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Indexed in MEDLINE, PubMed, and PubMed Central
National Library of Medicine
1. Dr Hogan is an Associate Editor of The Permanente Journal.
2. Patients in tertiary care hospitals are more complex than in the past, but the implications of this are poorly understood.
3. The study reveals that although National Surgery Quality Improvement Program-generated records were risk factors for major adverse events, the teamwork climate decreased 5.4% in interventional radiology and 16.6% in mammography. Perception of teamwork climate decreased 4.5% in mammography. The Joint Commission’s Universal Protocol of all patients with major adverse events in surgical suites to their workflows. The teams then adapted key interventions used in interventional radiology and 16.6% in mammography.
4. The study reveals that although National Surgery Quality Improvement Program-generated records were risk factors for major adverse events, the teamwork climate decreased 5.4% in interventional radiology and 16.6% in mammography. Perception of teamwork climate decreased 4.5% in mammography. The Joint Commission’s Universal Protocol of all patients with major adverse events in surgical suites to their workflows. The teams then adapted key interventions used in interventional radiology and 16.6% in mammography.
Special Report
38 Complex Case Conferences
Associated with Reduced Hospital
Admissions for High-Risk Patients
with Multiple Comorbidities.
Philip Tuso, MD, FACP; Heather L Watson,
MBA, CHM; Lynn Garafalo-Wright,
DPPD, MHA; Gail Lindsay, RN, MA;
Ana Jackson, PhD; Maria Taitano, MD;
Sandra Keyama, MD; Michael Kanter, MD
The authors studied the effect person-
focused care may have on reducing
avoidable admissions to the hospital.
Observed-over-expected hospital
readmission rates were lowest for
patients receiving a postdischarge visit
with a home health nurse and a follow-
up visit with their physician (0.54),
compared with solely a physician visit
(0.81), home health visit (1.2), or phone
call (1.55). Various social issues may
contribute to hospital readmissions,
including caregiver knowledge, ability
to care for oneself at home, and issues
related to medications (adherence, ability
to pay, and knowledge about potential
side effects).

Special Report
43 Early Detection of Breast Cancer
Using a Self-Referral Mammography
Process: The Kaiser Permanente
Northwest 20-Year History.
David Mosel, MD; John Thompson, MD
Ninety-five percent of women later
found to have breast cancer were seen
an average of 5 times in medical offices
in the year preceding diagnosis. By
2011, almost 50% of all mammograms
were scheduled using the self-referral
process, with more than 25% of cancers
diagnosed through this process that
year. As the number of screening tests
performed is used as the sole measure of
screening effectiveness, segments of the
at-risk population are likely to be missed.

REVIEW ARTICLES
49 Relationship between Tumor Necrosis
Factor-α Inhibitors and Cardiovascular
Disease in Psoriasis: A Review
Thao Nguyen, MD; Jashin J Wu, MD
Psoriasis, a cutaneous disease that is
increasingly recognized as a systemic in-
flammatory process, is associated with an
increased risk for the development of car-
diovascular disease. The authors review
the evidence in support of the beneficial
effects of tumor necrosis factor-α inhibi-
tors on cardiovascular health.

55 Investigation of Women with
Postmenopausal Uterine Bleeding:
Clinical Practice Recommendations.
Malcolm G Munro, MD, FRCSc, FACOG;
The Southern California Permanente
Medical Group’s Abnormal Uterine
Bleeding Working Group
Postmenopausal uterine bleeding can be
spontaneous or related to ovarian hor-
monal replacement therapy or to the use
of selective estrogen receptor modulators.
The guideline development group deter-
mined that, for initial management of
spontaneous postmenopausal bleeding,
primary assessment may be with either
endometrial sampling or transvaginal
ultrasonography. Guidelines are also pro-
vided for patients receiving selective es-
tragon receptor modulators or hormone
replacement therapy.

71 The Role of Eye Movement
Desensitization and Reprocessing
(EMDR) Therapy in Medicine: Addressing
the Psychological and Physical Symptoms
Stemming from Adverse Life Experiences.
Francine Shapiro, PhD
A substantial body of research shows
that adverse life experiences contribute
to both psychological and biomedical
pathology. Twenty-four randomized con-
trolled trials support the positive effects
of eye movement desensitization and
reprocessing therapy in the treatment of
emotional trauma and other adverse life
experiences relevant to clinical practice.
Twelve randomized studies of the eye
movement component noted rapid de-
creases in negative emotions and/or vivid-
ness of disturbing images.

78 Pay for Performance for Salaried
Health Care Providers: Methodology,
Challenges, and Pitfalls.
John R Britton, MD
Pay for performance has been recom-
manded by the Institute of Medicine as an
incentive to improve the quality of health
care, but it is important to separate provider
contributions from other influencing factors
within the health care system. If appropri-
ate methodology is not used, much time,
effort, and money may be expended in
gathering data that may be potentially
misleading or even useless, such that good
performance may go unrecognized and
mediocre performance may be rewarded.

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Original Visual Art
24 “Los Angeles Harbor Lighthouse
(Angel’s Gate), San Pedro, California”
Anil Thomas, MD
32 “Erice”
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86 “Sunset at Sukhna Lake, Chandigarh,
India”
Vishal Sharma, MD, DM
94 “The Man in the Mirror”
Phillip LaBorie

COMMENTS
NARRATIVE MEDICINE
87 Eluding Meaninglessness:
A Note to Self in Regard to Camus,
Critical Care, and the Absurd.
Thomas John Papadimos, MD, MPH
The author presents a medical narrative,
as a catharsis, regarding Albert Camus’s
The Myth of Sisyphus in an attempt to
elude meaninglessness in his difficult
everyday practice of critical care medicine.
It is well documented that physicians who
practice critical care medicine are subject
to burnout. A third alternative to Camus’s
faith in the divine or to commit suicide
is the acceptance of a life without prima
face evidence of purpose and meaning.

EDITORIAL
90 Person-Focused Care
at Kaiser Permanente.
Jim Bellows, PhD; Scott Young, MD;
Alide Chase, MS
Patient-focused care has been described
as an extension of patient-centered care,
recognizing that patients’ medical needs
are best understood and addressed in
the context of their entire lives, including
their life goals and social, economic,
emotional, and spiritual functioning. The
authors describe emerging examples
in several areas: interdisciplinary care
planning, behavior change, social care,
patient-reported outcome measures, and
Total Health.

NARRATIVE MEDICINE
92 The Man In The Mirror:
Reflections On Dealing With
A Family Member’s Dementia.
Phillip LaBorie
Original artwork accompanies this
reflection of a man’s care of his brother
with dementia, complicated by severe
cardiocirculatory and pulmonary disease.
“The good news is that all of his
symptoms and stresses disappear when
we’re making art together.”
ORIGINAl RESEARCH & CONTRIBUTIONS

Assessment of Quality of Life in Patients with Chronic Oral Mucosal Diseases: A Questionnaire-Based Study.
Bijina Rajan, BDS; Junaid Ahmed, BDS, MDS; Nandita Sheny, BDS, MDS; Geena Denny, BDS, MDS; Ravikiran Ongole, BDS, MDS; Almas Binnal, BDS, MDS

Seventy patients seen in the Department of Oral Medicine and Radiology with oral lichen planus, recurrent aphthous ulcers, and pemphigus were included in the study. Patients older than age 35 years reported significantly lower quality of life (QOL) in the domain of social and emotional status. Significant age-related differences in QOL were not observed in other domains. Men reported significantly better oral health-related QOL than women did in pain and functional limitation.

The Economic Impact of Hospitalization for Diabetic Foot Infections in a Caribbean Nation.
Shamir A. Cowich, MBBS, DM; Shantil Islam, MBBS; Seetharaman Hantharan, MBBS, FRCA; Patrick Haranarayan, MBBS, FRCS; Steve Budhoooram, MBBS, FRCA; Shivaa Ramsewak, MBBS; Vijay Narayansingh, MBBS, FRCS

There were 446 patients hospitalized with diabetic foot infections, yielding approximately 0.75% annual risk for patients with diabetes. A total of US $13,922,178 were spent to treat diabetic foot infections in these 446 patients during 1 year at this hospital. Each year, the government of Trinidad and Tobago spends US $85 million, or 0.4% of their gross domestic product, solely to treat patients hospitalized for diabetic foot infections. With this level of national expenditure and the anticipated increase in the prevalence of diabetes, it is necessary to revive the call for investment in preventive public health strategies.

CASE STUDIES

Plantar Fasciitis: A Concise Review.
Emily N. Schwartz, MD; John Su, MD

One of the challenges in the treatment of plantar fasciitis is that there are very few high-quality studies comparing different treatment modalities to guide evidence-based management. Current literature suggests a change to the way that plantar fasciitis is managed. This article reviews the most current literature on plantar fasciitis and showcases recommended treatment guidelines.

LETTERS TO THE EDITOR

Think of Salt in Preventing Falls in the Geriatric Population
Spodick’s Sign: A Helpful Electrocardiographic Clue to the Diagnosis of Acute Pericarditis

CLINICAL MEDICINE

ECG Diagnosis: The Effect of Ionized Serum Calcium Levels on Electrocardiogram.
Jonathan D. Gardner, MD; Joe B. Callins, Jr, MD; FACCP, FASE; Glen E. Garrison, MD, FACC

High and low levels of ionized serum calcium concentration can produce characteristic changes on the electrocardiogram. These changes are almost entirely limited to the duration of the ST segment with no change in the QRS complexes or T waves. High ionized serum calcium shortens the ST segment, and low ionized serum calcium prolongs the ST segment. Two common clinical scenarios are presented.

Image Diagnosis: Sudden Paraplegia in Abdominal Aortic Thrombosis.
Alexandre Costa, MD; Andrea Veiga, MD

A 79-year-old woman with a medical history of hypertension and cardiac surgery for mitral valve repair was seen in the Emergency Department after falling to the floor in her bedroom. Acute abdominal aortic occlusion is an uncommon condition frequently resulting from saddle embolism or thrombus of an atherosclerotic plaque. Sudden neurologic symptoms can occur.

Image Diagnosis: Spontaneous Hematoma from Scurvy.
Diane Apostolakos, MD, MS; Lee O. Halvorsen, MD

A 58-year-old alcoholic man presents with pain, swelling, and bruising of his right leg, without history of trauma or injury. He had had frequent spontaneous hematomas in his legs. This patient drank a 1.75 liter bottle of vodka daily, smoked cigarettes, and ate mostly precooked hash brown potatoes, pasta, and occasional canned tuna. He did not eat fresh vegetables and rarely ate fruit, leading to Vitamin C deficiency.

NURSING RESEARCH & PRACTICE

Research
Self-Reported Activities and Outcomes of Ambulatory Care Staff Registered Nurses: An Exploration.
June L. Rondinelli, RN, MSN, CNS; Anna K. Omery, RN, DNPSC, NEA-BC; Cecelia L. Crawford, RN, DNP; Joyce A. Johnson, PhD, RN-BC

Ambulatory care is a growing field of nursing practice. There has been an ongoing effort to identify the desired role of the staff registered nurses (RN) in outpatient care and provide linkages to preferred outcomes. Survey respondents were ambulatory care staff RNs from various primary and specialty care clinics (n = 187) in an integrated health care organization in Southern California. This research study supports what ambulatory care RNs say they are doing: daily, diverse, and complex patient care activities that influence multiple relevant patient outcomes.

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Cognitive Complexity of the Medical Record Is a Risk Factor for Major Adverse Events

Abstract

Context: Patients in tertiary care hospitals are more complex than in the past, but the implications of this are poorly understood because "patient complexity" has been difficult to quantify.

Objective: We developed a tool, the Complexity Ruler, to quantify the amount of data (as bits) in the patient's medical record. We designated the amount of data in the medical record as the complexity of the medical record (CCMR). We hypothesized that CCMR is a useful surrogate for true patient complexity and that higher CCMR correlates with risk of major adverse events.

Design: The Complexity Ruler was validated by comparing the measured CCMR with physician rankings of patient complexity on specific inpatient services. It was tested in a case-control model of all patients with major adverse events at a tertiary care pediatric hospital from 2005 to 2006.

Main Outcome Measures: The main outcome measure was an externally reported major adverse event. We measured CCMR for 24 hours before the event, and we estimated lifetime CCMR.

Results: Above empirically derived cutoffs, 24-hour and lifetime CCMR were risk factors for major adverse events (odds ratios, 5.3 and 6.5, respectively). In a multivariate analysis, CCMR alone was essentially as predictive of risk as a model that started with 30-plus clinical factors.

Conclusions: CCMR correlates with physician assessment of complexity and risk of adverse events. We hypothesized that increased CCMR increases the risk of physician cognitive overload. An automated version of the Complexity Ruler could allow identification of at-risk patients in real time.

Introduction

Patients in tertiary care hospitals are more complex than in the past, and complexity varies greatly between patients. Because there are finite limits on the brain's ability to assimilate and process information, greater patient complexity increases the risk of physician cognitive overload and medical error. Therefore, if one could quantify patient complexity, it is possible that this would provide a useful risk stratification tool.

Cognitive overload is a risk factor for cognitive failure in many domains, and techniques have been created in other fields to quantify complexity. Although there is no perfect method of quantifying complexity, one widely used operational definition is "the minimum amount of information required to fully describe something." Conceptually, one writes down the most parsimonious but complete description of something (eg, a car, a patient) and counts the number of bits required to store that description.

It is obviously impossible to write a perfect description of a patient and his/her illness or illnesses. We therefore hypothesized that the amount of data recorded in the medical record, which we designated the "complexity of the medical record" (CCMR), would be a useful surrogate for true patient complexity. Our testable hypothesis was that patients with greater CCMR are at higher risk of adverse events.

The algorithm for calculating CCMR is complex, but conceptually it is fairly simple. We count 1 bit for every character of English language text, and 3 bits for every individual numeric digit recorded in the record. (Although it takes 8 bits to store an English letter in ASCII code, English-language text is highly constrained, and thus 1 bit per character is a reasonable estimate of text complexity.) For images, which require artificially inflated storage space (every chest film in our institution is stored in a 5-megabyte file), we count the number of characters in the dictated report. For headings on standardized charts (eg, "blood pressure") we count the heading once per 24 hours.

To the best of our knowledge, no prior studies have attempted to quantify the data stored in the medical record, and there is thus no gold standard for CCMR. We therefore tested our tool by 1) comparing its ranking of CCMR to the complexity rankings of experienced clinicians and 2) testing its ability to predict major adverse events in a tertiary care pediatric hospital.
Cognitive Complexity of the Medical Record Is a Risk Factor for Major Adverse Events

Methods

Development of the Complexity Ruler

As discussed in the introduction, we used an estimate of one bit per character for English-language text and 3 bits per digit for numeric data. We counted redundant headings once per 24 hours, and counted the dictated reports rather than the data storage requirements of actual images. We included all data entered into the record, whether by nurse, physician, or other clinician, and included laboratory results, x-ray films, and any other information of any kind. The result is a single number to represent the CCMR for each patient during a given time period. The instructions for the full Complexity Ruler are available online at: www.thepermanentejournal.org/files/Winter2014/cr.pdf.

Face Validity

Three senior physicians rank ordered the complexity (not the acuity) of patients on four different inpatient medical services. We measured the CCMR of five randomly selected inpatients from each of these four services and estimated their lifetime CCMR. We hypothesized that agreement between the Complexity Ruler and expert clinicians would constitute face validity of the Complexity Ruler.

Cognitive Complexity of the Medical Record versus Major Adverse Events

We conducted a case-control evaluation of the 39 patients who had major adverse events at Boston Children’s Hospital, Boston, MA, in 2005 and 2006. A major adverse event was defined as an event of sufficient gravity to require reporting to an outside regulatory agency. Most of these events involved permanent injury to the patient or major complications, for example, unanticipated abdominal or cardiac surgery. Controls were 78 patients who were randomly selected from all admissions to Boston Children’s Hospital during 2005 to 2006.

24-Hour versus Lifetime Cognitive Complexity of the Medical Record

The 24-hour CCMR was measured in the 24 hours before the adverse event in the cases (eg, from 3 am the day before to 2:59 am if the event occurred at 3 am). Each control was randomly assigned a date and time of his/her “event,” and 24-hour CCMR was calculated for the 24 hours before the event. Cases and controls whose event occurred in the first 24 hours after admission were excluded from the 24-hour CCMR analysis.

The current Complexity Ruler is too labor-intensive to apply to long periods of time. We therefore estimated the lifetime CCMR by determining their lifetime number of inpatient hospital days and multiplying it by the average CCMR of an inpatient day, stratified by days in the intensive care unit (ICU) vs non-ICU days. All cases and controls were included in the analysis of lifetime CCMR.

Data Analysis

Mean CCMR was compared for cases (reportable event) and controls (no reportable event) using the 2-sample t test with unequal variances. Patient characteristics, admission characteristics, and nursing factors were compared for cases vs controls using the Wilcoxon rank sum test for continuous variables and Fisher exact test for categorical variables. Factors significant at the 0.10 level were included in logistic regression models predicting major adverse events; the odds ratio (OR) and 95% confidence intervals were estimated. The CCMR was dichotomized at a value that maximized the OR for predicting major adverse events.

The c statistic was calculated for each logistic regression model. The c statistic is a measure of the model’s ability to discriminate between patients who experienced a major adverse event and those who did not; a value of 0.5 is no better than random, whereas a value of 1.0 means the model predicts outcome perfectly. Multivariate analysis was performed using forward selection; a p value ≤ 0.05 was required for a variable to be retained in the final model. Statistical analyses were performed using SAS Version 9.2 (SAS Institute Inc, Cary, NC).

Figure 1. Mean 24-hour cognitive complexity of the medical record (CCMR) measured by the Complexity Ruler compared with physician rankings of complexity.

CCMR was measured from an average of 5 randomly selected patients on each of 4 inpatient medical services. MICU = Medical Intensive Care Unit.

Figure 2. Mean 24-hour cognitive complexity of the medical record (CCMR) and estimated CCMR for the preceding 3 years.

Data are for the same patients shown in Figure 1. The average intensive care unit patient had more than 3.5 million bits over the previous 3 years—a staggering amount of information for the human brain to assimilate. MICU = Medical Intensive Care Unit.
Results

Face Validity

All 3 senior physicians ranked patients on the short stay service as least complex and patients in the ICU as most complex. Two of the 3 physicians ranked cardiology patients as more complex than general pediatrics patients, and 1 reversed this order. Both 24-hour and lifetime CCMR agreed with the rankings of experienced clinicians (Figures 1 and 2).

