates of more than 27 million passengers having sailed worldwide in 2018, there is a high likelihood that 1 or more of your patients will be planning a cruise vacation. This underscores the importance for you to understand cruise ship-related health issues so that you can provide meaningful precruise advice and patient education.

Although cruises are relaxing and enjoyable, this changes quickly when a patient becomes seriously ill while on an ocean cruise, and the needed health care at sea may be several hours or even days away. This differs from the readily accessible care that may be found in most places at home. This fact is generally not well appreciated by primary care physicians, who at times are asked to give approval for their patients with unstable medical conditions to go on a cruise. For this reason, primary care physicians are the first line of defense to make certain that a seemingly minor health problem does not become a life-threatening emergency in the middle of the ocean.

To assist you in having an informed precruise dialogue with your patients, the following article provides an overview of the health care capabilities of a typical cruise ship, which is then followed by specific suggestions I believe will help you educate your patients so they can stay healthy and enjoy their cruises.

TYPICAL CRUISE SHIP CAPABILITIES:
AN EMERGENCY DEPARTMENT AT SEA
Although there may be some variation, in my experience the capabilities for providing care for critically ill patients at sea are similar among cruise lines. There are several considerations that might assist you in giving accurate advice to your patients. These include how long it might take to debark an ill passenger, the types of illnesses commonly encountered, the medications available on ships, and an overview of the ancillary services typically found on a ship.

How long does it generally take to transfer an ill passenger from a cruise ship to a shore-side medical facility? The answer is several hours to days depending on the itinerary as well on the capability of nearby ports. The longest timeframe would be when ships are on long oceanic crossings where there might be more than 4 days in the open ocean. In this setting, the assumption should be that your patient will be cared for on the ship with no opportunity for evacuation. Alternatively, some cruise itineraries may be episodically close to ports, but even then the time factor for debarking is an issue because it may take several hours for ships to get to ports. Add to this time factor the realization that some ports cannot provide care superior to what can be provided on the ship, then the dilemma as to how and when to debark a critically ill patient becomes clearer. Therefore, it is important for you to review your patient’s itinerary so you can decide if the cruise is suitable for him/her given his/her health status and medical needs.

What are the types of illnesses commonly encountered on cruise ships? Although I am not aware of comparative data, in my experiences the types and acuity of illnesses are similar to those in a busy Emergency Department. Cruise ships are basically small towns with a population between 1500 and more than 7000 guests and crew members. Thus, heart failure, myocardial infarctions, arrhythmias, reactive airway flare-ups, pregnancy complications, seizures, severe dehydration, and hyperglycemia are frequently seen on a ship. As a result of ship movement and wet surfaces, fractures and lacerations are also quite common. If your patient has mobility challenges, it is important to emphasize the challenges s/he might encounter on a cruise ship. Although your patient may not be receptive to the idea, you might suggest that s/he use a wheelchair while on the moving ship.

What medications are available on board? A cruise ship’s formulary for oral and parenteral medications and aerosols is usually robust to ensure that high-quality care can be provided for the wide spectrum of disorders seen. This includes sedation medications, oxytocic agents for obstetric-related problems, and thrombolytics for acute coronary events.

What ancillary services are typically found on a cruise ship? The laboratories of most ship medical centers can produce complete blood cell counts and chemistry panels and can perform several point-of-care procedures. Many have radiographic capabilities, and some have ultrasonography capabilities; the results of both can be exported digitally or burned to a disk for patients to take home to their physicians. In life-threatening situations, blood
can be typed and crossed from crew members or other guests and transfused as needed. Essential respiratory support is also available, including nebulizer treatment and ventilator support for an intubated patient.

**COPIES OF MEDICAL DATA: INFORMATION IS ESSENTIAL**

Most certainly an updated copy of medications and an active medical problem list are imperative. I also suggest you provide your patient with a copy of his/her most recent electrocardiogram and any pertinent imaging reports. You can imagine how helpful this information can be for comparison with the ship's x-ray films and electrocardiograms when the ship physician is caring for critically ill patients.

**BRINGING MEDICINES AND DEVICES: PACK WISELY**

Remind your patients to pack essential medicines and devices in their carry-on bag and not in their check-in luggage. Trying to replace forgotten or lost medicines, or devices such as continuous positive airway pressure (CPAP) machines, when at sea or in non-US ports can be difficult and at times impossible. Patients with implanted venous access ports should be reminded to bring extra access needles, usually unavailable on ships and most non-US ports.

Additionally, because a cruise ship's environment may be different from what your patients might be used to back home, it is important for you to prepare your patients with education and additional medication for contingencies. For example, because of moisture and humidity, respiratory allergies are not uncommon on ships, so patients with reactive airway diseases should be reminded to bring their rescue medications for flare-ups. Although these medications are generally available in ships' medical centers, having them readily at hand for the traveling patient is a good idea.

Also, considering a typical cruise ship's cuisine, your patients will have ongoing opportunities to dramatically increase their salt, sugar, and protein consumption. With that in mind, reminders on moderation might be helpful as well as instructions on when to adjust medications (eg, diabetes medications) to prevent a major health problem from developing.

Finally, encourage your patients to purchase travel insurance, which is essential if they were to require out-of-country medical care, and either evacuation or repatriation.

**MAJOR RECENT ILLNESS: CRUISE WHEN HEALTHY**

I cannot count the number of times a guest comes on a cruise with his/her family to celebrate the completion of a chemotherapy regimen or recovery from a major illness or surgery. Although celebrations of such milestones are important to the healing process, encourage your patients to wait for blood cell counts to return to normal and for their bodies to heal after major illnesses or procedures.

Minor complaints can become major problems on board a cruise ship. For example, a minor incident during pregnancy that may resolve easily on land can become a life-threatening event at sea. This may also be true for a new stomach irritation incident that could develop into gastrointestinal tract bleeding. Yes, ships have oxytocic medications on board, and we can transfuse blood, but life-threatening problems at sea become much more critical much faster and are best avoided. The same is true for any new neurologic symptoms, recent dose changes of major medicines, or other recent medical changes. Although the problem may be seemingly a minor concern at home, the situation should raise a major red flag when deciding if your patient is medically fit to sail. If in doubt, strongly advise patients with a potentially serious new complaint to delay their cruise.

Even chronic conditions may be a problem for some cruise travelers. I have learned over the years that some patients with conditions such as dementia and autism may find a cruise disorientating and stressful. On a case-by-case basis, you may want to discuss with families the wisdom of removing these individuals from their normal environment and taking them on a cruise.

**SCOPOLAMINE TRANSDERMAL PATCH: PRESCRIBE WITH CAUTION!**

Patients are often concerned about potential motion sickness and will approach their physicians for preventive medications. First and foremost, for the patient's safety and to help the ship's medical team, please do not prescribe the anticholinergic drug patch! Almost monthly when I work on a ship, I encounter patients with adverse effects from this patch, ranging from persistent fatigue to hemiparesis and ocular complaints that mimic severe neurologic events. In the middle of the ocean, these symptoms can be tremendously concerning. A ship's health care team typically checks for the presence of a patch behind an ear as part of its initial assessment and then will remove the patch if present. If
the symptoms are related to the patch, improvement is noticeable within the next few hours.