Lifetime Cognitive Complexity of the Medical Record versus Major Adverse Events

All 39 cases and 78 controls were included in this analysis. The mean estimated lifetime CCMR was much higher for cases (736,033 bits) than controls (119,707 bits), (p < 0.001). Having more than 70,000 bits in the lifetime medical record was associated with an OR of 6.5 for major adverse events (p < 0.001). Compared with more than 30 other risk factors, lifetime CCMR was 1 of 16 statistically significant risk factors for major adverse events and had the third highest OR of these factors (Table 1).

In a multivariate analysis, lifetime CCMR was an independent predictor of adverse events. Patients with a lifetime CCMR greater than 70,000 bits had an OR of 7.7 for adverse events (p < 0.001; Table 2). We compared the discrimination of the univariate model used to evaluate lifetime CCMR (c statistic of 0.72) with the goodness of fit from a multivariate analysis that excluded CCMR (c statistic of 0.78).

24-Hour and Lifetime Cognitive Complexity of the Medical Record versus Major Adverse Events

We hypothesized that 24-hour CCMR and lifetime CCMR might have different predictive values for major adverse events. However, for the analysis of 24-hour CCMR, we could evaluate only those patients whose event happened at least 24 hours after admission and, thus, for whom 24-hour CCMR could be measured (17 cases and 42 controls). We therefore analyzed this group of patients including both 24-hour CCMR and lifetime CCMR as potentially independent predictive variables. Because the datasets are not identical, the lifetime CCMR results are slightly different than in the analysis of all patients (Table 1).

Mean 24-hour CCMR was higher for cases (31,323 bits) than controls (14,454 bits), a significant difference (p = 0.008). Inclusion of more than 15,000 bits in 24 hours was associated with an OR of 5.3 for a major adverse event (p = 0.008). Compared with more than 30 other risk factors for adverse events, both 24-hour and lifetime CCMR were among the 10 statistically significant risk factors, and lifetime CCMR had the second highest OR of all factors (Table 3).

In a multivariate analysis after controlling for other factors, 24-hour and lifetime CCMR were not statistically significant. The c statistic for goodness of fit for the most predictive multivariate analysis was 0.87. When 24-hour CCMR was forced into the model, greater than 15,000 bits in 24 hours had an OR of 9.7 for a major adverse event (p = 0.02, c statistic = 0.86). When lifetime CCMR was forced into the model, greater than 70,000 bits had an OR of 19.3 for a major adverse event (p = 0.02, c statistic = 0.88; Table 4).

Discussion

Many authors have commented on the phenomenon of increasing patient complexity and hypothesized that complexity is a risk factor for errors and major adverse events. However, the impact of complexity on safety and quality has been difficult to study because it has not been quantifiable. We hypothesized that the data stored in the medical record (what we have designated the CCMR) would be a useful surrogate for true patient complexity and would therefore predict the risk of major adverse events.

---

### Table 1. Univariate analysis: All cases and controls

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds ratio</th>
<th>p value</th>
<th>95% Confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 70,000 Bits of lifetime CCMR</td>
<td>6.5</td>
<td>&lt; 0.001</td>
<td>(3.0-19.6)</td>
</tr>
<tr>
<td>≥ 1 G-tube medication</td>
<td>12.7</td>
<td>0.007</td>
<td>(3.7-39.9)</td>
</tr>
<tr>
<td>English not first language for parents</td>
<td>6.9</td>
<td>0.02</td>
<td>(2.5-18.1)</td>
</tr>
<tr>
<td>≥ 1 Nebulized medication</td>
<td>5.6</td>
<td>0.02</td>
<td>(2.1-13.8)</td>
</tr>
<tr>
<td>≥ 1 Assistive device</td>
<td>4.5</td>
<td>&lt; 0.001</td>
<td>(1.7-11.7)</td>
</tr>
<tr>
<td>≥ 2 Oral medications</td>
<td>4.4</td>
<td>0.002</td>
<td>(2.4-8.1)</td>
</tr>
<tr>
<td>≥ 4 Medications</td>
<td>4.2</td>
<td>0.002</td>
<td>(2.2-8.2)</td>
</tr>
<tr>
<td>Critically ill prior</td>
<td>4.0</td>
<td>0.03</td>
<td>(2.3-7.1)</td>
</tr>
<tr>
<td>Intubated</td>
<td>4.0</td>
<td>0.001</td>
<td>(2.3-7.1)</td>
</tr>
<tr>
<td>Day of week, Monday-Friday</td>
<td>3.8</td>
<td>0.01</td>
<td>(2.1-6.8)</td>
</tr>
<tr>
<td>≥ 2 IV medications</td>
<td>3.4</td>
<td>0.02</td>
<td>(2.2-5.9)</td>
</tr>
<tr>
<td>Any surgical or invasive treatment</td>
<td>3.2</td>
<td>0.01</td>
<td>(2.1-4.4)</td>
</tr>
<tr>
<td>Elective admission</td>
<td>3.1</td>
<td>0.007</td>
<td>(1.9-4.8)</td>
</tr>
<tr>
<td>ICU stay</td>
<td>2.4</td>
<td>0.09</td>
<td>(1.3-4.4)</td>
</tr>
<tr>
<td>≥ 2 Ongoing medical conditions</td>
<td>2.1</td>
<td>0.06</td>
<td>(1.3-3.7)</td>
</tr>
<tr>
<td>Any ongoing medical condition</td>
<td>1.6</td>
<td>0.3</td>
<td>(1.0-3.0)</td>
</tr>
</tbody>
</table>

* For this dataset, 24-hour CCMR information is not available. The following 24 risk factors did not have statistically significant results: admission type, median age, patient type, month of the year, primary service, median length of admission, median number of ongoing conditions, any serious ongoing medical condition, purpose of admission, condition at admission, any diagnostic examination, any medical treatment, any nonsurgical invasive treatment, any surgical treatment, time of event, level of assistance with daily living, level of nursing monitoring required, communicative ability of patient, continuous oxygen, noninvasive continuous positive airway pressure/biphasic positive airway pressure, treated with nebulizers, frequent respiratory treatment, median number of dressing changes, parent/caregiver present.

### Table 2. Multivariate analysis: All cases and controls

<table>
<thead>
<tr>
<th>Clinical factor</th>
<th>Odds ratio</th>
<th>95% Confidence interval</th>
<th>p value</th>
<th>c statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most predictive multivariate model—all factors</td>
<td>0.82</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 70,000 bits of lifetime CCMR</td>
<td>7.7</td>
<td>(3.0-19.6)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Day of week, Monday-Friday</td>
<td>5.1</td>
<td>(1.6-17.0)</td>
<td>0.007</td>
<td></td>
</tr>
<tr>
<td>Admission type: elective</td>
<td>3.2</td>
<td>(1.2-8.1)</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Univariate analysis of lifetime CCMR</td>
<td>0.72</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 70,000 bits of lifetime CCMR</td>
<td>6.5</td>
<td>(2.8-15.3)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Multivariate analysis with CCMR excluded</td>
<td>0.78</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 1 Assistive device</td>
<td>3.2</td>
<td>(1.2-8.5)</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>&gt; 4 Medications</td>
<td>3.6</td>
<td>(1.4-9.5)</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>Day of week, Monday-Friday</td>
<td>4.4</td>
<td>(1.3-14.6)</td>
<td>0.02</td>
<td></td>
</tr>
</tbody>
</table>

* 24-hour CCMR is not available for this dataset.

CCMR = cognitive complexity of the medical record.
Cognitive complexity is not the same as medical acuity. Although very sick patients will often be very complex, there are patients with cognitively straightforward problems (e.g., carbon monoxide poisoning) who are critically ill, and patients with very complex illnesses (long-standing diabetes) who are—at the moment—physically well.

**Robust Prediction of Risk**

Using a number of assumptions, we developed a tool to measure CCMR. We demonstrate in this project that both 24-hour and lifetime CCMR are risk factors for major adverse events. Naturally, our tool is preliminary and is subject to revision and improvement. However, even in its first iteration, it was very robust at predicting the risk of major adverse events. Most importantly, use of either 24-hour or lifetime CCMR alone was essentially equal in predictive power as multivariate models built on more than 30 clinical factors. Also important, use of 24-hour or lifetime CCMR alone was nearly as useful in predicting the risk of major adverse events as was a multivariate analysis starting with more than 35 clinical variables.

To implement risk reduction strategies, high-risk patients must be identified in real time, and risk stratification systems that incorporate multiple clinical variables are inherently difficult to implement in real time. On the other hand, CCMR could be readily “built into” the electronic medical record and be available continuously in real time.

If patients with high CCMR were identified in real time, potential risk-reduction strategies could be tested. Since cognitive capacity increases with experience, one hypothesis is that very complex patients should be managed by physicians with greater seniority. More complex patients might be provided with additional physician or nurse staffing. Determining which risk reduction strategies might be effective is far beyond the scope of this study, but it is impossible to test strategies scientifically unless one can identify the patients at high risk.

**Limitations**

The Complexity Ruler and this project both have many important limitations. Since there is no gold standard for cognitive complexity, we had to construct the Complexity Ruler de novo using multiple assumptions. Although the first version of the Complexity Ruler is predictive of adverse events, we are certain that it can be modified and improved. For example, different weightings of English-language text and digits might more accurately predict the likelihood of a major adverse event. The Complexity Ruler measures the total CCMR of the chart, including physician notes, laboratory tests, radiographs, nursing notes, flowsheets, and all other items. We did measure the different sections of the medical record separately but did not find any increased predictive value from looking at these as separate variables (data not shown). This could simply reflect the small size of our sample. Future studies will examine whether there are specific sections of the record whose CCMR is more predictive of major adverse events.

Because the Complexity Ruler measures the amount that clinicians write in the chart, it is possible that it overestimates the CCMR of patients whose clinicians are more verbose. This is a particular concern because clinicians can “cut and paste” sections of previous notes into current notes in the electronic medical record, increasing the amount of text without adding new information. There are computational tools to reduce or eliminate the redundancy from text (“compression algorithms”); therefore, it will be possible in future studies to determine whether verbosity and repetition are significant issues when measuring CCMR.

These data demonstrate that high CCMR is a risk factor for major adverse events but do not establish a causative link. We believe that the mechanism is cognitive overload of the physician, but additional studies will be needed to test that hypothesis.

Because we studied only very serious adverse events, we do not know if CCMR as measured by our tool is a risk factor for less serious adverse events.

<table>
<thead>
<tr>
<th>Clinical factor</th>
<th>Odds ratio</th>
<th>95% Confidence interval</th>
<th>p value</th>
<th>c statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 70,000 Bits of lifetime CCMR</td>
<td>16.7</td>
<td>&lt; 0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 1 G-tube medication</td>
<td>19.2</td>
<td>0.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 1 Nebulized medication</td>
<td>15.5</td>
<td>0.007</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 4 Medications</td>
<td>11.0</td>
<td>0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 1 Assistive device</td>
<td>7.3</td>
<td>0.003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 2 Oral medications</td>
<td>6.6</td>
<td>0.03</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intubated</td>
<td>4.8</td>
<td>0.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 2 IV medications</td>
<td>4.3</td>
<td>0.03</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elective admission</td>
<td>3.6</td>
<td>0.04</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Cases and controls included only those for whom 24-hour CCMR data were available. The following 28 risk factors did not have statistically significant results: primary service, location of service, median length of admission, any ongoing medical conditions, median number of ongoing conditions, any serious ongoing medical condition, purpose of admission, condition at admission, any diagnostic evaluation, any medical treatment, any nonsurgical invasive treatment, any surgical treatment, English not first language of parent, time of event, condition before event, level of assistance with daily living, level of nursing monitoring required, communicative ability of patient, treated with continuous oxygen, treated with noninvasive continuous positive airway pressure/biphasic positive airway pressure, treated with nebulizers, frequent respiratory treatment, median number of dressing changes, and parent/caregiver present.

CCMR = cognitive complexity of the medical record; G-tube = gastrostomy tube; IV = intravenous.

<table>
<thead>
<tr>
<th>Models</th>
<th>Odds ratio</th>
<th>95% Confidence interval</th>
<th>p value</th>
<th>c statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model 1: Most predictive model</td>
<td>21.6</td>
<td>(1.8-265.6)</td>
<td>0.02</td>
<td>0.87</td>
</tr>
<tr>
<td>&gt; 4 Medications</td>
<td>15.2</td>
<td>(1.2-200.3)</td>
<td>0.04</td>
<td></td>
</tr>
<tr>
<td>Model 2: Most predictive model that forces in 24-hour CCMR</td>
<td>9.7</td>
<td>(1.4-69.9)</td>
<td>0.02</td>
<td>0.86</td>
</tr>
<tr>
<td>&gt; 1 Nebulized medication</td>
<td>9.8</td>
<td>(1.0-93.7)</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Model 3: Most predictive model that forces in lifetime CCMR</td>
<td>19.3</td>
<td>(1.5-240.5)</td>
<td>0.02</td>
<td>0.88</td>
</tr>
<tr>
<td>&gt; 1 Nebulized medication</td>
<td>16.3</td>
<td>(1.3-207.3)</td>
<td>0.03</td>
<td></td>
</tr>
</tbody>
</table>

*The limited dataset includes only the 17 cases and 42 controls for which we have 24-hour CCMR. CCMR = cognitive complexity of the medical record.
Finally, our datasets were relatively small, and thus it was not possible to determine whether 24-hour CCMR and lifetime CCMR are independent risk factors for major adverse events.

Conclusion
A new instrument, the Complexity Ruler, was designed to measure the cognitive complexity of the medical record. In this study, the measured CCMR correlated with complexity as assessed by experienced clinicians, and it was a risk factor for major adverse events. Although unproven, it may be that the mechanism linking CCMR to major adverse events is cognitive overload.

An automated version of the Complexity Ruler is being developed. Automated, real-time information about complexity may have value in identifying patients at high risk of adverse events.

Disclosure Statement
Dr Connell is Chief Executive Officer of Knowledge Design Inc; Boston, MA. Boston Children’s Hospital, (Boston, MA) has applied for a patent for the method of determining patient complexity reported in this article. Draper Laboratory (Cambridge, MA) has sponsored this study with an unrestricted research grant. The authors have no other competing interests to disclose.

Both studies were approved by the Boston Children’s Hospital institutional review board.

Acknowledgments
The authors gratefully acknowledge the support of numerous clinicians at Boston Children’s Hospital, who helped us understand the many sources of information accumulating in the medical record. Kathleen Louden, ELS, of Louden Health Communications provided editorial assistance.

References

Besieged City
The physician should look upon the patient as a besieged city and try to rescue him with every means that art and science place at his command.

—Alexander of Tralles, c525-c605, one of the most eminent of ancient physicians
Immunomodulatory Agents and Risk of Postpartum Multiple Sclerosis Relapses

Brandon Emet Beaber, MD; Margaret D Chi, MPH; Sonu Malik Brara, MD; Jian Liang Zhang, MS; Annette M Langer-Gould, MD, PhD

Abstract

Objective: To determine whether treatment with an interferon beta or glatiramer acetate shortly after delivery reduces the otherwise increased risk of postpartum relapses of multiple sclerosis.

Methods: In a retrospective cohort of 112 women with multiple sclerosis and live births from Kaiser Permanente Southern California, complete medical and pharmacy records of the mothers and infants were reviewed. Propensity score-adjusted hazard ratios (HR) of time to first postpartum relapse were calculated.

Results: Of 80 women who breastfed little or not at all, 55 (69%) resumed treatment within 1 year postpartum, of whom 26 (47%) relapsed within 6 months postpartum. Resuming treatment within 2 weeks postpartum did not decrease the risk of relapse in the 2 years postpartum compared with women who resumed treatment later in the postpartum year (propensity score-adjusted HR = 1.3, 95% confidence interval = 0.5-3.4, p = 0.6). There was no difference in relapse rates between the groups in the first 6 months postpartum. However, later in the postpartum year those who resumed treatment early had fewer relapses ($p = 0.08$, Poisson regression).

Conclusions: Among women who breastfeed little or not at all, starting treatment with interferon beta or glatiramer acetate within two weeks postpartum does not reduce the risk of postpartum relapse of multiple sclerosis but may reduce the risk of subsequent relapses in the postpartum year.

Introduction

Multiple sclerosis (MS) is a chronic demyelinating disease of the brain and spinal cord, which predominantly affects women of childbearing age. Often MS is inactive during pregnancy (approximately 70% reduction in attacks during the third trimester) but causes frequent attacks in the postpartum period. Current immunomodulatory agents for treatment of MS, including glatiramer acetate, interferon beta, and second-line agents are not recommended during lactation because of safety concerns, so women are often untreated during this period.1,2

Multiple prior studies have demonstrated that women with more aggressive disease are less likely to breastfeed,3 partly because of the desire to restart treatment with immunomodulatory agents. However, no study has proved the efficacy of immunomodulatory agents in the early postpartum period.

Because a diagnosis of MS portends a major risk of disability over time, and because breastfeeding has multiple proven benefits for infants, it is important for neurologists to give informed, evidence-based advice on lactation. This is especially true given that glatiramer acetate and interferon beta reduce the risk of relapses by only approximately 25%4,5 and may take several months to take effect,6,7 and postpartum attacks often occur very early after delivery.1 This study aimed to evaluate the efficacy of early resumption of immunomodulatory agents in preventing postpartum relapses in women with MS. We focused on women who chose not to breastfeed exclusively because this behavior may reduce the risk of postpartum relapses,2 and including these women could lead to erroneous conclusions that resuming immunomodulatory agents is potentially harmful because these women rarely breastfeed exclusively.

Methods

Study Design and Subjects

The institutional review board of Kaiser Permanente Southern California (KPSC) approved this study. Informed consent was waived because this was only a database and chart review study.

For this retrospective cohort study, we identified 112 women with clinically definite MS6 and their 114 live infants born in the KPSC Region between 2004 and 2010. KPSC is a large prepaid health maintenance organization with more than 3.2 million members, including more than 2500 women with MS. It provides comprehensive health care coverage to approximately 20% of the population in the geographic area it serves. The costs of specialist consultations, hospitalizations, magnetic resonance images, other diagnostic tests, and medications are fully covered. The KPSC membership is representative of the general population in Southern California regarding ethnicity/race, age, sex, and socioeconomic status.7 After exclusion of 2 patients who had no KPSC encounters after delivery, the final cohort for data analysis included 112 deliveries.