Adverse effects to scopolamine such as hallucinations and confusion have been reported, and these and the aforementioned adverse effects are not problems that you want your patient to experience on a cruise ship. For that reason, my suggestion is to avoid prescribing this medication if at all possible. Although I am not aware of comparative studies on adverse effects, I suggest physicians recommend meclizine (eg, Bonine, original Dramamine) as an alternative. In my experience with ship-based motion sickness, although these over-the-counter options may not be as effective, the adverse effects are much less severe compared with scopolamine. In terms of alternative care options, I am not aware of large randomized studies establishing the value of pressure point bracelets (also called acupressure wrist bands) for motion sickness.

INFECTIOUS DISEASES: PROACTIVE IN PREVENTION

The cruise ship industry is monitored closely by various agencies, including the Centers for Disease Control and Prevention, the US Public Health Service, and the US Coast Guard. Their intense focus on safe water, food storage and preparation, and adherence to established procedures to contain viral illnesses should be reassuring to everyone.

However, considering that several thousand guests might be sailing at any one time, you can imagine how many viruses are brought onto the ship with each embarking day. Cruise ships are like any other heavily populated, enclosed space, where the spread of viral infections from contaminated surfaces can occur frequently. This is especially true for enteroviruses such as the norovirus and respiratory viruses such as influenza, both of which can live for hours on fomites such as a ship’s stair railings and elevators.

Remind your traveling patients that the best protection from viral illnesses on a cruise ship is frequent handwashing. The Centers for Disease Control and Prevention Vessel Sanitation Program Web site has helpful information for those vacationing on cruise ships that can be an excellent patient education handout for physicians to give their patients (see Sidebar: Health Resources on Cruise Ship Travel).

General advice for foreign travel applies to visits in foreign ports. When the ship’s destination is a concern for mosquito-borne illnesses, for patients of all ages recommend protection with proper clothing and insect repellants. Also, your patients should be encouraged to avoid unpurified water, which in most foreign ports includes avoidance of bottled water and ice—a major source for traveler’s diarrhea. Finally, because of the risk of rabies and other zoonotic infections, close contact with animals should be avoided. A good source for this information on foreign travel is the Centers for Disease Control and Prevention’s Travelers’ Health Web site included in the Sidebar: Health Resources on Cruise Ship Travel.

CONCLUSION

Cruising can be a wonderful vacation, but good health is a major prerequisite. A healthy cruise experience starts with preparation by the primary care physician, especially with the realization that most serious illnesses encountered on ships may be preventable.

I hope these suggestions, summarized in the Sidebar: Summary of Precruise Patient Communication Points, will help you prepare your patients so they can stay healthy and enjoy their cruise experience, and you can in good conscience wish them bon voyage!

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References
COMMENTARY

Legal Perspectives on Telemedicine Part 1: Legal and Regulatory Issues

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ABSTRACT

Telemedicine is defined as the remote delivery of clinical care services through audiovisual conferencing technology. A shortage of care practitioners combined with an aging population with disproportionately increasing care utilization patterns has created a “perfect storm” which since the late 1990s has propelled telemedicine as a potential solution to bridge this supply/demand and access gap. In critical care approximately 20% of nonfederal adult intensive care unit (ICU) beds in the US today are supported by some form of tele-ICU coverage. The literature has shown with increasing clarity during the last decade that correct tele-ICU implementation improves outcomes and has the potential to significantly improve the financial performance of health care systems. As is often the case in technology-driven innovations, the legal and regulatory framework has been moving slower than the clinical adoption of this new care delivery model, which is true not just in critical care, but in other medical specialties as well. This 2-part series focuses on legal perspectives on telemedicine. The first part discusses legal and regulatory challenges of telemedicine in general, with a more in-depth focus on tele-ICU. The second part will discuss the effects of telemedicine implementation on medicolegal risk, using the litigious critical care environment as an example.

INTRODUCTION

Telemedicine is defined as the remote delivery of clinical care services through audiovisual conferencing technology.1 In the US today, approximately 20% of nonfederal adult intensive care unit (ICU) beds are supported by some form of tele-ICU coverage.2-3 The literature has shown during the last decade that correct tele-ICU implementation improves outcomes and can significantly improve the financial performance of health care systems.4-5 This first of a 2-part commentary discusses legal and regulatory challenges of telemedicine in general, with a more in-depth focus on tele-ICU.

THE LEGAL AND REGULATORY LANDSCAPE TODAY

Implementation of telemedicine solutions is being encouraged and assisted by both state and federal government, as well as multiple medical associations, including the American Medical Association. At the federal level, the Department of Health and Human Services, largely through its Health Resources Services Administration and Office for the Advancement of Telehealth, has become increasingly involved in telehealth by administering telehealth grant programs (including a focus on licensure portability), providing technical assistance, developing telehealth policy initiatives to improve access to quality health services, and promoting knowledge exchange about “best telehealth practices.”6-7

In 2016, the American Medical Association adopted new guidelines for ethical practice in telemedicine.8-9 These guidelines advise physicians participating in telehealth/telemedicine to recognize the limitations of the relevant technologies and to take appropriate steps to overcome such limitations, recognizing that a coordinated effort across the profession is necessary to achieve the promise and to avoid the pitfalls of telemedicine. For example, physicians practicing telemedicine must ensure that appropriate protocols are in place to protect the security and integrity of patient information.

Although the government is helping in many ways to stimulate the growth of telemedicine, there is currently no uniform legal approach to telehealth, which continues to be a major challenge to its progress. Telehealth implementation varies widely from state to state in terms of how much service providers will be reimbursed for delivering telehealth services, as well as what sort of parity (defined as equivalent treatment of analogous services) is expected between in-person health services reimbursements vs telehealth reimbursements. Currently, 41 jurisdictions have laws that govern private payer reimbursement of telehealth.10

Thirty-six states and the District of Columbia have parity laws that cover private insurers and reimbursement for telehealth services.11 However, many variations exist in how states and private insurers pay reimbursements and what they cover. Twenty-three states and the District of Columbia have full parity, meaning coverage and reimbursement is comparable from in-person to telehealth services. However, the current telehealth coverage laws of 15 states lack parity language, meaning that reimbursement by health plans for telehealth services is not required to be at the same rate as what is paid for in-person services.12 Without parity, the incentive to provide telehealth services decreases, and telehealth may be prohibitive to adopt and use.

On the federal level, Medicare reimburses for synchronous communications (meaning real-time bilateral audiovisual interactions) and does not cover any store-and-forward services (eg, a radiologic

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Keywords: e-ICU, electronic intensive care unit, legal perspectives, medicolegal risk, regulation, tele-ICU, tele-intensive care unit, telemedicine
image that is taken, digitally forwarded, and stored, to be retrieved and interpreted later) or remote patient monitoring for chronic diseases, except in Alaska and Hawaii. The federal government places numerous limitations on Medicare reimbursement for telehealth services, based on the location of the patient and practitioner as well as the type of distant site facility. For example, patient location must be within an area considered to be a Health Professional Shortage Area or area outside a Metropolitan Statistical Area and be one of the following sites: Hospital, critical access hospital, dialysis center, skilled nursing facility, community mental health center, physician office, rural health clinic, or federally qualified health center.\(^\text{15}\)