To identify women with MS who delivered live infants in KPSC, we searched electronic databases for any mention of the International Classification of Diseases, Ninth Revision diagnostic codes for MS (340) and live birth (V30-39) (N = 122). An MS diagnosis was confirmed, and disability, relapses, and additional clinical details were extracted from full medical records, including all inpatient and outpatient records, computed tomographic scans and magnetic resonance images, and other laboratory diagnostic test results ordered through June 2011 by 2 neurologists (BEB or SMB and ALG).
A relapse was defined as the occurrence, reappearance, or worsening of symptoms of neurologic dysfunction that lasted for more than 48 hours. Transient, fever-related worsening of symptoms or fatigue alone was not considered a relapse. Symptoms that occurred within 1 month of each other were considered to be part of the same attack. The medical records were abstracted by a treating physician for documentation of signs and symptoms consistent with relapses and progression of disability.

Information about breastfeeding, formula feeding, and introduction of solid food was abstracted from the infant records by a research professional (MDC) blinded to the mother’s clinical history. This information is routinely recorded as part of a standard questionnaire administered by nursing staff at the infant well-baby/immunization visits at 2 days, 2 weeks, and 2, 4, 6, 9, and 12 months of age.

Statistical Analyses

The time to onset of the first postpartum relapse was determined by using the Kaplan-Meier method. Adjusted and unadjusted hazard ratios (HRs) were calculated by using the Cox proportional hazards regression method. Estimates of early treatment with immunomodulatory agents were adjusted, both singly and in combination, for disease duration (in years), relapse frequency in the 2 years before conception (0-1 or ≥ 2), treatment with immunomodulatory agents in the 6 months before pregnancy (yes/no), and age at the onset of pregnancy (in years). The independent effects of these factors were also tested.

Early resumption of immunomodulatory therapy was defined a priori as resuming treatment with interferon beta or glatiramer acetate within 15 days of delivery because it is well-known that most postpartum relapses occur in the first 3 to 4 months postpartum and that the immunomodulatory agents have a delayed onset of action. For the primary analyses, we chose to compare this group with those women who started regimens of immunomodulatory agents later in the postpartum year. We did so because we found that some women did not resume receiving immunomodulatory agents until they had a relapse and that the small group of women who resumed treatment after the first year postpartum or not at all had a very low risk of relapse. This could lead to the erroneous conclusion that early immunomodulatory treatment increases the risk of relapses. Sensitivity analyses were conducted to examine the effect of resuming immunomodulatory agents within 30 days of delivery vs later in the postpartum year and to compare women who received immunomodulatory treatment within 15 days of delivery with the women who resumed treatment later or not at all.

Exclusive breastfeeding was defined a priori as no regular formula feedings (at least one bottle a day) for the first two months postpartum. Nonexclusive breastfeeding was defined as either not breastfeeding at all, breastfeeding for less than two months, or starting regular supplemental formula feedings in the first two months postpartum.

Propensity score-adjusted Cox regression models were also examined. Predicted probability of resuming early treatment was modeled using a hypothesis-driven logistic regression model. This included the same covariates as in the standard multivariable models as well as breastfeeding (yes/no) and non-Hispanic, white race/ethnicity (yes/no). The Cox regression models were then adjusted for the propensity score quintiles derived from the logistic regression model.

An annualized relapse rate for each 6-month postpartum period was calculated until 24 months postpartum. The relapse rate was calculated in each time period by using the annualized relapses (calculated by dividing the actual relapses in the period by the time in years, which is 0.5 in our study) divided by the total number of patients in that period. The 95% confidence interval (CI) was calculated by assuming that the relapses were Poisson distributed. The p values of comparing 2 groups in each period were then calculated by Poisson regression.

The means and standard deviations of normally distributed variables were compared using 2-sample t tests; for variables with nonparametric distributions, the Wilcoxon rank-sum test was used; and for binary or categorical variables, χ2 with the Fisher exact test was used. Statistical significance was set at p = 0.05. No adjustment for multiple comparisons was made. All statistical analyses were performed using SAS version 9.2 (SAS Institute Inc, Cary, NC).

Table 1. Characteristics of women with multiple sclerosis at onset of pregnancy

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Resumed IMAs 0-15 days postpartum (n = 17)</th>
<th>Resumed IMAs 16-365 days postpartum (n = 38)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean disease duration, years (SD)</td>
<td>7.1 (5.1)</td>
<td>5.4 (4.4)</td>
<td>0.22</td>
</tr>
<tr>
<td>Mean age, years (SD)</td>
<td>33.6 (5.3)</td>
<td>31.5 (4.2)</td>
<td>0.12</td>
</tr>
<tr>
<td>Relapses 2 years before pregnancy, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>7 (41)</td>
<td>8 (21)</td>
<td>0.19</td>
</tr>
<tr>
<td>1</td>
<td>3 (18)</td>
<td>17 (45)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>6 (35)</td>
<td>8 (21)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1 (6)</td>
<td>3 (8)</td>
<td></td>
</tr>
<tr>
<td>≥ 4</td>
<td>0 (0)</td>
<td>2 (5)</td>
<td></td>
</tr>
<tr>
<td>Use of MS immunotherapies, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ever</td>
<td>17 (100)</td>
<td>36 (95)</td>
<td>&gt; 0.5</td>
</tr>
<tr>
<td>≤ 6 months before pregnancy</td>
<td>15 (88)</td>
<td>15 (39)</td>
<td>0.002</td>
</tr>
<tr>
<td>EDSS ≥ 4.0, no. (%)</td>
<td>0 (0)</td>
<td>6 (16)</td>
<td>0.16</td>
</tr>
</tbody>
</table>

EDSS = Expanded Disability Status Scale; IMAs = immunomodulatory agents: interferon beta and glatiramer acetate; MS = multiple sclerosis; SD = standard deviation.
Immunomodulatory Agents and Risk of Postpartum Multiple Sclerosis Relapses

Results

Of the 114 live births (112 women), 80 babies (70%) were breastfed little or not at all, 32 (28%) were breastfed exclusively for at least the first 2 months postpartum, and 2 (2%) had insufficient documentation in their medical records to determine the exposures or outcomes of interest (Figure 1). Of the 80 women who breastfed little or not at all, 55 (69%) resumed treatment with interferon beta (n = 34) or glatiramer acetate (n = 21) within 1 year postpartum, whereas the remainder resumed treatment either much later or not at all (Figure 1). Seventeen (31%) of the 55 women who resumed treatment continued with interferon beta or glatiramer acetate within 15 days postpartum, 29 women (53%) between 16 and 180 days, and 9 (16%) between 181 and 365 days. Thirty-seven (67%) of these 55 treated women relapsed within 2 years, most of whom (n = 25) relapsed within 6 months postpartum. Fourteen women waited until they had their first postpartum relapse before resuming treatment.

The baseline characteristics of women with MS who did not breastfeed exclusively and resumed immunomodulatory agents within the first 2 weeks postpartum and those who resumed treatment later in the postpartum year are presented in Table 1. Women who resumed treatment within the first 2 weeks postpartum were older, had longer disease duration, had slightly fewer relapses in the 2 years before pregnancy, were less likely to have clinically significant disability (Expanded Disability Status Scale score ≥ 4.0), and were more likely to have been treated in the 6 months before pregnancy. Only treatment within 6 months of pregnancy reached statistical significance (Table 1). Only 2 women in each group had relapses during pregnancy, and development of clinically significant disability progression during the 2 years postpartum was rare in both groups (Table 2).

Women who started treatment with interferon beta or glatiramer acetate even as early as 2 weeks postpartum had a similar risk of return of relapses in the 2 years postpartum and relapsed around the same time (unadjusted HR = 1.1, 95% CI = 0.56-2.2, p = 0.7) as did women with MS who resumed treatment with interferon beta or glatiramer acetate later in the postpartum year (Figure 2, Table 2). The lack of a robust protective effect of early treatment with interferon beta or glatiramer acetate remained even after adjusting for age, disease duration, pre-pregnancy relapse frequency, and pre-pregnancy treatment (standard multivariable adjustment HR = 1.2, 95% CI = 0.60-2.5, p = 0.6 and propensity score-adjusted HR = 1.3, 95% CI = 0.47-3.4, p = 0.6).

Among the 25 women who resumed immunomodulatory agents during the second year postpartum or not at all, only 8 (32%) relapsed during the 2 years postpartum. Inclusion of these women in the analyses still failed to show a protective effect of early immunomodulatory treatment on return of relapses (standard adjustment HR = 1.5, 95% CI = 0.74-3.1, p = 0.3). Additional sensitivity analyses comparing immunomodulatory treatment within 30 days postpartum vs later in the postpartum year also
failed to show a protective effect of early treatment (standard adjustment HR = 0.95, 95% CI = 0.48-1.9, \( p = 0.9 \)).

The annualized relapse rates and proportion of women with relapse in the 2 years after delivery are presented in Table 3. Relapse rates were significantly higher in the first year postpartum compared with the second year regardless of when immunomodulatory treatment was resumed. Overall, 26 women (47%) suffered 31 relapses in the first 6 months postpartum. However, there was no difference in the relapse rates of the 2 groups during this period. The women who resumed immunomodulatory agents in the first 2 weeks postpartum did appear to have a lower risk of relapse later in the postpartum year (unadjusted \( p = 0.08 \), Table 3), although this did not reach statistical significance even after adjusting for measures of disease severity (adjusted \( p = 0.08 \), Poisson regression). This difference was not sustained into the second postpartum year.

### Discussion
In this study, we found that starting treatment with interferon beta or glatiramer acetate as early as two weeks after delivery did not decrease the risk of a postpartum relapse. This was true even after taking into account the pre-pregnancy disease severity and reducing the potential for confounding by excluding women who chose to breastfeed exclusively or those who chose not to resume treatment at all. We also found a nonsignificant trend toward fewer relapses in the second half of the postpartum year among those women who resumed treatment early vs later in the postpartum year. Our findings suggest that among women who breastfeed little or not at all, starting treatment with interferon beta or glatiramer acetate even within two weeks postpartum does not dramatically reduce the risk of having a first postpartum relapse but may reduce the risk of subsequent relapses in the postpartum year.

No previous studies have examined whether forgoing breastfeeding in order to resume immunomodulatory agents reduces the risk of postpartum relapses—despite the clinical importance of the question. In fact, most studies of MS and pregnancy were conducted before the widespread use of immunomodulatory agents. However, our findings are not surprising because both interferon beta and glatiramer acetate have demonstrated a delayed onset of action in reducing time to first relapse, and the highest risk period for postpartum MS relapses is the first 4 months postpartum. In addition, the effect of interferon beta and glatiramer acetate in reducing the risk of relapse is modest at best, with no more than 25% reduction over 2 years. Another, less likely explanation for our findings is that the overwhelming immunologic changes of pregnancy may make the pathophysiology of postpartum relapses unlike relapses that occur during other phases of life and therefore resistant to treatment with immunomodulatory agents.

We set stringent criteria for the timing of resuming immunomodulatory agents postpartum and defining the comparison group to maximize the possibility of detecting a benefit of resuming immunomodulatory agents in preventing postpartum relapses. Because of the well-known delayed onset of action of interferon beta and glatiramer acetate, we required that immunomodulatory agents be resumed within 2 weeks postpartum. Because of the potential protective effects of exclusive breastfeeding, which could, in comparison, make resuming immunomodulatory agents look harmful, we excluded women who chose to breastfeed exclusively. Finally, some women seem to wait to resume immunomodulatory agents until after they have their first postpartum relapse, which may not occur until the second postpartum year or later. To avoid obscuring a treatment effect by including these women with relatively benign disease, we excluded those who did not breastfeed and did not

### Table 2. Clinical characteristics of women with multiple sclerosis during pregnancy and postpartum Years 1 and 2

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Resumed IMAs 0-15 days postpartum (n = 17)</th>
<th>Resumed IMAs 16-365 days postpartum (n = 38)</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women with relapses, no. (%)</td>
<td>2 (12)</td>
<td>2 (5)</td>
<td>&gt; 0.5</td>
</tr>
<tr>
<td>Postpartum Years 1 and 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women with relapses, no. (%)</td>
<td>12 (71)</td>
<td>25 (66)</td>
<td>&gt; 0.5</td>
</tr>
<tr>
<td>Time to first postpartum relapse, days</td>
<td></td>
<td></td>
<td>&gt; 0.5</td>
</tr>
<tr>
<td>Range</td>
<td>26-443</td>
<td>1-484</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>163</td>
<td>282</td>
<td></td>
</tr>
<tr>
<td>First quartile</td>
<td>119</td>
<td>61</td>
<td></td>
</tr>
<tr>
<td>EDSS ≥ 4.0, no. (%)</td>
<td>3 (17)</td>
<td>6 (16)</td>
<td>&gt; 0.5</td>
</tr>
<tr>
<td>Disability progression, no. (%)</td>
<td>3 (17)</td>
<td>2 (5)</td>
<td>0.17</td>
</tr>
</tbody>
</table>

* Defined as progression from Expanded Disability Status Scale (EDSS) of < 4.0 to \( \geq 4.0 \); or progression from EDSS of 4.0 to EDSS ≥ 6.0; or progression from EDSS of 6.0 to EDSS ≥ 7.0.

IMAs = immunomodulatory agents: interferon beta and glatiramer acetate.

### Table 3. Relapse during the 2 years postpartum in women with multiple sclerosis

<table>
<thead>
<tr>
<th>Months postpartum</th>
<th>Resumed IMAs 0-15 days postpartum</th>
<th>Resumed IMAs 16-365 days postpartum</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number (%) of women with relapse*</td>
<td>Number of relapses</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 (58.8)</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11.8 (0.72-1.82)</td>
<td>16 (42.1)</td>
<td>26 (47.3)</td>
</tr>
<tr>
<td></td>
<td>21</td>
<td></td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>1.11 (0.80-1.49)</td>
<td></td>
<td>1.13 (0.86-1.45)</td>
</tr>
<tr>
<td></td>
<td>0.11 (0.22-0.67)</td>
<td></td>
<td>&gt; 0.5</td>
</tr>
<tr>
<td></td>
<td>0.30 (0.15-0.56)</td>
<td></td>
<td>&gt; 0.5</td>
</tr>
</tbody>
</table>

* Seven women were lost to follow-up over the 2-year period; 2 who were treated 0 to 15 days postpartum and 5 who resumed treatment later.

\( \text{CI} = \text{confidence interval}; \text{IMAs} = \text{immunomodulatory agents: interferon beta and glatiramer acetate}. \)
resumed immunomodulatory agents within the first postpartum year. Despite this, we were unable to detect a significantly decreased risk of postpartum relapses in women who resumed immunomodulatory agents shortly after delivery.

“The nonsignificant trend toward fewer relapses in the second half of the first postpartum year in women who started interferon beta or glatiramer acetate treatment earlier rather than later may be the result of the delayed effect of glatiramer acetate and interferon beta. However, it is difficult to draw conclusions from such a small number of patients, and these findings need to be confirmed in a larger study.

Limitations of this study include the small sample size and reliance on routine medical records to identify relapses. This study does not exclude the possibility of a very small treatment effect; larger sample sizes are needed to address this issue. It is possible that women may not have sought care for minor relapses, although it seems unlikely that this would differ by exposure group. Furthermore, we observed a very similar annualized relapse rate and proportion of women with relapses during the first 6 months postpartum compared with the Pregnancy in Multiple Sclerosis (PRIMS) study (47.3% and 48%, respectively).

Strengths of this study are the complete and accurate pharmacy and health care records of mother and offspring in addition to the population-based source and clinical relevance of the question.

This study failed to demonstrate that resuming interferon beta or glatiramer acetate even as early as within the first 2 weeks postpartum could significantly decrease the risk of first postpartum relapse among women who choose not to breastfeed. However, the trend toward a decreased risk of relapse later in the postpartum year warrants further study. A larger collaborative study between KPSC and Kaiser Permanente Northern California funded by the National Multiple Sclerosis Society, New York, NY, is currently under way to confirm findings from this study.

Disclosure Statement
Dr Langer-Gould is the site principal investigator for 2 industry-sponsored Phase 3 clinical trials (Biogen Idec, Weston, MA; Hoffman-La Roche; Basel, Switzerland) and 1 industry-sponsored diagnostic assay observational study (Biogen Idec). She is also the principal investigator of an MS susceptibility study funded by the National Institutes of Health, Bethesda, MD, and a research grant from the National Multiple Sclerosis Society, New York, NY. The other authors have no potential conflicts of interests to disclose.

Authors’ Contributions
Brandon Emte Baebier, MD, contributed to the collection of the data as well as drafting and revising the manuscript. Margaret D Chi, MPH, and Soo Malik Brara, MD, contributed to the collection of the data as well as critical review of the manuscript. Jian Liang Zhang, MS, made substantial contributions to the data analysis and interpretation of the data. He contributed to drafting and revising the manuscript. Anneke M Langer-Gould, MD, PhD, made substantial contributions to the conceptualization and design of the study; contributed to data collection, analysis, and interpretation; helped draft and revise the manuscript; and supervised the study.

Acknowledgment
Leslie Parker, ELS, provided editorial assistance.

Sound of Gnawing

Even as I sit and write, millions of bacteria are gnawing away my precious spinal cord, and if you put your ear to my back the sound of the gnawing I dare say could be heard.

—The Journal of a Disappointed Man, Wilhelm Nero Pilatus Barbellion (Bruce Frederick Cummings), 1889-1919, English diarist
ORIGINAL RESEARCH & CONTRIBUTIONS

Accuracy of National Surgery Quality Improvement Program Models in Predicting Postoperative Morbidity in Patients Undergoing Colectomy

Jeffrey A Neale, MD, FACS, FASCRS; Craig Reickert, MD, FACS, FASCRS; Andrew Swartz; Subhash Reddy, MBBS; Maher A Abbas, MD, FACS, FASCRS; Ilan Rubinfeld, MD, MBA, FACS

Abstract

Background: The National Surgery Quality Improvement Program (NSQIP) is the standard for assessment of acuity-adjusted outcomes in surgery. The validity of NSQIP has not been well established in colorectal surgery. Technical and process variables, which NSQIP may not consider, affect morbidity rate.

Objective: A retrospective observational study was undertaken to determine the accuracy of NSQIP models in predicting morbidity for patients undergoing laparoscopic or open colectomy.

Methods: NSQIP participant use files for 2005 to 2008 were obtained. Data were selected using Current Procedural Terminology coding for open or laparoscopic colectomy. NSQIP-generated predicted morbidities were used to create area under the receiver operator curves (AUROCs).

Results: AUROCs demonstrated an accurate predictive model if the value was above 0.8 and indicated a marginal predictor model if below 0.7. The AUROC for the general NSQIP model was 0.817 (confidence interval [CI] = 0.815-0.819, p < 0.001). AUROC for the combined laparoscopic and open colectomy group was 0.703 (CI = 0.698-0.709, p value < 0.001). AUROCs for the individual laparoscopic and open colectomy groups were 0.627 (CI = 0.615-0.640, p < 0.001) and 0.701 (CI = 0.695-0.707, p < 0.001).

Conclusion: This study demonstrates that although NSQIP-generated morbidities used to create AUROCs are accurate for patients in an overall surgical model, predictive models for morbidity are marginal for laparoscopic and open abdominal colectomies. NSQIP risk models tend to emphasize comorbidities rather than intraoperative details or technical aspects of colonic resections.

Introduction

In 1994, the Veterans Health Administration (VHA) established the National Surgical Quality Improvement Program (NSQIP) for monitoring and improving the quality of surgical care across all VHA medical centers where major surgery is performed. The impact of NSQIP on quality of care was substantial, with a 47% decrease in the 30-day postoperative mortality and a 43% reduction in postoperative complications.1

This prospective, peer-controlled, and validated database includes 95% of the data points.2 The data represent a sample of institutional operative cases. Data are collected by specially trained nurse coordinators and validated by standard methods to ensure reliable comparison between institutions. This approach is gaining wide acceptance and is rapidly becoming a standard for measuring and improving quality of care for general, vascular, and colon and rectal surgery practices in many health care institutions in the US. Initiatives have been undertaken to broaden the implementation of NSQIP in additional surgical subspecialties, including gynecology, orthopedics, and neurosurgery; the “multispecialty” hospital membership includes these surgical subspecialties and more. In the colon and rectal surgical realm, NSQIP has had an impact on decreasing surgical site infections (SSI) and has been used to study the impact of a laparoscopic or open approach on the frequency of SSI.3,4 Fleming and colleagues3 recently used NSQIP data to demonstrate that a laparoscopic approach for restorative proctocolectomy was associated with a statistically significant reduction in both minor and major postoperative complications compared with the traditional open approach.

Currently, risk models for morbidity and mortality are adjusted each year,
and institutional outcomes are based on the acuity-adjusted observed-to-expected ratios. These models’ operative results are highly predictive when applied to the general population of NSQIP. For any of these models, accuracy can be judged by 2 components: its ability to separate diseased from nondiseased (discrimination) and its ability to correctly estimate the risk (calibration). The area under the receiver operating characteristic curve (AUROC) is one of the most common means of measuring discrimination. The AUROC and its associated c-statistic are functions of the sensitivity and specificity for each value of the measure or model. Because specificity and sensitivity can be manipulated on the basis of threshold choice, the c-statistic allows one to balance the view of the predictive model across the various metrics. The c-statistic value can range from 0.5 (no predictive ability) to 1 (perfect discrimination). The AUROC and its c-statistic are optimized semiannually to ensure accurate risk adjustment for reliable interinstitutional comparison. These models tend to favor demographic and comorbidity data, as these are common to all procedures. Another tool that one could use to evaluate goodness of fit in logistic regression is the Hosmer-Lemeshow test. However, this test cannot be used for large datasets such as ours because “it is with any statistical test, the power increases with sample size; this can be undesirable for goodness of fit tests because in very large data sets, small departures from the proposed model will be considered significant.” Given NSQIP’s need to gather a dataset common to all procedures, there are no specific colon and rectal data points collected. Despite proven broader surgical and specific colon and rectal predictive benefits, current NSQIP risk models are slightly better at predicting mortality than morbidity. In a review of semiannual reports, both mortality and morbidity are accurately predicted, with c-statistics on the AUROC curve of 0.94 (range = 0.85-0.87). We hypothesized that these models tend to emphasize comorbidity data rather than intraoperative details and technical aspects of surgery, and therefore are not solely reliable in predicting the outcome of patients undergoing colectomy.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open colectomy</td>
<td>44139, 44140</td>
</tr>
<tr>
<td></td>
<td>44141, 44143</td>
</tr>
<tr>
<td></td>
<td>44144, 44145</td>
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<tr>
<td></td>
<td>44146, 44147</td>
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<tr>
<td></td>
<td>44150, 44151</td>
</tr>
<tr>
<td></td>
<td>44152</td>
</tr>
<tr>
<td>Laparoscopic colectomy</td>
<td>44204, 44205</td>
</tr>
<tr>
<td></td>
<td>44206, 44207</td>
</tr>
<tr>
<td></td>
<td>44208, 44210</td>
</tr>
<tr>
<td></td>
<td>44211, 44212</td>
</tr>
<tr>
<td></td>
<td>44213, 44215</td>
</tr>
</tbody>
</table>

Materials and Methods

NSQIP participant use files were obtained under a data use agreement of the American College of Surgeons, and the study was approved by the Henry Ford Health institutional review board. We evaluated the most recent 4 years available at the time of analysis, January 1, 2005 to December 31, 2008. Patients were selected using Current Procedural Terminology (CPT) coding for major colectomy and labeled as either open or laparoscopic. For open colectomy and laparoscopic colectomy, the CPT codes are listed in Table 1. The noncolectomy group was defined as patients undergoing procedures other than those listed under open and laparoscopic colectomy. Postoperative morbidity was defined as the occurrence of 1 or more of the following events: SSI (superficial, deep, or organ space), wound disruption, pneumonia, unplanned intubation, pulmonary embolism, mechanical ventilation longer than 48 hours, renal insufficiency, acute renal failure, urinary tract infection, stroke or cerebrovascular accident, coma lasting longer than 24 hours, peripheral nerve injury, cardiac arrest requiring cardiopulmonary resuscitation, myocardial infarction, bleeding transfusions, graft/ prosthesis/ flap failure, deep vein thrombosis or thrombophlebitis, sepsis, and septic shock. It should be noted that each of these points, even though not directly applicable to colectomy surgery, are part of the standard NSQIP adverse events that all NSQIP surgical clinical reviewers look for. NSQIP-generated predicted morbidities were then used to create AUROCs for the various populations: all of NSQIP, noncolon-related surgeries, all colectomies, laparoscopic colectomies, and open colectomies. AUROC (a curve generated by the modeling process, the c-statistic gives you an objective understanding if that curve is a good one) is defined as the probability that predicting the outcome is better than that of chance. The c-statistic can range from 0.5 (no predictive ability) to 1 (perfect discrimination). AUROCs were judged by the c-statistic: < 0.70 (no clinical utility), 0.70 to 0.79 (marginal clinical utility), 0.80 to 0.89 (adequate clinical utility), and greater than 0.90 (excellent clinical utility). All analyses were verified using segmentation and subset methods. Data were analyzed using statistical analysis software (SPSS version 19; IBM SPSS, New York, NY), and p < 0.05 was considered significant.

Table 2. Findings by group

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All NSQIP procedures (N = 635,265)*</th>
<th>Noncolectomies (n = 589,620)*</th>
<th>All colectomies (n = 45,645)*</th>
<th>Laparoscopic (n = 12,455)*</th>
<th>Open (n = 33,190)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years</td>
<td>55.1</td>
<td>54.5</td>
<td>62.1</td>
<td>60.0</td>
<td>62.9</td>
</tr>
<tr>
<td>Male, %</td>
<td>42.6</td>
<td>42.2</td>
<td>48.1</td>
<td>48.4</td>
<td>47.9</td>
</tr>
<tr>
<td>Emergency procedure, %</td>
<td>12.9</td>
<td>12.4</td>
<td>18.6</td>
<td>3.6</td>
<td>24.2</td>
</tr>
<tr>
<td>Mean relative value unit</td>
<td>15.6</td>
<td>14.8</td>
<td>25.6</td>
<td>28.1</td>
<td>24.7</td>
</tr>
<tr>
<td>ASA 1, %</td>
<td>10.4</td>
<td>11.0</td>
<td>3.3</td>
<td>5.0</td>
<td>2.7</td>
</tr>
<tr>
<td>ASA 2, %</td>
<td>45.6</td>
<td>45.7</td>
<td>44.4</td>
<td>59.6</td>
<td>38.7</td>
</tr>
<tr>
<td>ASA 3, %</td>
<td>36.7</td>
<td>36.3</td>
<td>41.5</td>
<td>32.3</td>
<td>45.0</td>
</tr>
<tr>
<td>ASA 4, %</td>
<td>6.6</td>
<td>6.4</td>
<td>9.6</td>
<td>2.9</td>
<td>12.4</td>
</tr>
<tr>
<td>ASA 5, %</td>
<td>0.3</td>
<td>0.3</td>
<td>0.9</td>
<td>0.1</td>
<td>1.1</td>
</tr>
<tr>
<td>Average predicted morbidity</td>
<td>0.12</td>
<td>0.11</td>
<td>0.24</td>
<td>0.17</td>
<td>0.26</td>
</tr>
<tr>
<td>Actual morbidity occurrence</td>
<td>0.14</td>
<td>0.13</td>
<td>0.14</td>
<td>0.18</td>
<td>0.35</td>
</tr>
</tbody>
</table>

* Significant at p < 0.001.
ASA = American Society of Anesthesiologists class; NSQIP = National Surgical Quality Improvement Program.
Results

The general NSQIP population from January 1, 2005 to December 31, 2008 included 635,265 patients, of whom 45,645 underwent colonic resections (Table 2). Of the colonic resections, 12,455 (27.2%) were laparoscopic and 33,190 (72.8%) were open procedures. The mean age of all patients undergoing colectomy—“colectomy” group—was 62.1 years, and 48.1% were male. The patients undergoing procedures unrelated to the colon—“noncolectomy” group—were younger (mean = 54.5 years) and approximately the same proportion of male sex as in the other group. Emergent colectomies comprised 18.6% of all colectomies; 3.6% of laparoscopic colectomies were emergent, and 24.2% of open procedures were also emergent. Compared with other NSQIP-captured noncolorectal abdominal procedures, a higher proportion of colectomies were performed as emergency procedures, and most often employed the open approach. The AUROC for emergent morbidity, mortality, and elective morbidity and mortality were 0.73, 0.86, 0.64, and 0.88, respectively (Table 3). The mean relative value unit was 25.6 for all colectomies, 28.1 for laparoscopic colectomies, and 24.7 for open colectomies. As displayed in Table 2, the American Society of Anesthesiologists (ASA) status for colectomies was significantly higher than noncolectomy cases, especially for open procedures. As expected, the predicted morbidity of the colectomy group was much higher than that of the noncolectomy groups (24% for all colectomies vs 17% for laparoscopic colectomies, and 26% for open procedures; all univariate data significant at p < 0.001). The occurrence of actual morbidity for all of the NSQIP, all of NSQIP noncolectomy procedures, all colectomies, laparoscopic colectomies, and open procedures was 14.2%, 13.0%, 14.2%, 17.9%, and 34.9%, respectively.

The detail of each AUROC curve is aggregated and summarized in Table 4. The AUROC for the general NSQIP model was 0.817, which was accurate in predicting morbidity in the entire patient population; the confidence interval (CI) was appropriate, and the p value was of statistical significance. The AUROC for the combined laparoscopic and open

| Table 3. Morbidity and mortality by colectomy emergency status |
|-------------------|-------------|-----------------|--------|----------------|
| Colectomy emergency status | N   | AUROC* | Confidence interval | p value | Corresponding figure |
| Emergency Morbidity | 4408 | 0.73  | 0.72-0.74   | < 0.001 | 7                |
| Emergency Mortality | 1295 | 0.86  | 0.85-0.87   | < 0.001 | 8                |
| Elective Morbidity  | 9376 | 0.64  | 0.64-0.65   | < 0.001 | 9                |
| Elective Mortality  | 777  | 0.88  | 0.87-0.89   | < 0.001 | 10               |

* AUROC value > 0.8 (accurate predictive model); value ≤ 0.7 (marginal predictive model).

AUROC = area under the receiver operator characteristic curve.

| Table 4. Aggregation and summarization of AUROCs |
|-------------------|-------------|-----------------|--------|----------------|
| Group              | N    | AUROC* | Confidence interval | p value | Corresponding figure |
| All patients       | 635,265 | 0.817  | 0.815-0.819   | < 0.001 | 5                |
| Noncolectomy       | 589,620 | 0.816  | 0.814-0.818   | < 0.001 | 6                |
| Open colectomy     | 33,190  | 0.701  | 0.694-0.707   | < 0.001 | 3                |
| All colectomies    | 45,645  | 0.702  | 0.697-0.708   | < 0.001 | 4                |
| Laparoscopic colectomy | 12,455 | 0.627  | 0.619-0.647   | < 0.001 | 2                |

* AUROC Value > 0.8 is the accurate predictive model; value ≤ 0.7 is a marginal predictive model.

AUROC = area under the receiver operator characteristic curve.

The colectomy group was 0.703 and therefore marginal in predicting morbidity for the entire colectomy group. An appropriate CI was also obtained, and the p value demonstrated statistical significance. The AUROCs for the individual laparoscopic and open colectomy groups were 0.633 and 0.701, respectively. The NSQIP-generated AUROCs for these patient populations were marginal at predicting morbidity, which was supported by adequate sample size, CI, and p values (Figure 1). Figures 2 to 5 show AUROCs for morbidity and mortality for elective and emergency colectomies.

**Discussion**

Our review demonstrates that the NSQIP-generated morbidities used to create AUROCs are accurate for patients in an overall surgical model. However, NSQIP-generated morbidities used to create AUROCs to predict morbidity in patients undergoing open colectomy demonstrated marginal accuracy at best and even less reliability for laparoscopic colectomy. The NSQIP risk models tend to emphasize comorbidities rather than intraoperative details or technical aspects of colonic resections. It is our opinion that certain factors may affect the surgical morbidity, including the case volume experience of the surgeon, the surgeon’s training...
The NSQIP risk models tend to emphasize comorbidities rather than intraoperative details or technical aspects of colonic resections.

**Disclosures Statement**

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

**Acknowledgment**

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

**References**


**Not By Any Other Means**

Surgery cures diseases that cannot be cured by any other means, not by themselves, not by nature, not by medicine.

—Henri de Mondeville, 1260-1320, French surgeon
Effect of Transcendental Meditation on Employee Stress, Depression, and Burnout: A Randomized Controlled Study

Charles Elder, MD, MPH, FACP; Sanford Nidich, EdD; Francis Moriarty, EdD; Randi Nidich, EdD

Abstract

Context: Workplace stress and burnout are pervasive problems, affecting employee performance and personal health.

Objective: To evaluate the effects of the Transcendental Meditation program on psychological distress and burnout among staff at a residential therapeutic school for students with severe behavioral problems.

Design: A total of 40 secondary schoolteachers and support staff at the Bennington School in Vermont, a therapeutic school for children with behavioral problems, were randomly assigned to either practice of the Transcendental Meditation program or a wait-list control group. The Transcendental Meditation course was provided by certified instructors.

Main Outcome Measures: Outcome measures were assessed at baseline and at four months, and included perceived stress, depression, and burnout. A multivariate analysis of covariance was used to determine overall effects.

Results: Analysis of the 4-month intervention data indicated a significant improvement in the main outcome measures resulted from practice of the Transcendental Meditation program compared with controls (Wilks $\Lambda = 0.695; p = 0.019$). Results of univariate $F$ tests indicated a significant reduction of all main outcome measures: perceived stress ($F[1,32] = 13.42; p = 0.001$); depression ($F[1,32] = 6.92; p = 0.013$); and overall teacher burnout ($F[1,32] = 6.18; p = 0.018$). Effect sizes ranged from 0.40 to 0.94.

Conclusions: The Transcendental Meditation program was effective in reducing psychological distress in teachers and support staff working in a therapeutic school for students with behavioral problems. These findings have important implications for employees’ job performance as well as their mental and physical health.

Introduction

Workplace stress and burnout are pervasive problems, potentially affecting employee performance and personal health. The issue is thus of prominent importance not only to employers but also to health care professionals. Schoolteachers are among the professionals who may experience a tremendous amount of stress in their work environment. Research indicates that approximately 70% of teachers are under frequent stress, with student discipline problems contributing the most to teacher stress and burnout. Burnout, a syndrome of emotional exhaustion, negative attitudes toward others, and dissatisfaction with one’s job performance, is associated with increased absenteeism and job turnover, alcohol and drug abuse, and lower job performance. Burnout, especially exhaustion, and other psychological distress factors affect not only job performance but also mental and physical health.

Training in mind-body techniques may have the potential to counter the effects of employee stress and burnout. Such techniques could, in theory, provide employees with a pragmatic tool for mitigating or reducing the impact of ongoing stimulation of the “fight-or-flight” response in the face of chronic psychosocial stressors. In this way, training in such a mind-body program could aid the employee in adapting to and in functioning in a high-pressure work environment, and in combating the potential long-term health sequelae of chronic stress. One previously published study, carried out in educational settings, showed meditation instruction to reduce teachers’ perceived stress and burnout. Although these results were promising, the study deployed a meditation protocol that is not otherwise established in the biomedical literature, and the results have not been replicated.

Among the most widely studied meditation and relaxation programs is the Transcendental Meditation (TM) program. TM is a simple technique for reducing mental stress and is practiced twice daily for approximately 20 minutes. The technique was first introduced in the West by Maharishi Mahesh Yogi more than 50 years ago. For the purposes of rigorous scientific assessment and dissemination, important advantages of the TM program include a standardized and reproducible instruction format, a thorough certification program for instructors, and widespread availability of instructors in essentially all population centers in North America. Performed while sitting in a comfortable position, the mental technique allows the mind to experience finer levels of the thinking process and to achieve a state of deep relaxation. Research on the TM technique has shown significant reductions in psychological distress, including decreased anxiety, depressive symptoms, and emotional distress, as well as improvement in psychological well-being in individuals with chronic illnesses.

This program differs from other meditation programs in terms of how the brain functions during the practice. Focused-attention meditation, corresponding to gamma (20- to 50-Hz) electroencephalographic (EEG) waves, aims to improve one’s ability to...
focus attention during activity, which would be advantageous in dealing with a threat. Open monitoring, or mindfulness, techniques produce theta (4- to 8-Hz) EEG waves. Such techniques aim to cultivate a nonjudgmental attitude toward experience. Automatic self-transcending techniques, such as TM, involve the effortless use of a sound without meaning (mantra), which allows the mind to settle to quieter levels of thought. TM increases alpha EEG coherence and synchrony, which provide long-range integration of distal cortical-neural groups necessary for sensory, motor, and cognitive behavior. Meta-analyses have found that the TM technique was more effective than other meditation and relaxation techniques for reducing trait anxiety. The current study was, to our knowledge, the first study to investigate the effects of TM on stress and burnout in a group of employees (teachers and support staff) working at a therapeutic school, a special school for students with severe behavioral problems. The purpose of the study was to evaluate changes in perceived stress, depressive symptoms, and burnout in those employees randomized to learn TM compared with wait-list controls over a four-month period. Specifically, we hypothesized that TM instruction would result in reductions in stress, depression, and burnout among employees enrolled in the trial.