In 2017, a bipartisan Congressional Telehealth Caucus was formed, and 2 bills were relaunched in an effort to modernize how Medicare reimburses telehealth services and to expand coverage for Medicare beneficiaries. Both bills, the Medicare Telehealth Parity Act of 2017\(^\text{16}\) and the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2017\(^\text{17}\) are under consideration by Congress. On June 1, 2017, the Medicare Telehealth Parity Act was referred to the House Subcommittee on Health. On May 30, 2017, the CONNECT for Health Act was referred to the Senate Committee on Finance. Also being considered by the Senate Committee on Finance is the proposed Creating High-Quality Results and Outcomes Necessary to Improve Chronic Care Act of 2017,\(^\text{18}\) which includes a section that would allow greater use of telehealth. In a press release, Representative Mike Thompson (D-CA) stated that “Telehealth saves lives and reduces costs; it’s a win-win for both patients and providers.”\(^\text{19}\)

LEGAL AND REGULATORY CHALLENGES

Professional licensing for telemedicine practitioners is often cited as a barrier to the expanded use of telehealth and telemedicine. In one of the early cases addressing telemedicine, *Hageseth v Superior Court of California*,\(^\text{18}\) a California court asserted jurisdiction over Dr Hageseth, then a Colorado-licensed psychiatrist, and criminally charged him with practicing medicine without a license in California. Dr Hageseth had prescribed medication over the Internet to a patient in California, who then committed suicide.\(^\text{18}\)

After Dr Hageseth’s challenge to the court’s jurisdiction failed, he pled guilty and was sentenced to 9 months in prison. This case demonstrates the complexity of telemedicine from a legal perspective and the importance of physician education regarding licensure requirements for practicing telemedicine across lines.

Since *Hageseth* was decided in 2007, there has been considerable progress in the area of cross-state licensing for the practice of telemedicine. That said, current licensure requirements for practicing telemedicine across state lines vary widely from state to state. A detailed explanation of each state’s current laws and reimbursement policies for telehealth can be found at www.cchpca.org.\(^\text{12}\) Most states still require a physician to be licensed in the state in which the patient is located. Nine state medical (or osteopathic) boards issue special licenses or certificates related to telehealth, which could allow out-of-state practitioners to render services via telemedicine in a state where they are not located or allow clinicians to provide services via telehealth in a state if certain conditions are met, such as agreeing that they will not open an office in that state. Those states are Alabama, Louisiana, Maine, Minnesota, New Mexico, Ohio, Oregon, Tennessee (osteopathic board only), and Texas. Some states have laws that do not specifically address telehealth and/or telemedicine licensing but make allowances for contiguous states or for certain situations where a temporary license might be issued, provided the specific state’s licensing conditions are met. The most common licensure exceptions include physician-to-physician consultations, public health services, medical emergencies (“Good Samaritan”), or natural disasters.

Although attempts at federal legislation to address the cross-state licensure barrier to telemedicine have not yet succeeded, the issue has been addressed by the Federation of State Medical Boards in the Interstate Medical Licensure Compact (IMLC), which is expected to help streamline the licensure process by offering a voluntary expedited pathway to licensure for qualified physicians who wish to practice in multiple states. Nineteen IMLC member states currently serve as the state of principal license, processing applications and issuing licenses. Five states have passed IMLC legislation, but implementation is in process or delayed.\(^\text{19}\)

Twenty-nine state medical and osteopathic boards have endorsed the IMLC.

In addition to regulatory challenges, the move toward providing more telehealth-based services across state borders has raised legal concerns.\(^\text{20}\) For example, whereas some malpractice liability policies cover multiple states, most specify that coverage is available only for claims occurring in a specific jurisdiction. A telehealth physician sued in a state other than the jurisdiction in which s/he is covered might find that no coverage is available. Practitioners also need to confirm that their policies include coverage for telemedicine.

RECOMMENDATIONS

As more studies demonstrate increased quality of care and patient satisfaction and the institutional cost savings resulting from telemedicine,\(^\text{15-21}\) the health care industry should embrace it in multiple disciplines. Given practitioner shortages throughout the US, in both rural and urban areas, telemedicine has a unique capacity to increase and improve service to millions of new patients. However, there are important steps that must be taken in the regulatory and legal contexts, to maximize the impact of telemedicine:

- A uniform standard and/or a streamlined process to obtain medical licenses for physicians who practice telemedicine in multiple jurisdictions should be established;
- Congress should provide clarity on reimbursement rates so that practitioners understand which telemedicine services private and public insurance policies will reimburse;
- Medicare coverage of telehealth services, including remote patient monitoring, should be expanded beyond rural areas.
• Universal parity laws should be enacted to reduce barriers to entry for hospital systems and providers to implement these services.

• State legislatures should consider codifying a heightened standard of care in malpractice cases against health care providers using telemedicine in place.

• Research funding for telemedicine should increase, to advance the field by supporting important research on implementation, resource utilization, quality improvement, and clinical outcomes.

Additionally, health care institutions, schools, and practitioners should take the following actions to promote telemedicine:

• Professional associations should increase education regarding the resources available to support and encourage telemedicine development, including the existence of policies and protocols for telehealth, should be easily accessible to health care practitioners.

• All health care entities should explore the utility of forming or partnering with Departments or Centers for Telemedicine, to increase access to central telemedicine expertise to clinicians and to take advantage of synergies in organization, implementation, coordination, and support of telemedicine projects across the spectrum of care (similar to how information technology has evolved as an entity in modern medicine).

• Telemedicine must become an integral part of graduate and postgraduate medical education for physicians and nurses. Medical schools and nursing schools should develop comprehensive telehealth curricula, including lecture series, clinical clerkships, and rotations. The next generation of health care practitioners must be well educated on how to incorporate telemedicine into their clinical practices.

• Health care practitioners should stay informed of pending legislative and regulatory developments in telehealth, especially those relating to reimbursement and license portability.

CONCLUSION

To expand a care delivery model that improves patient care, increases access for patients, and enhances the capabilities of practitioners, while at the same time having the potential to greatly lower health care costs in multiple sectors, it is essential to establish a uniform standard for licensing physicians who practice telemedicine, and to provide clarity on reimbursement rates, and to educate the health care industry regarding the many resources available to support and encourage telemedicine development.

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COMMENTARY

Why I Treat Obesity

Adam Gilden Tsai, MD, MSCE, FACP

ABSTRACT

In this narrative, I describe a patient who has lost 25% of her starting body weight and the behaviors that she practices to maintain this weight loss. Patients who have lost weight have reductions in metabolism that are out of proportion to their amount of weight loss. They also have increases in appetite. I propose that physicians must improve in their treatment of obesity as a chronic disease. To achieve this, they must understand the physiologic and behavioral barriers to long-term weight loss, and they must be open to the use of medications for treating obesity.

MY PATIENT DELLA

I look forward to seeing Della (name changed). She comes to see me every 3 months like clockwork. Della is 58 years old. When I first met her, she weighed 241 pounds, down from her highest recorded weight of 273 pounds. My colleagues referred her because she needed to lose more weight. I prescribed an extended-release form of phentermine-topiramate and asked her to replace 2 of her 3 daily meals with a high-protein shake supplemented with vitamins and minerals. She lost an additional 22 pounds during the next 6 months, and 10 months later, she achieved her lowest weight of 196 pounds. At her last visit, a few weeks ago, she weighed 204 pounds. Despite regaining 8 pounds from her lowest weight, and although her body mass index of 33 kg/m² means she still has class 1 obesity, she has maintained a weight loss of 69 pounds for more than 2 years. This amount of weight loss equals 25% of her highest body weight and is the amount typically seen after bariatric surgery. In fact, her coworkers have asked whether she had weight loss surgery.

She now follows a strict eating plan limited to 1500 calories a day, which includes religiously counting every calorie, measuring portion sizes, and weighing the food she is about to eat. She exercises multiple times a week. All of these behaviors are supported as evidence-based practices by studies on behavioral treatment of obesity.1 Her hemoglobin A1C level has been in the prediabetes range since our practice started measuring, but her most recent value was in the normal range. This patient is one of the hardest-working and most successful patients in my practice of obesity medicine.

WHY IT IS HARDER FOR HER TO KEEP OFF THE WEIGHT

The science of obesity supports the idea that Della must work harder to maintain weight loss than other patients who weigh the same as she does but have not lost weight. The reason is that the extent of metabolic adaptation to weight loss is out of proportion with the amount of weight loss because of “adaptive thermogenesis.” Specifically, individuals who lose 10% of their body weight burn about 300 fewer calories per day than those with similar but stable weight.2 The reduction in metabolism that occurs with weight loss is persistent. For example, in a rigorously matched study of trios of subjects (each trio included a subject who was at stable weight, a subject who was maintaining weight reduction of 10% after recent weight loss, and a subject who had maintained a 10% weight loss for 1 year), a reduction in 24-hour energy expenditure was observed in both groups that had lost weight. This reduction in energy expenditure was out of proportion with the amount of weight lost, and the reduction persisted 1 year after the weight loss.3 The changes in energy balance include changes in appetite. For example, increases in ghrelin (the hunger-signaling hormone) persist for at least 1 year after weight loss.4 Increases in food intake were also demonstrated in an experiment using canagliflozin, which is an inhibitor of the SGLT-2 receptor and is US Food and Drug Administration approved for the treatment of diabetes. It works by inducing a glucose diuresis, which can lead to weight loss. When study subjects took canagliflozin, there was an increase in food intake of 100 kcal per day for every kilogram of weight lost. Thus, the increase in energy intake in response to weight loss was 3 times larger than the reduction in metabolic rate.5 This information about appetite strongly supports the long-term use of medications to treat obesity, given that increases in appetite can be treated but reductions in metabolism cannot.

The changes in energy expenditure and food intake in response to weight loss described above suggest that body weight is preferentially maintained at its highest weight level.4 The mechanisms controlling the set point (where a biological organism establishes homeostasis) of body weight are likely multiple, and are incompletely understood. The underlying science and the experience of patients like Della support the idea that obesity is a chronic disease (Table 1), and this idea was endorsed by the American Medical Association in 2013.6 Obesity is a chronic metabolic condition that can be managed but not cured. In this respect, managing obesity is like managing chronic pain or a substance use disorder. All these conditions involve changes in normal physiologic function (brain chemistry or basal metabolism) that predispose patients to relapse.

HOW PRIMARY CARE PHYSICIANS CAN HELP

Despite the studies outlined above, many physicians still see obesity as a lifestyle choice. Better education might help these physicians understand the issues better. Recent studies show that many
Several randomized trials have found that the combination of high-intensity behavioral treatment and medications nearly double the weight loss achieved, compared with either therapy alone.

criteria for using weight-loss medications on a long-term basis. One reason for this lack of knowledge may be the relative absence of questions about obesity in medical-licensing examinations. For example, only 19% of internists and 16% of family physicians know the US Food and Drug Administration criteria for starting a medication to treat obesity, and only 39% of internists and 36% of family physicians know the criteria for using weight-loss medications on a long-term basis. One reason for this lack of knowledge may be the relative absence of questions about obesity in medical-licensing examinations. For example, only 19% of internists and 16% of family physicians know the US Food and Drug Administration criteria for starting a medication to treat obesity, and only 39% of internists and 36% of family physicians know the criteria for using weight-loss medications on a long-term basis. One reason for this lack of knowledge may be the relative absence of questions about obesity in medical-licensing examinations.

For the practicing internist or family physician, treatment for obesity is best understood as multimodal and long term. Lifestyle changes (reduced calorie intake, increased physical activity) are necessary, and high-intensity behavioral treatment to help meet these targets is recommended for all patients. The addition of medically supervised diets, pharmacotherapy, or weight loss surgery can help some patients meet and sustain those behavioral targets. Several randomized trials have found that the combination of high-intensity behavioral treatment and medications nearly double the weight loss achieved, compared with either therapy alone. Thus, combination therapy is additive. Finally, monthly or more frequent contact with a trained interventionist (eg, registered dietitian, behavioral psychologist) is recommended to ensure longer-term success with maintenance of weight loss. Increased exercise is critical for the long-term maintenance of weight loss, in part because of its ability to improve resting metabolic rate. Data from the National Weight Control Registry (a database of individuals who have successfully maintained a weight loss of at least 30 pounds) provide insight into the behaviors required for long-term success. On the particular question of long-term use of medications to treat obesity (a question I receive frequently from colleagues), randomized trial data strongly suggest that medications are only effective for as long as the patient continues to take them. Clinical guidelines on pharmacotherapy for obesity indicate that medications are most appropriately used as a chronic therapy.

There are not enough physicians who are willing to treat obesity. As I write this, I also am emailing 2 obesity medicine colleagues in other practices who are trying to help friends in distant locations find a physician who will prescribe a medication to help manage their weight. In addition, nearly every week I work with physicians in my health care system who are hesitant to prescribe any medication for weight control. I look forward to a time when I do not need to be informally consulted to find physicians to prescribe a weight-loss medication. For Kaiser Permanente clinicians interested in prescribing, a brief continuing medical education video can be found at: https://clm.kp.org/wps/portal/cl/CO/search_iframe?query=obesity&x=0&y=0. All clinicians (Kaiser Permanente and non-Kaiser Permanente) can learn more about pharmacotherapy by reviewing the clinical guideline on medications to treat obesity.

I treat obesity because of patients like Della, who restricts her calories, monitors her diet, and exercises regularly to maintain her weight loss. Certainly, the number of physicians who treat obesity is increasing. For example, more physicians are now taking the board examination for obesity medicine than are becoming certified for some traditional internal medicine subspecialties, such as endocrinology and infectious diseases. I also look forward to the day when all physicians understand and treat obesity as a chronic disease, like they do for diabetes and hypertension.

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Table 1: A weight-loss and 24-hour energy expenditure comparison between patient A and patient B

<table>
<thead>
<tr>
<th>Patient</th>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>5 ft, 6 in</td>
<td>5 ft, 6 in</td>
</tr>
<tr>
<td>Weight</td>
<td>200 lbs</td>
<td>200 lbs</td>
</tr>
<tr>
<td>Sex</td>
<td>Woman</td>
<td>Woman</td>
</tr>
<tr>
<td>Weight loss</td>
<td>Weight stable since early adulthood</td>
<td>Lost 10% of body weight in the past year (22 lbs)</td>
</tr>
<tr>
<td>Estimated 24-h energy expenditure</td>
<td>2191</td>
<td>1891</td>
</tr>
<tr>
<td>Hunger level</td>
<td>Stable</td>
<td>Increased</td>
</tr>
</tbody>
</table>

Ft = foot; in = inch; lb = pound.

physicians lack knowledge about the metabolic adaptations to weight loss, and also that they lack basic knowledge about how to treat obesity. For example, only 19% of internists and 16% of family physicians know the US Food and Drug Administration criteria for starting a medication to treat obesity, and only 39% of internists and 36% of family physicians know the criteria for using weight-loss medications on a long-term basis. One reason for this lack of knowledge may be the relative absence of questions about obesity in medical-licensing examinations.