### Methods

#### Subjects and Setting

From among approximately 75 potentially eligible employees working at a residential therapeutic school for students with behavioral problems, 40 teachers and support staff volunteered for the study. They were randomized to 2 groups: either TM (n = 20) or wait-list controls (n = 20). Recruitment, intervention, and follow-up took place between February 2010 and August 2010.

The study took place at the Bennington School in North Bennington, VT, a therapeutic school for children with behavioral problems. This residential school was thought to represent an excellent location for the project because the teachers at such an institution, in the face of students who need a higher level of care, are presumed to be especially at risk of stress and burnout. In addition, the administrative team at the Bennington School was highly supportive of the project.

#### Interventions

The treatment group was taught the TM technique in a standard 7-step course. Two certified TM instructors who had previously undergone 6 months of residential training and had more than a dozen years of teaching experience were used for this study. The same standardized TM course sequence was used for all study participants; this sequence is well described in the literature. Participants attended 2 didactic lectures, followed by an individual interview with the instructor. After these steps, the instructor provided individual instruction in the technique to each participant. On each of the 5 days after individual instruction, participants met with the instructor as a group to review and discuss experiences. Participants were advised to practice the technique twice a day for 15 to 20 minutes at home. Adherence to the instruction protocol was achieved through regular communication among the two teachers and the principal investigator of the study (SN).

Subjects in the wait-list control group continued with their usual schedule and were not instructed in TM until after the four-month intervention study was concluded.

#### Outcome Measures

After completing written informed consent, participants were administered a battery of tests at baseline, before instruction in the TM program. The baseline testing took place at the end of March 2010. Subjects were then administered the same battery of tests approximately four months later, at the beginning of August 2010.

The primary outcome measures were stress, depression, and burnout. The Perceived Stress Scale was used to assess participants' stress. This scale is a 14-item instrument that measures the degree to which situations in one's life are appraised as stressful. Each item is ranked on a 5-point scale. Coefficient α reliability is reported to be 0.85. Previous research has shown the instrument to be sensitive to changes induced by mind-body practice.

The Mental Health Inventory-5, which was used to assess depressive symptoms, is taken from the 36-Item Short-Form Health Survey. The Mental Health Inventory-5 has been found to have high sensitivity and specificity for detecting depression. Results from this instrument have also been well correlated with the Zung Self-Rating Depression Scale. The Mental Health Inventory-5 consists of 5 questions rated by the participant on a 6-point scale. Total scores range from 5 to 30.

The Maslach Burnout Inventory-Educators Survey was used to evaluate teachers' burnout. This is a 22-item inventory with total score and emotional exhaustion (9 items), depersonalization (5 items), and personal accomplishment (8 items, higher scores are better) subscales. Scores on each item range from 0 to 6. The Cronbach α range from 0.76 to 0.90. Younger teachers have been found to have higher levels of burnout than older teachers. Previous research has shown the instrument to be sensitive to changes induced by practice of mind-body stress reduction.

Lower scores on all primary outcomes—perceived stress, Mental Health Inventory-depression, and overall teacher burnout—are more desirable.

Compliance with home practice of TM was measured by each participant's self-report at posttesting.

#### Randomization and Allocation Concealment

Simple randomization procedures were used to assign participants to groups. The schedule of treatment group allocations was concealed by the study statistician, with individual treatment group assignments revealed to the project manager only when study participants completed baseline testing and were ready to commence treatment. All measures were self-administered questionnaires, to avoid any tester bias.

The consent form and all study procedures were approved by the institutional review board at Maharishi University of Management, Fairfield, IA.
Statistical Analysis
A multivariate analysis of covariance, covarying for baseline dependent variables and age, was used to determine overall effects. Univariate F tests were then used to determine specific effects on the main outcomes of the study. All p values were reported as two-tailed.
Sample size was dictated by funding and pragmatic limitations, as is typical for pilot studies of this type.

Results
Table 1 shows the demographic characteristics of the study participants by group. Overall, about 48% of subjects were men, the average age was 36.1 years, and the ethnicity was predominantly white.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Transcendental Meditation (n = 20)</th>
<th>Wait-list control (n = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, % men</td>
<td>50</td>
<td>45</td>
</tr>
<tr>
<td>Ethnicity, % white</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age, years (SD)</td>
<td>33.68 (8.31)</td>
<td>38.60 (10.90)</td>
</tr>
<tr>
<td>Perceived Stress Scale, mean (SD)</td>
<td>38.90 (6.48)</td>
<td>36.70 (6.68)</td>
</tr>
<tr>
<td>Mental Health Inventory-5 (depression), mean (SD)</td>
<td>12.95 (3.64)</td>
<td>13.10 (3.74)</td>
</tr>
<tr>
<td>Maslach Burnout Inventory, mean (SD)</td>
<td>37.60 (20.95)</td>
<td>37.50 (18.19)</td>
</tr>
</tbody>
</table>

Table 1. Demographic and baseline data
SD = standard deviation.
All p values > 0.05.

Analysis of the 4-month intervention data indicated a significant improvement in the main outcomes of the study due to practice of the TM program compared with controls (Wilks $\Lambda [3,28] = 0.695; p = 0.019$), as detailed in Table 2. Results of univariate F tests indicated a significant reduction of all main outcome measures: perceived stress ($F[1,32] = 13.42; p = < 0.001$); Mental Health Inventory-5 (depression) ($F[1,32] = 6.92; p = 0.013$); and overall teacher burnout ($F[1,32] = 6.18; p = 0.018$). Effect sizes (Glass’ $\Delta$) ranged from 0.40 to 0.94, suggesting moderate to large effects.

For the individual Maslach Burnout Inventory scales, there was a significant decrease in emotional exhaustion in the TM group ($-2.73 \pm 7.63$) compared with wait-list controls ($1.40 \pm 5.33$; $F[1,32] = 6.60; p = 0.040$). For personal achievement, which is a positive factor, the TM group showed an increase of $0.98 \pm 3.79$ compared with a reduction in personal achievement in the control group of $-2.16 \pm 6.61$ ($F[1,32] = 3.35; p = 0.077$). Change in the depersonalization scale was in the predicted direction but did not reach statistical significance.

Compliance with practice of the TM technique was high; 100% of the participants meditated at least once a day. Of those, 56% meditated regularly at home twice a day.
Participants reported no unexpected, study-related serious adverse events.

Discussion
The results of this randomized controlled study indicate that the TM program was effective at four-month follow-up in reducing psychological distress and burnout in employees working in a therapeutic school for students with behavioral problems. Significant reductions were found in the TM group compared with controls for all of the main outcome variables: perceived stress, depressive symptoms, and teacher burnout. Medium to large effect sizes were observed, with the largest effect on perceived stress.

Psychological distress and exhaustion are associated with physiologic wear and tear, called allostatic load, and have important health implications. Chronic psychological and physiologic stress factors have been linked to hypertension, obesity, and negative health behaviors, which are major contributors to cardiovascular morbidity and mortality, as well as other chronic diseases. A ten-year prospective study indicated that total burnout and emotional exhaustion scores on the Maslach Burnout Inventory were strong predictors of increased risk of mortality.

Studies indicate that practice of TM reduces psychological and physiologic response to stress factors, including decreased sympathetic nervous system and hypothalamic-pituitary-adrenal axis, and reductions in elevated cortisol (stress hormone) levels. Research also shows a more coherent and integrated style of brain functioning, evidenced by EEG imaging, which is associated with lower stress reactivity.

Recent research with college students practicing TM, compared with controls, indicated significant reductions in psychological distress, including anxiety and depression, which were associated with decreased blood pressure. In addition, the practice of TM has been shown to reduce risk of mortality compared with controls.

Strengths of the present study included a randomized controlled design, with subjects allocated to either immediate start of TM or a wait-list control group. All study participants worked in the same school; therefore, the effects of the work environment were equivalent between groups. Compliance with the daily practice of the TM technique was high.

Study limitations included potentially limited generalizability because the project was carried out at a single site. Adherence among participants was high, and results likewise may not be generalizable to other meditation or stress management programs in which there may be potentially less motivation to adhere to a...
daily home program. In addition, because participants could not be blinded to their treatment assignment, the use of self-report outcome measures introduced the possibility of bias. It is worth reemphasizing, however, that TM practice has been shown to achieve reductions in serum cortisol levels and other physiologic markers of stress in numerous previously published reports, as reviewed earlier.

We elected to use a wait-list control as the comparison group for this project. A chief advantage of the wait-list control is that every participant eventually gets the intervention. This, in turn, facilitates both recruitment and retention. An attention control intervention, such as a support group, also offers some advantages but can have a nocebo effect, and some participants assigned to such a control arm might be “disappointed” and inclined to drop out. Although the wait-list control was thus an appropriate choice for this project, it is possible that our findings could be attributable in part to the additional attention, or group social interaction, experienced by the participants assigned to learn TM before the follow-up data collection.

Health care utilization was not measured in our study. An economic analysis would be a useful addition to any future studies of mind-body techniques for employee wellness. Previously published data do suggest that the TM program can result in reductions in health care utilization.41-42

We described 3 main outcome measures but did not adjust for multiple comparisons, because this was intended primarily as an exploratory study. Nevertheless, introducing a Bonferroni correction would have left 2 of the 3 main outcomes (perceived stress and depression), with p values still statistically significant (below a critical value for significance of 0.017), with the third measure very close to being significant (p < 0.018 for the Maslach Burnout Inventory).

Overall, 90% of the participants were posttested. The participants who were not posttested were out of town at the time of test administration and could not be reached. Intent-to-treat analysis, using composite mean change scores for missing data, continued to show significant differences in perceived stress, depression, and teacher burnout (p < 0.025). Future studies are encouraged to include larger numbers of school employees from different backgrounds.

The study has important implications for reducing psychological distress and burnout in teachers and support staff. This, in turn, may affect both classroom teaching and mental and physical health. Results suggest that additional studies of TM in other stressful work environments, such as health care, may also be warranted.

Disclosure Statement
Randi Nidich is a part-time consultant to Maharishi Foundation USA Inc, Fairfield, Iowa. The other authors have no conflicts of interest to disclose.

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17. Travis F, Shear J. Focused attention, open monitoring and automatic self-transcending: categories to organize meditations from Vedic, Buddhist and...
Effect of Transcendental Meditation on Employee Stress, Depression, and Burnout: A Randomized Controlled Study


Antidote

Meditation is the antidote to all the poisons of your life.
It is the nourishment of your authentic nature.

—Chandra Mohan Jain, 1931-1990, professor of philosophy, Indian mystic, guru, and spiritual leader
The Los Angeles Harbor Lighthouse, also known as “Angel’s Gate,” welcomes ships into the Los Angeles harbor. This photograph was taken at sunset using a Nikon D90 at f5.6, 1/200 sec, ISO 400.

Dr. Thomas is a Urologist at the Sunnyside Medical Center in Clackamas, OR.
Weight Patterns Before and After Total Joint Arthroplasty and Characteristics Associated with Weight Change

Maria CS Inacio, PhD; Donna Kritz Silverstein, PhD; Rema Raman, PhD; Caroline A Macera, PhD; Jeanne F Nichols, PhD; Richard A Shaffer, PhD; Donald Fithian, MD

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Abstract

Context: Although prevalence of obesity and incidence of total joint arthroplasty (TJA) have dramatically increased over the last two decades in the US, little is known of the preoperative and postoperative weight patterns of patients undergoing TJA.

Objective: To describe the preoperative and postoperative weight patterns of patients undergoing TJA and evaluate characteristics associated with these patterns.

Design: Retrospective cohort study. A cohort of patients undergoing total hip arthroplasty (THA) or total knee arthroplasty (TKA) between January 1, 2008, and December 31, 2010, was identified. Using weight obtained at patient encounters, patients were categorized into gainers (increased weight by 5%), losers (decreased weight by 5%), or remained the same (changed < 5%) for the preoperative and postoperative periods. Patients were characterized by sex, age, and race.

Main Outcome Measures: Weight change before and after TJA.

Results: Of 30,632 patients with TJA identified, 34.5% underwent THA and 65.5% had TKA. Most patients remained the same weight during the year before (THA, 71.5%; TKA, 75.7%) and after the procedure (64.0% and 68.5%, respectively). Before and after THA, men were less likely to lose or gain weight than were women. Older patients were less likely to gain weight. Among patients undergoing TKA, men were less likely to lose weight preoperatively or postoperatively, or gain weight postoperatively, and older patients were less likely to gain weight before or after arthroplasty. Some racial associations with weight patterns were observed.

Conclusions: Specific groups are more susceptible to weight change and could benefit from weight management interventions.

Introduction

In 2009 in the US, 1,124,000 total joint arthroplasty (TJA) procedures were performed. Both the prevalence of obesity and the incidence of joint arthroplasty (specifically in knees and hips) have dramatically increased during the last 2 decades in this country. The incidence of arthroplasty is expected to continue to increase; according to Kurtz et al, by 2030, the incidence of total hip arthroplasty (THA) will increase by 174% and total knee arthroplasty (TKA) will increase by 673% compared with 2005 figures. Additionally, the time between procedures in the contralateral joint is expected to decrease because there is a higher risk of bilateral osteoarthritis in obese patients, and the age at TJA is also significantly younger. The increased TJA incidence and decreased time between multiple joint arthroplasty procedures have been largely, but not exclusively, attributed to the increase in the prevalence of obesity in the US population. Although the prevalence of obesity and TJA is known, little is known of the preoperative and postoperative weight patterns of patients who have already undergone TJA.

Obese candidates for TJA are often advised to lose weight because of the detrimental effects of obesity after surgery. However, whether patients actually lose weight is not known. To our knowledge, only two studies looking at preoperative weight changes in patients undergoing TJA have been published, and no description of the patients more susceptible to and successful in weight management were described. Riddle et al, in both studies, report preoperative weight loss association with postoperative weight gain.

Conversely, several studies have focused on weight changes of patients after TJA, but with inconclusive findings. These inconclusive results, which are also inconsistent, may have been because of the heterogeneity of study eligibility and analyses performed, small sample sizes, or overall quality. Thus, no conclusive evidence exists that weight improves, remains the same, or negatively progresses any time after TJA procedures.

The purpose of this study was to describe the preoperative and postoperative weight patterns of patients undergoing TJA in a large integrated health care system. In addition, this study also evaluated patient characteristics associated with different weight patterns one year before through one year after TJA.

Patients and Methods

Study Design and Sample

A retrospective review of the weight history of patients who underwent TJA at Kaiser Permanente (KP) from January 1, 2008, to December 31, 2010, was undertaken. All patients who were at least 18 years old and underwent primary, unilateral, lower limb TJA (knee or hip) for treatment of osteoarthritis at...
the 35 Medical Centers of the two largest Regions covered by KP (Northern and Southern California) were included in the study sample ($N = 36,015$). Patients who had a TJA performed for any reason other than osteoarthritis and those with multiple joint arthroplasties within 1 year of the procedure were excluded from the sample ($n = 3601$ patients/5222 procedures). Patients who underwent a bariatric surgical procedure were also excluded ($n = 161$).

Internal review board approval was obtained before commencement of the study.

Data Collection

Data were extracted from KP’s Total Joint Replacement Registry (TJRR) and electronic health records (EHRs). Using the TJRR, patients with TJA were identified. The structure, capture, validation, and data quality of the TJRR have been previously published. In brief, the TJRR is voluntary, with 90% to 95% participation in 2010. The registry captures the institution’s TJA population and records detailed information on patient characteristics, procedure diagnosis, specific procedures performed, surgical techniques, implant characteristics, and outcomes associated with the procedures.

The EHR was used to extract the weight measures whenever a patient encounter occurs. Weight measures from all encounters during 1 year before through 1 year after TJA were extracted. There was no standard protocol for weight assessment. If more than 1 weight per period was recorded, the median weight was used. Weight data were extracted for the time intervals of 1) 181 to 365 days preoperatively, 2) 91 to 180 days preoperatively, 3) 0 to 90 days preoperatively or intraoperatively, 4) 1 to 90 days postoperatively, 5) 91 to 180 days postoperatively, and 6) 181 to 365 days postoperatively.

Outcomes and Exposures of Interest

Patients were categorized into 3 groups for both the preoperative and postoperative periods: gainers (increased weight by 5%), losers (decreased weight by 5%), and remained the same (change < 5%). A change of 5% or more in preoperative or postoperative weight was considered a clinically significant weight change and was used to categorize the patients studied, as suggested by the US Food and Drug Administration definition. Weight was recorded for the intervals described and weight changes were calculated using the time period 0 to 90 days as the referent weight for change.

Patients were characterized according to demographic information (sex, age, and race/ethnicity) and type of procedure performed (TKA or THA).

Statistical Analysis

Rates for categorical variables and descriptive statistics for continuous variables were calculated. Data from the THA and TKA samples were analyzed separately. Preoperative weight patterns by starting obesity levels (nonobese < 30 kg/m$^2$, obese ≥ 30 kg/m$^2$) are provided. Postoperative weight patterns by intraoperative obesity levels (nonobese [< 30 kg/m$^2$], obese [30-34 kg/m$^2$], and morbidly obese [≥ 35 kg/m$^2$]) are provided. Chi-square tests and analysis of variance were used to compare characteristics by weight pattern group. Polychotomous logistic regression was used to model the 3 weight groups: loser, gainer, and “remain the same.” Separate models for preoperative and postoperative weight patterns and for TKA and THA were created. Those patients whose weight remained the same constituted the largest group and were used as the reference category. Age, sex, and race/ethnicity (Asian, black, Native American, white, Hispanic, other, and unknown) associations with weight changes were examined.

Missing data were excluded, and analyses were conducted to determine whether our estimations were biased by missing data. Collinearity of variables and outliers were also evaluated. Tolerance values less than 0.10 were used as thresholds for collinearity indication; outliers were manually reviewed. Unadjusted and adjusted odds ratios (OR) for the association of the dependent variables with weight patterns and 95% confidence intervals (CI) are provided. The Wald $\chi^2$ test p-value is also provided for each variable. All analyses were 2-tailed with $\alpha = 0.05$ used as the statistical significance threshold; analyses were performed using SAS for Windows 9.2 (Cary, NC).