For the practicing internist or family physician, treatment for obesity is best understood as multimodal and long term. Lifestyle changes (reduced calorie intake, increased physical activity) are necessary, and high-intensity behavioral treatment to help meet these targets is recommended for all patients. The addition of medically supervised diets, pharmacotherapy, or weight loss surgery can help some patients meet and sustain those behavioral targets. Several randomized trials have found that the combination of high-intensity behavioral treatment and medications nearly double the weight loss achieved, compared with either therapy alone. Thus, combination therapy is additive. Finally, monthly or more frequent contact with a trained interventionist (eg, registered dietitian, behavioral psychologist) is recommended to ensure longer-term success with maintenance of weight loss. Increased exercise is critical for the long-term maintenance of weight loss, in part because of its ability to improve resting metabolic rate. Data from the National Weight Control Registry (a database of individuals who have successfully maintained a weight loss of at least 30 pounds) provide insight into the behaviors required for long-term success. On the particular question of long-term use of medications to treat obesity (a question I receive frequently from colleagues), randomized trial data strongly suggest that medications are only effective for as long as the patient continues to take them. Clinical guidelines on pharmacotherapy for obesity indicate that medications are most appropriately used as a chronic therapy.

There are not enough physicians who are willing to treat obesity. As I write this, I also am emailing 2 obesity medicine colleagues in other practices who are trying to help friends in distant locations find a physician who will prescribe a medication to help manage their weight. In addition, nearly every week I work with physicians in my health care system who are hesitant to prescribe any medication for weight control. I look forward to a time when I do not need to be informally consulted to find physicians to prescribe a weight-loss medication. For Kaiser Permanente clinicians interested in prescribing, a brief continuing medical education video can be found at: https://clm.kp.org/wps/portal/cl/CO/search_iframe?query=obesity&x=0&y=0. All clinicians (Kaiser Permanente and non-Kaiser Permanente) can learn more about pharmacotherapy by reviewing the clinical guideline on medications to treat obesity.

I treat obesity because of patients like Della, who restricts her calories, monitors her diet, and exercises regularly to maintain her weight loss. Certainly, the number of physicians who treat obesity is increasing. For example, more physicians are now taking the board examination for obesity medicine than are becoming certified for some traditional internal medicine subspecialties, such as endocrinology and infectious diseases. I also look forward to the day when all physicians understand and treat obesity as a chronic disease, like they do for diabetes and hypertension.

Disclosure Statement
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References
COMMENTARY

Why I Treat Obesity


Food Preparation

Obesity rates are inversely correlated with the amount of time in food preparation. The more time a nation devotes to food preparation at home, the lower its rate of obesity.

— Michael Pollan, b 1955, American journalist, author, and activist
Novel Use of Apple Watch 4 to Obtain 3-Lead Electrocardiogram and Detect Cardiac Ischemia

Cesar O Avila, MD

ABSTRACT

Background: Early recognition and treatment of ST-elevation myocardial infarction (STEMI) results in better outcomes.

Objectives: To describe a novel technique using the Apple Watch 4 (Apple Inc, Cupertino, CA) to obtain a 3-lead electrocardiogram (ECG) and confirm the watch’s feasibility to detect cardiac ischemia in selective cases with a particular injury pattern.

Methods: Two male patients in the Emergency Department had STEMI apparent on their ECGs. These findings were compared with those from the Apple Watch 4, whose positioning was adjusted for 3-lead ECG.

Results: The patients’ real-time, watch-based, 3-lead ECG tracings matched the traditional ECGs demonstrating STEMI, confirming the potential ability of this device to uncover myocardial ischemia. In each patient, cardiac catheterization revealed severe, 100% occlusion of the right coronary artery.

Conclusion: The Apple Watch 4 could lead to earlier detection of acute coronary artery disease, but sensitivity and specificity remain unknown.

INTRODUCTION

One in 4 people die of heart disease in the US. Urgent revascularization is indicated in patients with ST-elevation myocardial infarction (STEMI), and earlier treatment reduces morbidity and mortality.

Multiple barriers have been identified in preventing the early recognition of STEMI, including preexisting bias of symptoms, incorrect rationale, attribution to other medical conditions, and lack of awareness of the importance of rapid treatment. There are educational recommendations for health care practitioners, patients, and family to receive information about acute myocardial infarction to improve on treatment delays. Extending the availability of electrocardiograms (ECGs) could lead to earlier recognition and prompt treatment of acute coronary artery disease.

Millions of people own the Apple Watch 4 (Apple Inc, Cupertino, CA), which can perform a single-lead ECG. Inadvertently, I noted the watch’s ECG lead reversal when wearing the watch on the right wrist instead of the left. Subsequently, I tested the watch’s capability to create a 3-lead ECG by adjusting the positioning of the watch using the Einthoven triangle as a guide. The watch has electrodes built into the digital crown (negative) and the back crystal (positive) to detect cardiac electrical signals. Lead I can be obtained using the watch as intended: Wearing the watch on the left wrist and the right index finger touching the digital crown. However, leads II and III can also be obtained by placing the positive electrode (back of the watch) against the midabdomen and using the negative electrode (digital crown) with the right or left index finger (Figure 1).

METHODS

By adjusting the use of the Apple Watch 4, as shown in Figure 1, a 3-lead ECG can be obtained. These lead tracings were confirmed in control participants (Figure 2). Additionally, the watch’s 3-lead ECG was tested in 2 patients to determine concordance with ECGs showing STEMI.

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Keywords: Apple Watch 4, Apple Watch 4 as electrocardiogram, cardiac ischemia, detection of acute coronary artery disease, ECGs demonstrating STEMI, novel use of Apple Watch 4
Novel Use of Apple Watch 4 to Obtain 3-Lead Electrocardiogram and Detect Cardiac Ischemia

RESULTS

Case 1

A 52-year-old man presented to the Emergency Department with chest pain. He reported that his symptoms started “fairly quickly” with 9 of 10 epigastric and retrosternal chest pressure. He reported a history of back pain, but this episode was “much worse than usual” and involved his chest. On presentation, his ECG revealed a STEMI. There was notable ST-segment elevation in leads III/aVF with reciprocal changes including ST-segment depression I/aVL (Figure 3). Results of the initial laboratory studies were notable for an elevated troponin level.

The patient was treated for acute coronary syndrome. While the patient was awaiting transport to the cardiac catheterization laboratory, I obtained informed consent to perform a 3-lead

Figure 2. Electrocardiogram (ECG) lead tracings vs Apple Watch 4 tracings in control.

Figure 3. Electrocardiogram reveals a ST-elevation myocardial infarction in a 52-year-old man (case 1).

Figure 4. Lead tracings of traditional electrocardiogram (ECG) and Apple Watch 4 in case 1. STEMI = ST-segment elevation myocardial infarction.
ECG with the Apple Watch 4 to determine concordance of its leads against the patient’s STEMI-demonstrating ECG (Figure 4). The real-time, watch-based, 3-lead ECG tracing matched the traditional ECG waveforms. Cardiac catheterization revealed severe, 100% occlusion at the ostium of the right posterolateral branch of the dominant right coronary artery.