Results

Of 30,632 patients who underwent TJA, 34.5% ($n = 10,572$) had THA and 65.5% ($n = 20,060$) underwent TKA. Women were in the majority ($n = 18,612$; 60.8%), but a higher proportion of women were in the THA sample ($n = 12,493$; 62.3%) compared with the TKA sample ($n = 6119$, 57.9%). The cohort’s mean age was 67.4 years old, and patients who underwent THA were slightly younger than patients with TKA (66.9 vs 67.7 years old) and had...
The mean weight of the sample at the time of TJA was 87.2 kg (192 lb) (standard deviation [SD] = 19.5 [43], range = 36.3-202.5 kg [80-446 lb]), and the mean body mass index (BMI) was 30.7 kg/m² (SD = 6.0, range = 15.0-67.5 kg/m²). Patients with THA had slightly lower mean weight (84.0 kg [185 lb], SD = 20.0 [44], range = 37.2-192.5 kg [82-424 lb]) and BMI (29.2 kg/m², SD = 5.7, range = 15.0-58.5 kg/m²) than did patients with TKA (mean weight = 89.0 kg [196 lb], SD = 19.5 [43], range = 37.7-219.7 kg [83-484 lb], BMI = 31.5 kg/m², SD = 6.0, range = 15.4-67.5 kg/m²). Figure 1 shows the mean weight of patients with THA and TKA. Weights are highest (for both patients with THA and TKA) at 6 months to 1 year preoperatively and lowest at the 3-month postoperative period.

Of the patients with THA, 9.6% (n = 1019) did not have a preoperative weight measure and 12.6% (n = 1336) did not have postoperative weight measured. Of the patients with TKA, 7.5% (n = 1512) did not have a measure of preoperative weight and 9.3% (n = 1866) did not have postoperative weight measured. The cases with missing data were more likely to be men and to be younger than those without missing data. There were no differences between cases with missing data and those with complete data with respect to intraoperative BMI, year of the operation, or operative side.

Table 1 shows the characteristics of the sample by whether they lost, gained, or remained the same weight during the 1 year before and after TJA. Most patients with THA and TKA remained the same weight during the year before their procedure (71.5% and 75.7%, respectively) and during the year after the procedure (64.0% and 68.5%). Figures 2A and 2B show the patterns of weight change both preoperatively and postoperatively. Most patients remained the same weight preoperatively and postoperatively (61.0% of the THA group and 63.8% of the TKA group).

Table 1. Patient characteristics by weight change during the preoperative and postoperative period by total hip arthroplasty (THA) and total knee arthroplasty (TKA), 2008-2010

<table>
<thead>
<tr>
<th>Sample</th>
<th>Preoperative weight group</th>
<th>Postoperative weight group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gainer</td>
<td>Loser</td>
</tr>
<tr>
<td>Total (N = 30,632)</td>
<td>1993 (6.5)</td>
<td>3355 (11.0)</td>
</tr>
<tr>
<td>THA (N = 10,572)</td>
<td>596 (8.7)</td>
<td>1394 (13.2)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>238 (39.4)</td>
<td>494 (35.4)</td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>64.2 (10.4)</td>
<td>68.0 (11.5)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>451 (75.4)</td>
<td>1119 (80.3)</td>
</tr>
<tr>
<td>Black</td>
<td>56 (9.4)</td>
<td>115 (8.3)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>43 (7.2)</td>
<td>94 (6.7)</td>
</tr>
<tr>
<td>Asian</td>
<td>27 (4.5)</td>
<td>31 (2.2)</td>
</tr>
<tr>
<td>Otherb</td>
<td>9 (1.5)</td>
<td>23 (1.7)</td>
</tr>
<tr>
<td>Unknown</td>
<td>12 (2.0)</td>
<td>12 (0.9)</td>
</tr>
<tr>
<td>TKA (N = 20,060)</td>
<td>1395 (7.0)</td>
<td>1961 (9.8)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>933 (66.9)</td>
<td>1326 (67.6)</td>
</tr>
<tr>
<td>Men</td>
<td>462 (33.1)</td>
<td>635 (32.4)</td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>65.0 (8.9)</td>
<td>67.5 (9.7)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>950 (68.1)</td>
<td>1375 (70.1)</td>
</tr>
<tr>
<td>Black</td>
<td>146 (10.5)</td>
<td>197 (10.1)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>199 (14.3)</td>
<td>257 (13.1)</td>
</tr>
<tr>
<td>Asian</td>
<td>66 (4.7)</td>
<td>76 (3.9)</td>
</tr>
<tr>
<td>Otherc</td>
<td>19 (1.4)</td>
<td>42 (2.1)</td>
</tr>
<tr>
<td>Unknown</td>
<td>15 (1.1)</td>
<td>14 (0.7)</td>
</tr>
</tbody>
</table>

a Gainer: weight increase ≥ 5% compared with weight at operative time. Loser: weight decrease ≥ 5% compared with weight at operative time. Remain the same: weight change no greater than ± 5%. Values are number (percentage) except where otherwise indicated. Some percentages do not total to 100 because of rounding.

b Includes multiracial Native American patients.

SD = standard deviation.
Weight Patterns Before and After Total Joint Arthroplasty and Characteristics Associated with Weight Change

Asians were less likely to lose weight (OR = 0.74, 95% CI = 0.66-0.84) than whites, and older patients were less likely than younger patients to gain weight (2.0% decrease in risk of being a gainer per 1-year age increase, 95% CI 2.0%-3.0%). After THA, men were less likely to lose weight (OR = 0.79, 95% CI = 0.69-0.92) or gain weight (OR = 0.86, 95% CI = 0.77-0.96). Additionally, older patients were less likely to be gainers (1.0% decrease in odds per 1-year increase, 95% CI = 1.0%-2.0%), and those who were black were more likely to be gainers (OR = 1.22, 95% CI = 1.00-1.47) compared with white patients (Table 2).

Before TKA, men and Hispanics had lower odds of losing weight (OR = 0.76, 95% CI = 0.69-0.84 and OR = 0.74, 95% CI = 0.64-0.85, respectively) or gaining weight (OR = 0.78, 95% CI = 0.70-0.88 and OR = 0.77, 95% CI = 0.66-0.91, respectively). Asians were less likely than whites to lose weight (OR = 0.63, 95% CI = 0.49-0.80), and older patients were less likely to gain weight (OR = 3.0% decrease per year of age increase, 95% CI = 3.0%-4.0%). After TKA, men were less likely than women to lose weight (OR = 0.62, 95% CI = 0.57-0.68), and Asians and Hispanics were less likely than whites to lose weight (OR = 0.69, 95% CI = 0.56-0.84, vs OR = 0.85, 95% CI = 0.71-0.99).

Figure 2A. Proportion of patients in each weight group by preoperative and postoperative status for total hip arthroplasty. Postop = postoperatively; preop = preoperatively.

Figure 2B. Proportion of patients in each weight group by preoperative and postoperative status for total knee arthroplasty. Postop = postoperatively; preop = preoperatively.

Figure 3. Pretotal joint arthroplasty weight pattern by preoperative obesity status.*

Figure 4. Posttotal joint arthroplasty weight pattern by intraoperative obesity status.

*BMI = body mass index; Intra-op = intraoperative; THA = total hip arthroplasty; TKA = total knee arthroplasty.
95% CI = 0.76-0.96, respectively). Older patients (OR = 2.0% decrease per year of age increase, 95% CI = 1.0%-3.0%) were less likely to be gainers, as were Asians and Hispanics compared with whites (OR = 0.76, 95% CI = 0.60-0.97, OR = 0.78, 95% CI = 0.67-0.91) (Table 2).

**Discussion**

Most patients undergoing TJA procedures in a number of community-based practices were found to remain the same weight before and after the TJA procedure (61% of the THA group and 64% of the TKA group). However, certain groups of patients were more likely to gain or lose a clinically significant amount of weight before and/or after the surgery. Specifically, women were more likely than men to change their weight (either gain or lose) preoperatively in both the THA and TKA groups and postoperatively in the THA group. Younger patients were more likely to gain weight than older patients both before and after THA and TKA. Several racial differences were observed, and the proportion of patients who gained and lost weight postoperatively varied depending on the intraoperative weight of the patient.

Few studies have explored the association of sex with post-TJA weight change, and to our knowledge, no studies have examined this issue for preoperative weight change. Results of the present study are in contrast with those of Dowsey et al., who evaluated patients undergoing THA and TKA as well as intraoperative variables associated with a 5% weight loss postoperatively and reported sex not to be associated with weight loss. Differences in the studies by Dowsey et al may be attributed to their smaller sample size (511 patients with THA and 573 patients with TKA), sample heterogeneity (Australian samples, no mention of racial distribution), and differences in weight ascertainment (the studies actively measured all their study participants with a standard protocol). A multitude of biochemical, behavioral, and socioeconomic reasons were noted for the higher prevalence of obesity, dieting, and difficulty of weight loss in women, possibly explaining why women in our study were more susceptible to weight change.

Age has also not been studied as a risk factor for pre-TJA weight change, to our knowledge, but has been reported to be associated with postoperative weight changes. Older age has been found to be associated with weight loss one year after TKA, although the inverse (association of weight gain) was not observed. Similarly, Lachiewicz and Lachiewicz reported age to be significantly associated with post-TKA weight change, reporting younger patients as more likely to be obese than older patients. The prevalence of obesity in patients with TJA is also higher than in the general population, and the obese patients are younger than nonobese patients. Younger age being associated with an increased likelihood of gaining more weight is likely because younger patients are already heavier, have a longer history of weight-related issues, and have comorbid conditions that affect their ability and commitment to weight management.

Racial differences in prevalence of obesity and weight loss, management, and perception are well documented in the literature. Non-Hispanic blacks have the highest prevalence of obesity of all racial/ethnic groups in the US, with a prevalence of obesity reported at 38% for men and 50% for women age 60 years and older (group representative of our sample). The higher likelihood of black patients to gain even more weight in this study is not unexpected because these patients already are at a higher risk of being obese. Previous studies report a higher risk of complications and revision procedures in black patients, which could explain the increase in weight postoperatively of these patients, who may be more debilitated, unable to participate in physical activity, or may be taking medication that influences weight gain and activity levels. In addition, Asians and Hispanics were found at certain times (Asians before THA and both before and after TKA; Hispanics after TKA) to be less likely to change their weight than whites. This lower susceptibility to weight change in these races could be indicative of lower overall postoperative weight change.

<table>
<thead>
<tr>
<th>Table 2. Associations of age, sex, and race with preoperative and postoperative weight change: adjusted odds ratios (ORs) and 95% confidence intervals (CIs) by total hip and knee arthroplasty.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Arthroplasty type</strong></td>
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<tr>
<td></td>
</tr>
<tr>
<td><strong>THA</strong></td>
</tr>
<tr>
<td>Men vs women</td>
</tr>
<tr>
<td>Age (1-year increments)</td>
</tr>
<tr>
<td>Asian vs white</td>
</tr>
<tr>
<td>Black vs white</td>
</tr>
<tr>
<td>Hispanic vs white</td>
</tr>
<tr>
<td>Other vs white</td>
</tr>
<tr>
<td>Unknown vs white</td>
</tr>
<tr>
<td><strong>TKA</strong></td>
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<tr>
<td>Men vs women</td>
</tr>
<tr>
<td>Age (1-year increments)</td>
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<tr>
<td>Asian vs white</td>
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<tr>
<td>Black vs white</td>
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<tr>
<td>Hispanic vs white</td>
</tr>
<tr>
<td>Other vs white</td>
</tr>
<tr>
<td>Unknown vs white</td>
</tr>
</tbody>
</table>

* Polychotomous logistic regression, with “remain the same” as the reference group.

**References**

1. Wald χ² test for THA: adjusted preoperative: sex (p < 0.001), age (p < 0.001), and race/ethnicity (p = 0.051); adjusted postoperative: sex (p < 0.001), age (p < 0.001), and race/ethnicity (p = 0.121).

2. Denotes statistical significance (p < 0.05).

3. Includes multiracial and Native American patients.

4. Wald χ² test for TKA: all p < 0.001 (preoperative and postoperative).

THA = total hip arthroplasty; TKA = total knee arthroplasty.
The different patterns of postoperative weight change by the intraoperative obesity level for the THA group are also of note. Morbidly obese patients with THA had a higher proportion of patients losing weight postoperatively, although the difference was small. It is likely that the sacrifice of mobility and relief from symptoms did indeed lead these patients to a weight reduction postoperatively. This was not observed in patients with TKA, who had similar proportions of gaining, losing, and remaining the same weight at all intraoperative obesity levels, and were generally heavier than were patients undergoing THA.

Successful rehabilitation can be more challenging for a heavier patient with other comorbidities, such as osteoarthritis in other joints, and slow recovery has been reported after both arthroplasty procedures in obese patients.30 This study has some limitations. First, selection bias could be present due to the sampling frame. Patients not covered by KP were not included. However, the KP membership was generally composed of similar age, sex, and race as the population in the geographical area it covers.30,31 Second, the data source used for this study is voluntary and participation in the registry is reportedly 95%. However, contributing sites may have idiosyncratic rates of participation in the registry, and we do not expect this to affect the study findings. Third, the cohort evaluated had an attrition rate of 1.1%. Of these patients lost to follow-up, only 11% had missing postoperative weight estimates, a similar proportion of missing weight data as the overall cohort. Fourth, there is the potential for inclusion of patients in the sample who have had surgical weight interventions outside the system. Although it is unlikely, we cannot be certain that procedures did not happen before the 2001 EHR records or at another institution. Since the prevalence of surgical weight loss intervention is very low in the US,33 we do not expect this to bias our sampling. Fifth, the protocol for weight assessment was not standard, and measurements were subjected to reporting bias as well as observer bias. Sixth, missing data were present (<12.6% depending on procedure and period). We found that patients with missing data were more likely to be men and younger, but no other differences were noted. It is possible the sex associations were overestimated for women (of most men without weight measures were the ones changing weight before and after the procedure), but because of the small amount of missing data and the large sample size, we believe this underestimation to be minimal. However, age estimations were probably not overestimated because we found younger patients to be more likely to gain weight than to remain the same weight for all groups, despite the higher numbers of missing weight. Finally, because of the limited information available in the data source of this study, we do not have information on the history of physical activity and psychological characteristics of the evaluated patients, which could have an impact on the estimations presented.

This study’s strengths include the generalizability of the findings, the utilization of an EHR from a closed integrated health care system, and low likelihood of data handling and response bias. Most importantly, the cases, surgeons, and medical centers that make up the sample are believed to be representative of community-based orthopedic practices in the US. The patient samples of each location are of various case mix levels and are similar to the larger state population with regard to age, race, and sex distribution.30,31,33 More than 300 surgeons and 27 hospitals contributed to the sample evaluated, and they are of various training levels, settings (eg, urban, rural, academic), and volumes. Additionally, this study used a common EHR and a TJRR to obtain data. The ability to link records, using one common unique identifier in a sample of this size, cannot be reproduced by any other larger national samples (Healthcare Cost and Utilization Project Nationwide Inpatient Sample) or regional TJRR registries. Finally, using the EHRs to obtain the weight measurements also decreased the possibility of response bias that could arise from obtaining this information from the patients directly.

This study found women to be the most susceptible group to weight change either before or after TJA procedures, younger patients to be most likely to gain weight before and after TJA, and black patients most likely to gain weight after their procedure. Additionally, this study described a different postoperative weight trend in patients with THA depending on their intraoperative obesity level, with the morbidly obese having the highest proportion of patients losing weight after the procedure. This information is important to clinicians and surgeons because it characterizes specific groups that can benefit from weight management interventions. Interventions suitable for the patients identified as more susceptible to weight change should be pursued.

Conclusion

Targeting specific groups will result in increased efficiency of interventions, decrease the financial and personnel burden on implementing interventions, and potentially result in cost savings from reducing the number of patients who need to undergo preoperative counseling for weight loss and other comorbidity optimization efforts.

Disclosure Statement

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

Acknowledgments

The authors would like to thank all Kaiser Permanente orthopedic surgeons and the staff of the Department of Surgical Outcomes and Analysis who have contributed to the success of the National Total Joint Replacement Registry. Kathleen Louden, ELS, of Louden Health Communications provided editorial assistance.

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Arthroscopy

We believe arthroscopy to be a key procedure in the study of joint physiology and pathology. The method as yet is still in its infancy.

—Michael S Burman, MD, 1901-1975, pioneer in the field of arthroscopy
SOUL OF THE HEALER

“Erice”
photograph

Samuel H Glassner, MD

The well-preserved medieval town of Erice sits roughly 2400 feet above the Tyrrenian Sea in the Trapani province of Sicily. Ancient remains include walls with Phoenician inscriptions, fragments of the temple of Venus Erycina, 60 churches, a castle built by Normans, and a castle built by Saracens. This unretouched image was captured with a Panasonic Lumix DMC-ZS19.

Dr Glassner is an Emergency Physician at the Walnut Creek Medical Center in CA.
Highly Reliable Procedural Teams: The Journey to Spread the Universal Protocol in Diagnostic Imaging

Julie Ross, MBA, MPH; Debby Wolf, RN, MBA; Kimberly Reece, MD

Abstract
Context: The Joint Commission's Universal Protocol has been widely implemented in surgical settings since publication in 2003. The elements improved patient safety in operating rooms, and the same rigor is being applied to procedures occurring in other health care arenas, in particular, diagnostic imaging.

Objective: In 2011, Kaiser Permanente West Los Angeles's Diagnostic Imaging Department desired to adapt previous work on Universal Protocol implementation to improve patient safety in interventional radiology and mammography procedures.

Design: The teams underwent human factors training and then adapted key interventions used in surgical suites to their workflows. Time-out posters, use of whiteboards, “glitch books,” and regular audits provided structure to overcome the risks that human factors present.

Main Outcome Measures: Staff and physician perceptions of the teamwork and safety climates in their modalities were measured using the Safety Attitudes Questionnaire at baseline and at 18 months after training. Unusual Occurrence Reports were also reviewed to identify events and near misses that could be prevented. Implementation of key process changes were identified as process measures.

Results: Perception of the safety climate improved 25% in interventional radiology and 4.5% in mammography. Perception of the teamwork climate decreased 5.4% in interventional radiology and 16.6% in mammography. Unusual occurrences were underreported at baseline, and there is ongoing reluctance to document near misses.

Conclusion: This work provides important considerations of the impact of organizational cultures for the implementation of the Universal Protocol in procedural areas. It also reveals unexpected challenges, and requires long-term effort and focus.