**Case 2**

A 68-year-old man arrived at the Emergency Department with chest pain. His symptoms started while working in the yard. He described the pain as pressure with associated nausea and vomiting. On presentation, his ECG also revealed a STEMI with notable ST-segment elevation in lead III/aVF and reciprocal ST-segment depressions in lead I/aVL (Figure 5). He was treated for acute coronary syndrome. I obtained informed consent to perform a 3-lead ECG with the Apple Watch 4 to determine concordance against the patient’s ECG demonstrating STEMI (Figure 6). The real-time, watch-based, 3-lead ECG tracing matched the traditional ECG waveforms. Cardiac catheterization revealed severe, 100% occlusion of the right coronary artery.

**DISCUSSION**

In these selected cases, the 3-lead ECG tracings obtained from the Apple Watch 4 matched the waveforms of the traditional ECGs demonstrating STEMI, confirming the potential ability of this smart watch to uncover myocardial ischemia.

Recent innovations in mobile health care technologies are disrupting traditional medical practice. Numerous publications reveal the use of these devices in early detection of arrhythmias, heart blocks, and cardiac ischemia. With this new watch function, the potential early detection of cardiac ischemia may permit earlier lifesaving intervention that could have a major impact on morbidity and mortality. The Apple Watch 4 reports a 98.3% sensitivity in atrial fibrillation detection. However, the sensitivity and specificity of the watch’s 3-lead ECG to detect cardiac ischemia are yet to be determined. The watch is also currently limited by an inability to detect precordial leads, which could miss cardiac ischemia in other cardiac regions. Further studies are needed to verify if the watch could yield valuable diagnostic information.

**CONCLUSION**

This article reveals a novel use of the Apple Watch 4 to obtain a 3-lead ECG. Adjustments to its software might yield the capability to obtain the augmented limb leads generating a 6-lead ECG. The watch has already received clearance from the US Food and Drug Administration for detection of atrial fibrillation and the novel technique described here could expand its function. This additional function of the watch may serve to implement a low-cost but high-value method of patient empowerment in the earlier detection of acute coronary artery disease.

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COMMENTARY

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References

Electrocardiography

This instrument—the string galvanometer—is essentially composed of a thin silver-coated quartz filament, which is stretched like a string, a strong magnetic field. When an electric current is conducted through this quartz filament, the filament reveals a movement which can be observed and photographed by means of considerable magnification.

— Willem Einthoven, 1860-1927, Dutch physician and physiologist who invented the first practical electrocardiogram, 1924 Nobel Prize winner in medicine
We Can Save a Million Hearts

Thomas E Kottke, MD, MSPH; Sarah Horst, MA

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ABSTRACT

The decline in cardiovascular disease mortality is stalling, and Million Hearts, a nationwide cardiovascular risk factor control campaign, is only halfway to its goal. In this commentary we identify 3 barriers beyond public reporting of performance that are hard stops for many Medical Groups that are participating in the Million Hearts initiative: 1) the inability of many physicians to access and visualize their patient panel electronic medical record data for patient and quality management, 2) a lack of compensation for the cost of team-based primary care, and 3) external support for single-condition registries rather than a single registry that contains the information that is necessary to manage all conditions of interest. These barriers have been overcome by high-performing Medical Groups and, if their innovations are adopted as standard practice by the US health care community, we believe that the Million Hearts goal can be achieved.

INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of death in the US, and after decades of decline in heart disease and stroke death rates as well as improvement in CVD risk factor levels, the trends have stalled or even reversed.1-4 In response, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) co-led the launching of Million Hearts in 2012, a cardiovascular risk factor control initiative with a 5-year goal of preventing 1 million cardiac events.5,6

In September 2018, Janet Wright, the Million Hearts Executive Director, published with her colleagues an editorial updating the progress the campaign had made, the missed opportunities, and the prospects for the future.7 Although they cited evidence that the campaign had contributed to the prevention of around 500,000 cardiovascular events by the end of 2016, they candidly reported that groups that allocate the resources to access and visualize their data perform well in meeting the Million Hearts hypertension control goals.

Achieving goals like those of Million Hearts is critical if the country is to control the rise of chronic disease and disability, and the Million Hearts goal requires risk factor control—by a healthy diet, adequate physical activity, weight control, and abstinence from tobacco and nicotine, and through pharmacologic treatment of hypertension, nicotine addiction, and dyslipidemia. We have calculated that eliminating current gaps in the delivery of evidence-based care to patients hospitalized for acute cardiac events would prevent or postpone less than 10% of the deaths in the middle-aged US population.8 By contrast, achieving all behavioral and risk factor targets could prevent or postpone more than 50% of all deaths in the middle-aged US population. Given the evidence that accountability for performance improves performance,9 it seems obvious to us that adding asking about and referring to counseling for tobacco use and blood pressure control to the list of accountability measures for all adults, not just those with CVD or diabetes or patients who have high blood pressure, would substantially promote the Million Hearts goal. However, there are 3 other barriers to performance in US ambulatory care that may not be as obvious to many policy makers.

In 1970, Eliot Freidson10 observed that the practice environment is a powerful determinant of physician behavior. Reports in the literature and years of participating on various teams organized with the intent of improving health and well-being have led us to believe that 3 hard-stop barriers lie between Million Hearts and its goals:

• Many physicians do not have the capability to access and visualize their patient panel electronic medical record data (EMR) data for the purposes of patient management and quality improvement
• Primary care physician groups are not compensated for team-based care
• A focus on single-condition disease prevention and control creates programmatic fratricide.

LOCKED OUT

The American Board of Family Medicine requires self-assessment of practice performance as one of its continuing certification requirements.11 We interpret this requirement as recognition that, when lacking evidence to the contrary, physicians tend to equate their intent to perform with actual performance. Decision support addresses this problem and can improve physician performance,12 but decision support for patient management cannot occur in the absence of data. Even so, it has been repeatedly observed that many physicians cannot access, much less visually observe, their own EMR data.13,14 Data for quality improvement should be accessed at monthly or even shorter intervals and ideally, data supporting patient management decisions should be available in real time. Manual data extraction is too cumbersome and costly for these tasks.

Reports in the literature and the Minnesota Health Scores reports document that groups that allocate the resources to access and visualize their data perform well in meeting the Million Hearts hypertension control goals.15,16 Groups that either do not have the resources or fail to commit them do not do as well. Small to medium-sized care groups, or small clinic sites that are satellites of a larger group that has not made risk factor control a priority, tend to fall into this latter category. These small care delivery sites rarely have an individual on-site who has the skills to manage the activities required...
or training to manipulate the EMR for quality improvement initiatives or patient management tools such as previsit planning. They are essentially locked out of their own medical records for the purpose of data-driven health enhancement.

**NOT COMPENSATED**

The management of chronic conditions requires that at least 3 events occur: The condition is identified, an appropriate treatment plan is developed, and the treatment plan is implemented. When organized correctly and the factors that influence performance are addressed,17 team-based care increases the likelihood that management of chronic conditions will happen and risk factor control will be achieved.19 Although the knowledge and skills of a licensed clinician are necessary to develop the treatment plan, highly effective Medical Groups assign the identification of risk factors and disease indicators to clinic staff working from protocols at the time of, or between, visits. Likewise, highly effective Medical Groups assign the implementation of the treatment plan to individuals who can take the time necessary to work with patients to identify and to overcome any barriers to success. Working in teams improves chronic-condition management while leaving the licensed clinicians free to do what they do best: Make diagnoses and develop treatment plans.

However, team-based care generates a cost,19,20 most of which is incurred by primary care. An expectation that primary care, whether solo physicians or physicians in groups, will use team-based care to achieve risk factor control without compensation that offsets their expenses is unrealistic. Without compensation, team-based care is not fiscally prudent.

We have calculated that team-based care for patients with CVD could generate net savings if overall (eg, primary, specialty, hospital, and drugs) costs of care were reduced by as little as 2%.20 Given the number of potentially preventable events that lead to hospitalization and the amount of low-value and no-value care delivered in the US, savings of this magnitude or greater are not beyond imagination. However, at least some of those savings must be used to finance the teams that produced them; they cannot stop at the payers.

**VICTIMS OF “FRATRICIDE”**

The list of risk factors and diseases that various agencies and organizations ask primary care to manage is long: Heart disease, cancer, diabetes, chronic lung disease, depression, physical inactivity, tobacco use, substance-use disorder, and now the social determinants, to name a few. Unfortunately, we do not know of any Medical Group that has been able to maintain a registry for each of these conditions; most groups have difficulty supporting even 1 registry. Therefore, when a funding agency supports an initiative to implement a single-condition registry, the result is “fratricide”; the new registry kills the use of any other registry that the group is using. Million Hearts and the Agency for Healthcare Research and Quality counterpart, Evidence NOW,21 are not exempt from this phenomenon. An alternative is a single, searchable registry that tracks multiple conditions: 1 row for each patient and 1 column for each condition. When one is assessing performance vis-à-vis a risk factor or condition, for example, hypertension, data in the relevant column can be manipulated and analyzed. When one assesses the management of a particular patient, the data in that patient’s row can be accessed and examined.

A sophisticated multicondition registry and decision-support system has been developed and tested.22,23 After the medical assistant moves the patient to a room, the acquired patient data on tobacco use, blood pressure, serum cholesterol, blood glucose, weight, and aspirin use are encrypted and sent to a remote server in the Cloud. A risk calculator on the server calculates the patient’s 10-year risk of fatal or non-fatal heart attack or stroke and prioritizes a set of interventions by potential impact. A detailed report is generated for the clinician, and a simpler report is generated for the patient, and both are encrypted and sent back to the patient’s medical record. This tool is not linked to a particular EMR product.

Although this decision-support system has been shown to improve risk factor control in patients with diabetes, the attributes that a decision-support system must have if it is to change decisions and improve care have not been established. However, registry and decision-support systems require support. Although large groups that are committed to risk factor control have the required clinical and informatics skills in-house, this is not the case with many of the solo practices, independent practices, and small groups that make up most of the US health care system. Likewise, solo practices and these groups cannot afford the fees charged by the EMR vendors to customize their software. One option would be to make registry functionality for multiple-condition patient and quality management a criterion for health information technology certification.24 Alternatively, we believe that accountable care organization support or the formation of nonprofit collaboratives could make these support services affordable in all sites if the accrued savings were shared appropriately.

**SCENARIO FOR SUCCESS**

High-performing Medical Groups are prima facie evidence that these 3 disease prevention hard stops can be overcome. For example, Kaiser Permanente was able to increase hypertension control from around 45% to 80% by attending to systems and data, and in Minnesota 80% control by a clinic is considered just “average.”15,16 With proper support, primary care service units can continuously access their data for decision support and quality improvement cycles. The concept of shared savings is not new; it just needs to be applied to team-based care for risk factor control and disease management. Finally, funding agencies and advocacy organizations need to stop the fratricide of its health registries and promote development of multicondition, rather than condition-specific, registries. The technology is there for the taking. The next step is to implement it and, in the process, achieve the goals of Million Hearts and the many other stakeholders who are committed to promoting health and well-being.
Giving Bad News

Toney Welborn, MD, MPH, MS

E-pub: 07/08/2019

Editor's note: This Graphic Medicine piece is a commentary on communication in medicine, health literacy, and how far we sometimes are from our patients in oral communication. This story is loosely based on the physician-author's own experience of being diagnosed with bone cancer at age 15. At a writing retreat, she was encouraged to draw her story—pairing words with images.

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Keywords: graphic medicine, malignant tumor, metastasis
Giving Bad News

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In 1991, I served on a Kaiser Permanente team to prepare staff for the Patient Self-Determination Act and how to speak with patients and their families about advance directives. Years later, I mentored Permanente Medical Group and Group Health physicians in teaching their colleagues how to have conversations about death and dying. In 2016, my partner of 36 years unexpectedly died. During this time I wrote the following haiku about my experience.

BEFORE AND DURING
Doing the right thing
Consequences multiply. Right?
Yes, but still sad
Heart breaks when he says
“I want to come home with you.”
That’s what I want too
“it’s out of your hands”
Striving to do what I can.
Limits are unclear
What to do? I asked
Be present. Speak up. Hold him.
More than good enough
Feel nausea heart quakes
Dead. Gone. Ashes.
Nevermore. Am I in a dream?

AFTER
Sliding through each day
Without notice: remember.
Images flood mind
Going through motions
Get up, walk, eat, pretending.
Act as if I live
Time drags me under
Too much time not enough time.
I succumb to time
These are early days
Four and one half months so fresh.
Walking the Bardo
Open or push down
Each moment offers a choice.
Present/Distraction
My constant mantra
He’s not suffering. He’s safe.
I did my best
Easter services
Happy? No, just not crying.
Solace in a crowd
I am sore angry
“Get on with it,” one voice says.
I will not be pushed
She’s speaking my words
Only someone who’s been there.
Echoing my truth
I am very strong
No proving needed; just ask.
People want to help

Disclosure Statement
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Keywords: advanced directive, caregiver, death, family, soul of the healer
NARRATIVE MEDICINE

D is for Donna

Laurie Cruz, MD
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You're one of the few people who really know me. You never said, “Don't take it personally,” or “You are too emotional.” You knew me, and with that came your love and support.

You asked if my husband would take care of me, and raised your right eyebrow when I insisted I didn't want to be taken care of. You smiled when I told you my second husband would always take care of me.

You wanted my life to be easy, yet you supported me going to medical school when I was 32 years old. You questioned how I would be able to handle children dying when I told you about pediatric palliative care. You didn't have your own palliative care team yet, but they would come soon. And you said, “You can do it.”

When you dropped me off freshman year you cried. I thought it was ridiculous. I'm sure I rolled my eyes and ran up the stairs to my new room—my freedom. You weren't sobbing or wailing, just holding a tissue in your right hand, the back of your left hand to your mouth, as I find myself doing these days. Just a few tears escaped your eyes as you sat in the passenger seat and Dad drove away. I breathed.

Thirty-six years later, I told you that I had dropped my son off at college and that I had cried. “Of course you did,” you said. It was one of the most coherent things you had said in months.

I learned a term last week called “ambiguous grief,” which is what I am experiencing. You're here, yet you're not. I would call you, but you don't understand how to use a phone. I visit and tell you about what's going on in my life, and sometimes you ask me about the dog you see on the floor. I ask how to keep my tomato plants alive, and you smile, nod your head, and say, “That's good.” Because you're here, I will continue to read to you like you read to me when I was little. I'll tell and retell the story of us dropping lampshades at Target and laughing uncontrollably until those ladies asked us to leave. And I'll give laminated copies of your chicken tetrazzini recipe to Eli and Gillian even though they were never taught to read cursive.