Introduction
The Joint Commission’s Universal Protocol has been widely implemented in surgical settings across the country since its publication in 2003. Following implementation of the 3 key elements of the protocol—1) pre-procedure verification, 2) site marking, and 3) a time-out—rates of wrong site, wrong procedure, and wrong person surgery were shown to significantly decrease. For example, Haynes et al measured the impact of the implementation at 8 hospitals in 8 cities as part of the World Health Organization’s Safe Surgery Saves Lives program in 2007 and 2008. The total inhospital rate of death dropped from 1.5% to 0.8%, and the rate of complications fell from 11% to 7%. They also reported that “the overall rates of surgical-site infection and unplanned reoperation … declined significantly.”

Institutions promoting patient safety are advocating for implementation beyond the surgical suite. According to a recent article in the Pennsylvania Patient Safety Advisory, “Despite quality improvement efforts, the prevalence of these errors in other disciplines, namely, radiology services, may be more common than generally expected and reported in the literature.” The work described in this article is the first reported work of its kind at Kaiser Permanente (KP), where the Universal Protocol has been applied to procedural areas in a Diagnostic Imaging Department to decrease errors and improve patient safety.

A three-pronged approach to improve safety in these settings was proposed: 1) use human factors concepts and training to create highly reliable procedural teams and to reduce procedural errors, 2) identify a core bundle of metrics that measure performance improvement and rigorously support improvement, and 3) implement simulation-based education. The literature in this arena further shows that teams that “exhibited less teamwork behaviors were at a higher risk for death or complications [and therefore] supports arguments in favor of human factors training for surgical teams.”

In KP West Los Angeles (WLA), the goal of the Diagnostic Imaging Department’s leadership was to build on the recommendations in the arena of patient safety in the surgical suite and to apply them to diagnostic imaging procedures. This article will provide lessons learned and tools that other Diagnostic Imaging Departments can use, leading to improved reliability of patient safety in their interventions over time.

Methods
Literature Search
Literature searches were conducted in 2010 and 2012 for state-of-the-art patient safety procedures in interventional radiology and mammography. There are emerging publications addressing the transfer of learnings from the surgical arena to interventional radiology. In 2006, Children’s Hospital of Boston published its work about developing a checklist for interventional radiology, taking into account the unique challenges of the diagnostic imaging environment relative to the rapidly changing scope of interventional radiology.
This early work has been followed by more general recommendations. In 2008, Angle et al proposed guidelines for implementation of the Universal Protocol in interventional radiology, and recommended that “each institution/hospital ... define thresholds as needed for the process steps ... to meet its quality improvement program needs.” In 2011, the Cardiovascular and Interventional Society of Europe created a task force to create a checklist for interventional radiology based on the World Health Organization surgical safety checklist. The intention was to create a template for interventional radiology care across Europe in recognition of the effectiveness of checklists in surgical suites and to document complication rates in interventional radiology. For example, Lewis et al reported a 0.2% complication rate in interventional radiology when vascular surgical intervention was needed.

Literature searches revealed a dearth of information on Universal Protocol implementation in mammography. In September 2012, after this work began at KP WLA, the Institute for Clinical Systems Improvement published a Non-Operating Room Procedural Safety protocol. The Institute provided tools and workflows for pre-procedural verification and time-outs, listing breast biopsies as one of the “invasive, high-risk or surgical procedures” to which their work applies. The American College of Radiology references the Universal Protocol and time-outs in their practice guidelines for breast procedures.

Participants

Leadership at KP WLA initiated this project and titled it “Highly Reliable Procedural Teams” (HRPT), following the model of KP’s previous implementation of “Highly Reliable Surgical Teams” (HRST), which expands on use of the Universal Protocol in KP surgical suites. Interventional radiology and mammography were identified as the targets for the work. Interventional radiology was identified by KP WLA leadership as an area of vulnerability, and the modalities had been identified as such by the American College of Radiology, as cited in Miller et al, and by the previously mentioned Pennsylvania Patient Safety Advisory. Mammography was included in response to staff vocalizing concern with the safety climate and their inability to effect change.

A Steering Committee was established with key leaders from across the Medical Center, as well as staff from the department. Invited members included the senior leaders from the service line; Diagnostic Imaging departmental administrative and physician leadership; staff and physician leaders from both modalities; the patient safety officer; the quality physician lead; the Director of Risk Management; the Director of Quality and Accreditation, Regulation, and Licensing; and a project manager.

Measures

Safety Attitudes Questionnaires were completed by staff and physicians in the mammography and interventional radiology modalities before kickoff and 18 months later. This questionnaire has proved to be a psychometrically sound and highly reliable instrument on the basis of analysis of responses from 10,843 health care workers in 203 clinical settings and 3 countries. The Teamwork and Safety Climate Survey version of the Safety Attitudes Questionnaire was chosen for this project. It is made up of 27 questions organized into 2 sections, the results of which give the team a sense of overall teamwork and safety climates.

The second piece of data came from Unusual Occurrence Reports submitted electronically by staff over the two years before the project and throughout the project implementation. The KP WLA Risk Management Department maintains these data. Reports of events, including near misses, were sorted according to modality and type of event and were reported to the Steering Committee. Annual updates are conducted to measure impact. Several process measures were identified as well. First, data on the percentage of staff and physicians that attended human factors training were collected. Participation rates were used to show engagement by leadership and staff in both modalities, and to establish a strong foundation on which to build. Additional process measures identified were the completion of selected deliverables identified by the Steering Committee.

Procedure

The Steering Committee met monthly to direct the structure of the project and to support work teams in each modality. A charter was established, and KP’s Rapid Improvement Model served as a guide for goal development and change management. The next step was administering baseline Safety Attitudes Questionnaires in early 2011. This was overseen by a project manager who was independent of the department to eliminate potential response bias. The KP National Environmental Health and Safety team provided data analysis support.

The HRPT project was formally kicked off with human factors training for all staff and radiologists involved in procedures in both modalities. The modalities were closed down for a half day, and attendance was required. The service line administrative and physician leads attended the session to establish the case for the work and to show leadership support. KP leaders in patient safety adapted the surgical training to the specifics of imaging modalities for our project.

Human factors training covered three topics. First was to build the case for HRPT using examples of errors and the resulting costs, including patient suffering, staff morale, and financial consequences. Second was to review the research on behaviors that have been shown to create risks to patient safety and clinical outcomes. This included a discussion of avoidable distractions and limits to human memory, as well as unresolved conflict and lack of respect among team members.
Highly Reliable Procedural Teams: The Journey to Spread the Universal Protocol in Diagnostic Imaging

Meet twice a month to build momentum and facilitate regular discussion of progress. The deliverables accomplished were as follows: solidifying all pieces of the time-out process, creating a poster of the checklist to reference in examination rooms, and implementing the new process for every procedure in both modalities. Ongoing projects included using “glitch books” (books used to capture glitches then document and track follow-up) for timely communication and follow-up on issues, use of whiteboards for patient information and flow, development and implementation of a monitoring tool, and an effective hand-off communication process. Work teams reported monthly to the Steering Committee.

Interventional radiology’s time-out poster (Figure 1) was posted and referenced in each procedure room. The poster clearly demarcated who was responsible for checking each element before the procedure and incorporated the patient in the time-out whenever possible. A debriefing process was also detailed. Use of this workflow was reinforced through monitoring and regular feedback. A similar poster was created for mammography procedures.

Results

Safety Attitudes Questionnaire results from baseline in 2011 and follow-up in 2012 can be seen in Figure 2. A greater than 90% response rate for staff and physicians was achieved for both modalities surveyed. At baseline, 92.9% of respondents in interventional radiology rated the teamwork climate “good,” and 50% rated the safety climate “good.” A score above 80% indicated a good culture. At the 2012 follow-up, the interventional radiology modality’s teamwork climate rating decreased 5.4% and the safety climate rating increased 25%. In contrast, at baseline just 42.9% of mammography respondents rated the teamwork climate as good, and 42.9% rated the safety climate as good. At follow-up, the mammography modality’s teamwork climate rating decreased 16.6%, and the safety climate rating increased 4.5%. As is seen in other settings, there was a discrepancy between physician and staff perception of teamwork in both modalities, with physician ratings more than 15% higher in both areas. Notably, the drop in teamwork climate in mammography was entirely driven by a decrease in staff perception, whereas physician perception remained the same.

Unusual Occurrence Report data from 2009, 2010, and 2011 showed 4, 10, and 11 items reported per respective year for the interventional radiology modality and 5, 0, and 5 items reported per year for mammography. Since kickoff, no sentinel events or near misses were reported in either modality. The goal continues to be accurate reporting of sentinel events and near misses, as well as to have zero sentinel events and minimal near misses in 2011 and beyond.

The percentage of staff and physicians that attended human factors training was tracked. For both modalities, 94% of

!["Time out" is conducted using a briefing process](image)

**Figure 1.** Highly Reliable Procedural Teams’ time-out poster for interventional radiology.

DNR = do not resuscitate; KP = Kaiser Permanente; lab = laboratory; Med = medication; MR# = medical record number; prep = preparation; RN = registered nurse; Tech = technician.
staff and 100% of radiologists attended the training. Critical event team training was more recently completed for the interventional radiology team. This was done using simulation, a recommended alternate way to improve teamwork and safety outcomes.

Discussion

The HRPT implementation journey at KP WLA led us down 2 disparate paths. At the outset, it was clear that the cultures in the mammography and interventional radiology modalities were very different, as the baseline Safety Attitudes Questionnaire data reflected. In particular, the teamwork climate varied greatly between the 2 groups (92.9% for interventional radiology and 42.9% for mammography).

The interventional radiology team is historically a small and stable group, with strong internal leadership. The team's culture has promoted effective communication among all team members, evidenced by the high baseline and follow-up results for teamwork climate. This culture, which has historically been a strength, revealed itself as a challenge during implementation. As Jim Collins19 writes in Good to Great, “To go from good to great requires transcending the curse of competence…. Just because you’ve been doing it for years, or perhaps even decades does not necessarily mean you can be the best in the world at it.” The interventional radiology team’s strong self-perception of doing high-quality work became a hurdle for implementing the changes necessary to hardwire the highest level of safety. This is evidenced by inconsistently used checklists, debriefings, and glitch books as well as underreporting of near misses that continues after implementation. Safety climate scores increased to 75% because of HRPT efforts, and with continued focus should continue to move above the 80% benchmark for a good score.

Before HRPT, the mammography staff voiced concern over their discomfort in speaking up around issues of patient safety. Human factors training provided the needed entrée to open lines of communication in this modality. This increased awareness of the shared responsibility to improve coordination and communication was likely the cause of the decreased teamwork scores, because inconsistent physician engagement continues to be a barrier in achieving true collaboration and has increased staff’s frustration. The safety climate scores remained stable, and as new members join the department, we are encouraged by their commitment to this work and their impact on future results of the Safety Attitudes Questionnaire.

Although the issues in either modality are unique, a higher-level reason these presented as problems is that the program was initiated by senior leadership, rather than driven by departmental leadership. A complicating factor was that since kickoff of the project, the Diagnostic Imaging Department and both modalities have hired new managers. This turnover made it difficult to remain consistent in use of the improved processes. Most recently, the Steering Committee has reengaged around consistent audits, structured time-outs, and use of whiteboards. We look forward to the impact of our refined focus as the new managers and physicians engage around tightened requirements. In addition, as part of orientation, staff is oriented to the HRPT standards to ensure they are clear on expectations for procedures from Day 1.

The Steering Committee believed that the baseline data for Unusual Occurrence Reports reflected an overall low level of reporting, a problem regularly discussed in the patient safety literature.20,21 This is evidenced by near misses that have been discussed during Steering Committee meetings but continue to not be entered into our Unusual Occurrence Report system. Continued underreporting of unusual occurrences leaves us unaware of the true levels of errors and near misses. It has been communicated to staff that increased reporting of errors or near misses is evidence of a more open and just environment, and that the group’s intention is to focus on learning from mistakes in the system.

Figure 2. Kaiser Permanente West Los Angeles Diagnostic Imaging Department’s teamwork and safety climate scores over time.
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**Conclusion**

Implementation of the Universal Protocol in procedural areas in diagnostic imaging is increasingly important as the scope and volume expands. This work has shown that cultural change is paramount in achieving patient safety goals. Cultural change here includes physician and staff engagement in changing how work is done. Health care professionals must gain comfort with and a willingness to report, discuss, and learn from errors. Finally, health care teams should not allow a culture of good to hinder them from moving to a culture of great.

**Disclosure Statement**

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

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Stephen Lin, MD, led the implementation of the Highly Reliable Procedural Teams in the Kaiser Permanente West Los Angeles Diagnostic Imaging Department. Frederick D Lee II, RT (R), MBA, led the implementation in his role as the Director of Diagnostic Imaging. Debra Osborn, RN, MPH, CPHQ, CPHRM, a Senior Nurse Consultant in Patient Safety at the Kaiser Permanente Southern California Regional Office assisted the team in translating the learnings from the Highly Reliable Surgical Teams project to allow for implementation in Diagnostic Imaging. She is involved in implementation of the Highly Reliable Procedural Team’s work in interventional radiology across Kaiser Permanente Southern California.

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

**References**


**To Be Better**

Freedom is nothing but the chance to be better.

—Albert Camus, 1913-1960, French Nobel Prize-winning author, journalist, and philosopher
ORIGINAL RESEARCH & CONTRIBUTIONS

Special Report

Complex Case Conferences Associated with Reduced Hospital Admissions for High-Risk Patients with Multiple Comorbidities

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Ana Jackson, PhD; Maria Taitano, MD; Sandra Koyama, MD; Michael Kanter, MD

Editor’s note: For more information on Kaiser Permanente’s commitment to Total Health, please see the editorial on page 90.

Abstract

Objectives: Reducing avoidable hospital readmissions presents an opportunity to improve health care quality and reduce avoidable costs. We studied the effect person-focused care may have on reducing avoidable admissions to the hospital.

Methods: Among patients with heart failure discharged from the hospital, we evaluated the effect on 30-day readmissions of transitions-in-care interventions: home health visits, follow-up phone calls, and physician office visits. We also used a standardized diagnostic tool to interview readmitted patients to identify social reasons that may have contributed to the readmission. Finally, we used the learnings from both interventions to develop a new intervention: a single complex disease case conference that included the entire health care team. We measured hospital admissions for 21 patients during the 6 months before and after their complex case conferences.

Results: Observed-over-expected hospital readmission rates were lowest for patients receiving a postdischarge visit with a home health nurse and a follow-up visit with their physician (0.54), compared with solely a physician visit (0.81), home health visit (1.2), or phone call (1.55). Various social issues may contribute to hospital readmissions, including caregiver knowledge, ability to care for oneself at home, and issues related to medications (adherence, ability to pay, and knowledge about potential side effects). Substantially fewer hospital admissions occurred after complex case conferences.

Conclusions: Complex case conferences with disease-focused and person-focused interventions may be associated with reduced hospital admissions for patients with heart failure and multiple comorbidities.

Introduction

It is estimated that health care costs Americans almost $2 trillion per year and that more than 20% of the dollars spent on health care are wasteful. Examples of waste include overtreatment, failures of care coordination, failures in execution-of-care processes, administrative complexity, pricing failures, and fraud and abuse. For this reason, the US Centers for Medicare and Medicaid Services have begun a process to eliminate waste in health care. Each year billions of dollars are spent on hospital care. One area of potential waste in hospital care is avoidable readmission to the hospital.

Dharmarajan et al reported hospital readmission rates among Medicare beneficiaries for heart failure, myocardial infarction, and pneumonia of 24.8%, 19.9%, and 18.3%, respectively. Approximately one-third of readmissions occurred within 7 days of discharge, and the proportion of patients readmitted with the same diagnosis as the index admission for these 3 conditions was 35.2%, 10.0%, and 22.4%, respectively. Many patients who are readmitted to the hospital have multiple hospital admissions during a 1-year period.

Two key reasons for multiple readmissions are complex underlying medical conditions and complex social issues. Annema and Jaarsma reported that about one-third of readmissions to the hospital could have been prevented if patient adherence to treatment were higher, if patients had requested help earlier, and if patients and caregivers had available access to adequate multidisciplinary health care teams. Hansen et al reviewed 45 studies of interventions to reduce readmissions that included pre-discharge interventions, post-discharge interventions, and bridging interventions. The authors deduced that no single intervention implemented alone was regularly associated with reduced risk of 30-day rehospitalization.

These findings underscore the complex nature of readmissions to the hospital and that no single solution is likely to address the multiple issues contributing to rehospitalization. Over the past five years, numerous programs have emerged to reduce hospital readmissions. However, disease-focused programs have not significantly reduced readmission rates. Efforts moving forward should involve implementation of broad, person-focused...
approaches that engage all members of a care team and take into consideration psychosocial factors that may contribute to recurrent hospital admissions.

The purpose of this report is to share knowledge from the Kaiser Permanente Southern California (KPSC) readmission reduction program on the effect that person-focused care might have on reducing avoidable readmissions to the hospital.

Heart Failure Transitional Care Program

Approximately 40,000 KPSC members have heart failure. In 2007, KPSC developed the Heart Failure Transitional Care Program, an evidence-based program designed to improve quality of care and reduce avoidable hospital readmissions. Implementation at each of the 13 KPSC Medical Center areas required local sponsorship support by the executive leadership team and local heart failure physician and administrative champions; development of an operational partnership between the hospital and Departments of Home Health, Population Care Management, and Cardiology; and deployment of existing heart failure staff and/or redefinition of roles to address local resource disparities. The program was designed around a heart failure “bundle” that includes inpatient heart failure education and 3 outpatient care elements: 1) a home health visit within 48 hours of discharge, 2) a follow-up appointment with a physician within 7 days of discharge, and 3) a follow-up phone call from a heart failure care manager within 7 days of discharge.

Although the literature suggests that multidisciplinary interventions reduce hospital readmissions for heart failure, the evidence is less clear on the impact of specific interventions used to reduce readmissions. To understand the effect of the Heart Failure Transitional Care Program’s outpatient bundled care on heart failure readmissions, we compared readmission rates of patients who received a home health visit, a physician visit, and a follow-up phone call within 7 days, or any combination of these 3 elements. We included KPSC members with a primary diagnosis of heart failure who were discharged between October 2010 and February 2011; 2076 all-cause readmissions within 30 days occurred during this period. We compared observed-over-expected readmission rates, calculating expected readmission rates according to Healthcare Employer Data and Information Set specifications and stratifying patients into 8 groups on the basis of the outpatient bundle elements they received from the Heart Failure Transitional Care Program.