I think of you when I text or email funny things to the kids, fondly remembering the newspaper and magazine clippings you sent me with notes in your beautiful handwriting. I never could forget your “D.” I have always been envious and proud of that distinct cursive. You drew one of those D's the other day when you signed your name to allow me on your Health Insurance Portability and Accountability Act form, just like you did when you wrote “Love, Donna” on a Valentine’s Day card for Dad earlier this year. You tried to eat and the food fell off your fork, so you lifted the empty tines to your lips and opened your mouth.

But you had made the D.

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Keywords: ambiguous grief, palliative care
Her tiny, frail body lay in the middle of the room. The EMTs were busy trying to save her. I had never been in my neighbor’s house and didn’t know much about her apart from the fact that she was a second-generation Japanese woman who had been married to an African-American man. He had passed away years ago. Her children were around. Every spring she would gather daisies from my garden to honor the dead. As she grew weaker she asked me to cut the daisies for her. The last 2 years she had not come out of her house.

I was the neighbor who happened to be a doctor. Now I found myself going between her daughter and the EMTs. I would explain what the EMTs were doing and then turn around to ask the lead EMT to call the code. The EMT reluctantly informed me that protocol had to be followed.

I understood, but I still wanted to shout at the EMTs to stop trying to save her and let her die. I wanted to break down and cry as I imagined the pain her daughter was feeling.

Her daughter wanted me there as a doctor. I was her buffer between the ugliness of resuscitation and her heart, her flowers.

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Ty Ennis lives and works in Portland, OR. He graduated from Pacific Northwest College of Art in 2003 with a Bachelor of Fine Art in Printmaking. Ennis is represented by Nationale in Portland, OR.

Accompanying artwork: Her Heart, Her Flowers by Ty Ennis
Quality improvement has become a part of medical practice, certification, and education, and if you are looking for advice on how to introduce your findings and interventions to your departments or to publish them, look no further than David P Stevens’s *Writing to Improve Healthcare: An Author’s Guide to Scholarly Publication*. Although traditional scientific research in medicine adheres to standards and methodology in scholarly publication, publication of quality improvement and innovations is less established. The dissemination of quality improvement research and analysis helps the medical community stay current in knowledge of innovation, provide positive health outcomes, and decrease waste in health services. In *Writing to Improve Healthcare*, Stevens proclaims that health care improvement is incomplete until it is published, and he provides a unique guide to publication for this new category of writers.

An adjunct professor at the Dartmouth Institute for Health Policy and Clinical Practice (Lebanon, NH) and editor emeritus of the *British Medical Journal Quality & Safety in Healthcare*, Stevens has vast experience in teaching and publishing health care improvement. This experience allows him to give the reader an insightful but succinct history of quality improvement publications and research, as well as in the development of publishing guidelines, such as the Standards for QUality Improvement Reporting Excellence (SQUIRE).

The book provides best practices on how to turn quality improvement into scholarly contributions. Stevens dispenses specific advice regarding important topics such as the value of writing style, coauthor collaboration, and peer review, and how they relate specifically to writing to motivate change in health care. *Writing to Improve Healthcare* is not a mere description of an intervention—it encompasses the study of the intervention itself, the rationale behind it, and the application of the intervention to other health care settings.

Recognizing that health care improvements are realized through contextual features such as culture, leadership, and connectivity, Stevens stresses the importance of reporting on context in health care writing. For readers and quality improvement writers to apply and report on improvements in their own context, they must understand the circumstances under which the improvements were carried out. Stevens further acknowledges that the heterogeneous study settings in which improvement initiatives are conducted diverge from traditional biomedical research, and he provides information on where to find resources on statistical methods to establish validity.

Finally, Stevens shares tips on the submission process to a journal, including what to consider when selecting a journal. Overall, *Writing to Improve Healthcare* draws a roadmap from health care innovation to scholarly contribution and offers a practical reference guide along each step of the way.

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**Keywords:** health care improvement, publication, quality improvement, writing guide
Section A.

Article 1 (page 17) Rapid Implementation of Intraoperative Ultrasonography to Reduce Wire Localization in The Permanente Medical Group

Which statement is true? Preoperative localization of breast lesions
☐ a. increases incidence owing to mammographic detection of nonpalpable lesions
☐ b. is most commonly facilitated by intraoperative ultrasound
☐ c. alleviates patient stress on the day of surgery
☐ d. improves the efficiency of the operating room

Which statement is true? Intraoperative ultrasound facilitated by hydrogel clips
☐ a. requires surgeons to obtain breast ultrasound certification before performing this technique
☐ b. takes a long time to master
☐ c. relatively expensive
☐ d. can eliminate an extra procedure for patients before surgery

Article 2 (page 29) Resident and Faculty Perspectives on Prevention of Resident Burnout: A Focus Group Study

Respondents identified which of the following as the single most important strategy to address resident physician burnout
☐ a. reducing residents’ workload
☐ b. teaching residents stress management techniques
☐ c. reducing residents’ administrative work
☐ d. decreasing the stigma of burnout
☐ e. no single strategy was identified as most important

The majority of factors identified as contributing to resident burnout were:
☐ a. individual factors
☐ b. social factors
☐ c. learning and work environment factors
☐ d. health policy factors

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.

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

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

Section C.

What other changes, if any, do you plan to make in your practice as a result of reading these articles?

Section D. (Please print)

Name  ☐ Physician  ☐ Non-Physician

Title

Email

Address

Signature

Date

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**LETTERS TO THE EDITOR**

Joshua Tree National Park was a spectacular night. On the evening of August 2, 2019, Dr. Ramirez states: "This photograph was taken at approximately 10:30 pm in Joshua Tree National Park, California. The Milky Way, the most prominent feature of the night sky, was visible. The photograph was taken at the entrance of the park, with the silhouette of a Joshua tree in the foreground. The park is known for its diverse plant and animal life, including the Joshua tree, which is unique to the park."
ADDITIONAL CONTENT

ORIGINAL RESEARCH & CONTRIBUTIONS

- Twitter Conversations and English News Media Reports on Polio in Five Different Countries, January 2014 to April 2015
- Mastectomy or Breast-Conserving Therapy: Which Factors Influence A Patient’s Decision?
- Rapid Implementation of Intraoperative Ultrasonography to Reduce Wire Localization in The Permanente Medical Group
- Epidemiology of Chemotherapy-Induced Anemia in Patients with Non-Hodgkin Lymphoma
- Resident and Faculty Perspectives on Prevention of Resident Burnout: A Focus Group Study
- Effect of Hemoclot agents on Treatment of Unplanned Intra-Deficiency Anemia

SPECIAL REPORTS

- The Kaiser Permanente Los Angeles Annual Research Week Abstracts
- The Kaiser Permanente Los Angeles Annual Research Week Abstract Summaries
- A Daily Hospital Progress Note that Increases Physician Usability of the Electronic Health Record by Facilitating a Problem-Oriented Approach to the Patient and Reducing Physician Clerical Burden

REVIEW ARTICLES

- Self-Management of Depression: Beyond the Medical Model
- The Critical Response Team in Airway Emergencies

COMMENTARY

- Legal Perspectives on Telemedicine Part 1: Legal and Regulatory Issues
- Legal Perspectives on Telemedicine Part 2: Legal and Regulatory Issues

EDITORIAL

- We Can Save a Million Hearts