Table 1 summarizes the results. No single intervention alone was associated with reduced readmission rates. However, patients receiving the bundle of all 3 interventions had a lower observed-over-expected readmission ratio (0.78, \( p = 0.03 \)). A very small number of patients who did not receive any interventions also had a low observed-over-expected readmission ratio; however, this finding was not statistically significant. Members who received only a postdischarge phone call had the highest observed-over-expected readmission ratio (1.55, \( p = 0.01 \)).

The data in Table 1 suggest that disease-focused care provided by a postdischarge visit with a physician, home health visit, and phone call significantly reduced readmissions among patients with heart failure. However, there appeared to be other factors leading to readmissions that were not addressed by the bundle elements. To better understand whether there were other opportunities to improve observed-over-expected ratios, we decided to develop a program designed to understand reasons for readmission from the perspectives of both the patient and physician.

Readmission Diagnostic Tool

To understand barriers to preventing readmissions, we adapted the Institute for Healthcare Improvement readmission worksheet. The readmission diagnostic tool, which includes a patient interview, provides common reasons for readmission and helps identify key areas for improvement. KPSC heart failure case managers completed a diagnostic tool for 241 readmitted patients with heart failure. The tabulated results indicated multifactorial reasons for readmission (Table 2): clinical issues (present in 212 instances [87%]), social issues (142, 58%), failures associated with patient assessment (118, 48%), failures following discharge (116, 47%), and failures in handover communication (70, 29%). Social issues, including caregiver support and nonadherence to treatment, were clearly important factors in readmissions.

The findings from the readmission diagnostic tool supported our assumption that no single intervention would improve heart failure readmission rates. Consequently, we aimed to improve care across the continuum, focusing on social issues related to adherence to medication, the self-care plan, and caregiver support.

Complex Case Conference

To improve transitional care for patients with heart failure, we used the learnings from the readmission diagnostic tool survey to gain more insight about frequently

<p>| Table 1. Relationship between receipt of transitional care bundle and readmission rates for heart failure |</p>
<table>
<thead>
<tr>
<th>Bundle elements (&lt;7 days after hospital discharge)</th>
<th>Number of readmissions</th>
<th>Number of index admissions</th>
<th>Expected (E) readmissions (%)</th>
<th>Observed (O) readmissions (%)</th>
<th>O/E ratio</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician office visit</td>
<td>4</td>
<td>24</td>
<td>20.6</td>
<td>16.7</td>
<td>0.81</td>
<td>0.73</td>
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<tr>
<td>Home health visit</td>
<td>23</td>
<td>108</td>
<td>17.7</td>
<td>21.3</td>
<td>1.20</td>
<td>0.50</td>
</tr>
<tr>
<td>Phone call</td>
<td>73</td>
<td>259</td>
<td>18.2</td>
<td>28.2</td>
<td>1.55</td>
<td>0.01</td>
</tr>
<tr>
<td>Office visit + home health visit</td>
<td>8</td>
<td>77</td>
<td>19.1</td>
<td>10.4</td>
<td>0.54</td>
<td>0.13</td>
</tr>
<tr>
<td>Office visit + phone call</td>
<td>42</td>
<td>201</td>
<td>19.3</td>
<td>20.9</td>
<td>1.07</td>
<td>0.73</td>
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<tr>
<td>Home health visit + phone call</td>
<td>123</td>
<td>660</td>
<td>19.4</td>
<td>16.6</td>
<td>0.96</td>
<td>0.71</td>
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<tr>
<td>Office visit + home health visit + phone call</td>
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<td>693</td>
<td>19.3</td>
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<td>None</td>
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</tbody>
</table>
admitted patients, seeking to understand factors outside the Heart Failure Transitional Care Program’s bundled interventions that might contribute to readmissions. In 2011, KPSC Medical Centers started monthly complex disease case conferences. A multidisciplinary care team conducted an in-depth chart review of members with heart failure, chronic kidney disease, and multiple readmissions. These individuals were often managed by more than one health care team and may have received conflicting information. For instance, a patient with a low ejection fraction and congestive heart failure may experience acute kidney injury after aggressive diuretic management. When this occurs, care management becomes complicated or even contradictory; the renal team may recommend hydration, whereas the cardiology team may recommend continued diuretic therapy.

The results from these conferences were informative. A key finding was that many physicians across different teams that cared for high-risk patients never met in person, although they might have talked on the phone. Another key finding was the observed benefit of having all team members agree on a unified treatment plan for the patients. Adherence would theoretically be easier if patients were not receiving conflicting or confusing messages from different physicians. Other learnings included: 1) standardized patient care plan documentation in the electronic health record helps to ensure every physician at every patient touch point has access to the plan of care, and 2) multidisciplinary teams (eg, hospitalist, subspecialist, primary care physician, social medicine, and continuing care) are needed to develop collaborative care plans to avoid readmission secondary to psychosocial factors. Another observation was that earlier palliative care consultation referrals are needed to prevent readmissions for patients who may benefit from end-of-life care. Many patients with heart failure reviewed in complex care conferences had high mortality risk but had not been referred to the inpatient palliative care team for evaluation. As a result, they often returned to the hospital to seek care, even though no further intervention would improve their quality of life or life expectancy. KPSC’s experience is not unique; a recent study reported that 64.2% of Medicare patients with heart failure were admitted to a hospital in the last 30 days of life; one-third died in the hospital, and only 39% participated in a hospice program.8

Consequently, rather than relying on “gut” feelings to refer patients to inpatient palliative care teams, hospital care teams began referring heart failure members with a Walter Prognostic Index score of 6+ to the inpatient palliative care team.9 Of patients who received a consultation, 50% transferred to an end-of-life plan (ie, home-based palliative care, hospice, skilled nursing facilities for end-of-life care, or expired in hospital). Complete hospitalization data for 6 months before and 6 months after the complex case management conference was available for 21 patients. In the preconference period, 81 admissions occurred; in the postconference period, 22 admissions occurred, a reduction of 68% (Figure 1).

### Table 2. Heart Failure Transitional Care Program’s diagnostic tool

<table>
<thead>
<tr>
<th>Diagnostic tool category</th>
<th>Number (%) of 244 responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical issues (patient nonadherent to medications and diet)</td>
<td>212 (87)</td>
</tr>
<tr>
<td>Social issues (caregiver lack of knowledge on how to care for patient at home)</td>
<td>142 (56)</td>
</tr>
<tr>
<td>Patient assessment (patient unable to care for self at home)</td>
<td>118 (48)</td>
</tr>
<tr>
<td>Failure following discharge (patient unable to pay for medications)</td>
<td>116 (47)</td>
</tr>
<tr>
<td>Education (patient lacks knowledge about potential side effects of medications)</td>
<td>113 (46)</td>
</tr>
<tr>
<td>Handover communication (functional status not assessed before and after hospital discharge)</td>
<td>70 (29)</td>
</tr>
</tbody>
</table>

**Discussion**

 Patients with heart failure and multiple comorbidities are at high risk of readmission. The findings from our assessment of the Heart Failure Transitional Care Program’s bundle elements confirm published evidence that no single intervention alone reduces heart failure all-cause readmission.10,11 Our findings suggest that follow-up with a physician combined with a home health visit may reduce readmission rates. Potential mechanisms for this observation include that home health visits may help improve adherence to medications and the treatment plan and that physician office visits may help assess and treat conditions that could result in a readmission. The highest rates for readmission were observed in patients who received only a postdischarge phone call. The mechanism underlying this finding is unclear; perhaps patients who accepted only the phone call (which does not require any travel or coordination) are less adherent or sicker. Further work is needed to confirm and understand this observation.

The findings from the readmission diagnostic tool analysis and complex case management conferences confirmed the contribution of social issues to readmissions. The diagnostic tool analysis revealed that multiple causes were associated with the readmissions. The outcomes from the complex case conference strongly suggest that communication between physicians...
and patients is a key ingredient to reducing readmissions for individuals with heart failure. These findings may extend to patients with other complex diseases such as chronic kidney disease, cancer, chronic obstructive pulmonary disease, pneumonia, and myocardial infarction; further investigation is required to confirm this.

Our findings suggest the opportunity for additional studies to investigate the importance of changing the predominant paradigm from a disease focus to care that is disease- and person-focused. One strategy might be to apply our learnings upstream during the index admission to the hospital to evaluate whether addressing disease and social issues together reduces readmissions.

A hundred years ago, physicians took care of most of a patient’s medical issues, providing person-focused care. Person-focused care refers to interrelations over time and considers episodes of care as part of a life course of disease alternating with health. In contrast, disease-focused care is usually episodic, focused on one disease at a time, and exemplified by the current care system that focuses on a specific disease during an office or hospital visit. Most primary care physicians do not see their patients when they are admitted to the hospital; similarly, hospitalists do not see patients outside the hospital. One specialist may see a patient in the hospital, whereas his or her partner may see the patient in the clinic for follow-up care after an index hospital visit. Specialists such as cardiologists will see a patient with heart failure but are reluctant to advise therapy for another disease like chronic kidney disease or chronic obstructive pulmonary disease.

Both disease-focused care and person-focused care require adequate recognition of health problems as they are experienced by patients. Care may be improved if we recognize a person with a disease instead of a disease that happens to be affecting a particular person. Person-focused care implies a time focus rather than a visit focus. It extends beyond communication and includes the concept that a person does not care how much you know until they know how much you care. Readmissions may occur because the paradigm of care is fragmented and no one takes ownership of the care for the person with the disease. As shown by our complex case conference, improved coordination and communication between health care team members reduced readmissions in patients with multiple comorbidities.

In a 2008 article, Donald Berwick outlined a paradigm of care that allows us to understand the benefit of treating both a disease and a person, referencing the work of Pawson and Tilley. Pawson and Tilley argued that quality-improvement efforts in health care that involve complex social issues (such as those to reduce rehospitalizations) are a subset of the work being done to reduce avoidable admissions. Therefore, the knowledge we gain from successfully reducing heart failure readmission may be applied to upstream efforts to reduce index admissions. Reducing both index hospital admissions and readmissions will reduce health care waste and increase the capacity of the health care system to care for unavoidable admission without the need to build more hospitals.

**Conclusion**

Reducing readmission rates will not be easy. To improve outcomes, we must change our paradigm from one that focuses on a single intervention to one that includes both a mechanism (bundle of elements that focus on improving care transitions from the hospital) and context...
Complex Case Conferences Associated with Reduced Hospital Admissions for High-Risk Patients with Multiple Comorbidities

Stream of Life

A hospital is a living organism, made up of many different parts having different functions, but all these must be in due proportion and relation to each other, and to the environment, to produce the desired general results. The stream of life which runs through it is incessantly changing; patients and nurses and doctors come and go, today it has to do with the results of an epidemic, tomorrow with those of an explosion or a fire, the reputation of its physicians or surgeons attracts those suffering from a particular form of disease, and as the one changes so do the others. Its work is never done; its equipment is never complete; it is always in need of new means of diagnosis, of new instruments and medicines; it is to try all things and hold fast to that which is good.

—John Shaw Billings, 1838-1913, American librarian and surgeon, first director of the New York City Library

David Moiel, MD; John Thompson, MD

Abstract

Objectives: Breast cancer is the most common malignancy in women in the Kaiser Permanente Northwest Region. Ninety-five percent of women later found to have breast cancer were seen an average of 5 times in the medical offices in the year preceding diagnosis. Until 1991, screening mammography depended on clinician ordering. However, 20% of at-risk women were left out of the process because they had no clinician visit in the preceding year. Self-referral mammography was introduced as one of a number of processes to provide more comprehensive screening.

Methods: The Region’s tumor registry database was examined to assess the effect of self-referral screening on early diagnosis, stage of disease, and family history.

Results: From 1991 to 2010, more than 995,000 mammograms were performed and 8752 breast cancers were diagnosed. By 2011, almost 50% of all mammograms were scheduled using the self-referral process, with more than 25% of cancers diagnosed through this process that year. The tumor registry provided both active and passive roles in the quality of cancer screening.

Discussion: The expected result of improving access to screening has been demonstrated over the last two decades. Beginning with the self-referral mammography program, each successive effort enhanced overall organizational effectiveness of care for the average-risk patient but failed to translate into any improvements for the higher-risk patients. As the number of screening tests done is used as the sole measure of screening effectiveness, segments of the at-risk population are likely to be missed, compromising overall early detection efforts.

Introduction

Primary care clinicians are called on to assess and integrate large amounts of information, and with the complexity of ongoing care needs, preventive screening is often a secondary consideration during the office visit. Over the 20-year study period, 95% of patients with a diagnosis of breast cancer, colon cancer, and melanoma were in the medical offices 4 to 5 times in the preceding year. Until 1991, mammography screening in the Kaiser Permanente (KP) Northwest (KPNW) Region was limited to patients with breast complaints. Mammography was ordered only after a clinician’s breast examination. In 1983, mammography began to be used to screen asymptomatic women. With the certification of a regional tumor registry in 1960, cancer care was documenting and tracking outcomes. In 1976, the role of the registry initiated a “red dot” clinician reminder system to ensure that highly suspicious x-ray findings were evaluated completely in the subsequent 6 weeks. As more mammograms were obtained, interpretation became more difficult as the size of cancers that were detectable was smaller and more questionably suspicious areas were seen that needed follow-up. The need to repeat imaging at 3 or 6 months became the responsibility of the overworked clinician, leading to the creation of the “yellow dot” system in the tumor registry, modeled after the “red dot” system. During the last 30 years, 35% of “red dot” cases have proved to be malignant, whereas less than 2% of the “yellow dot” cases were. These tracking databases provided performance measures for radiologists who were interpreting thousands of mammograms yearly.


1983 to 1990

Before 1983, because mammography was limited to women with breast complaints, almost no screening mammography was performed. By 1983, national studies began demonstrating the benefits of screening for the early diagnosis of breast cancer. It became the responsibility of the individual clinician, or...
the insistent patient, for mammography to be ordered. Within months, mammography began to be performed more frequently in women between the ages of 50 and 70 years.

In 1989, a multidisciplinary Breast Cancer Task Force examined the overall program, focusing on the Region’s alignment with national guidelines. The deliberations with the Departments of Primary Care, Surgery, Radiology, Oncology, and Pathology and with KP Center for Health Research researchers provided the Region with a comprehensive roadmap. The task force recommended screening mammography every 1 to 2 years for women between 40 and 75 years of age, after clinical breast examination. They also recommended improvements in mammography capacity, clinical examination availability, and patient and staff education. Radiology efficiency improvements included report standardization, the introduction of a motorized mammography viewer (Rolloscope, Control Research, Inc; Redondo Beach, CA), and increased support staffing. As the volume increased, the radiologists adopted a blinded double-reading process. Managerial sponsorship was critical in accomplishing the goals.

1991 to 2001

By early 1991, mammography screening had increased, but the requirement for a clinician to initiate the process meant that many at-risk women were not getting a mammogram. For that reason, a proposal for self-referral mammography was put forward to provide an opportunity for patient-directed access to both imaging and breast examinations. Because the patients we were missing were already coming to our facilities, a low-cost outreach campaign to these women through our clinics was a practical first step.

On September 30, 1991, the self-referral mammography program was piloted at one medical office, and after a 2-month trial, the project was rapidly expanded to all check-in modules in each of the 31 medical and dental clinics. Using medical office resources to identify women wishing to be screened as well as a centralized triage to establish appointments, the system was enthusiastically adopted. From the outset, women were provided a consistent message about the value of screening, age guidelines, and the importance of clinical breast examinations. Clinical breast examinations were scheduled for those women who had not had a current examination in the past 6 months, or who did not expect to get a follow-up appointment with their personal clinician in the following 6 months.

Three challenges faced the design team for the self-referral mammography program. These included triage and scheduling, results reporting, and meeting the follow-up needs of the patient who did not have a primary care physician. Triage and scheduling of mammography and clinical breast examinations could be managed from information provided in the patient request form. The request form asked:

- Have you had a mammogram in the last 12 months?
- Who is your primary physician?
- Have you had a breast physical examination in the last 6 months, or do you expect to have an appointment with your physician in the next 6 months?
- Have you had either a breast implant or personal history of breast cancer?
- Do you have either a new breast lump or bloody nipple discharge?

For women who had a breast complaint (pain, mass, or discharge) or were outside the age range in the mammography guideline, a Breast Clinic appointment was arranged. Those patients meeting the guidelines for screening had a mammogram scheduled and clinical breast examinations, if required. For patients who were not yet due for screening, a future appointment was offered. In the first year, screening mammography (2-view imaging) was scheduled for 93% of women, with 7% subsequently triaged for diagnostic mammography (2-view mammogram with additional compression and magnification images and ultrasound imaging). Several issues in the reporting of results were also addressed by standardizing the radiology report adjusting the following text:

- Normal mammography result, with a recommendation for mammography in 2 years.
- Normal mammography result, with a recommendation for mammography in 1 to 2 years.
- There is a need for further imaging studies. A radiologist-supervised diagnostic mammogram will be scheduled. This evaluation might include additional mammography views and possibly ultrasound imaging.

Suspicous (“red and yellow dot”) studies were dictated individually, and results were directed to the patient’s clinician and the registry reminder program. The process was improved by linking report transcription to an automated printing and mailing system, so that a patient letter was mailed within 24 hours and a copy directed to the ordering clinician, thus eliminating the need for the clinician to perform these steps directly.

Because some women who went through the screening process were not associated with a primary care physician, it was necessary to establish a clinician for follow-up care for these members. An individual who could be responsible for them was identified to ensure that results were seen and clinical follow-up occurred.

### Table 1. Breast cancer screening at Kaiser Permanente Northwest

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Year begun</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-office</td>
<td></td>
</tr>
<tr>
<td>Routine physical examinations at Health Appraisal Centers</td>
<td>1970-1995</td>
</tr>
<tr>
<td>Self-referral mammography program</td>
<td>1991</td>
</tr>
<tr>
<td>HEDIS initiatives</td>
<td>2003</td>
</tr>
<tr>
<td>Panel Support Tool</td>
<td>2006</td>
</tr>
<tr>
<td>EMR Best Practice Alerts</td>
<td>2007</td>
</tr>
<tr>
<td>Outreach</td>
<td></td>
</tr>
<tr>
<td>Self-referral mammography program expanded to KP Dental</td>
<td>1992</td>
</tr>
<tr>
<td>EMR</td>
<td>1994</td>
</tr>
<tr>
<td>Safety Net program</td>
<td>1995</td>
</tr>
<tr>
<td>HEDIS initiatives</td>
<td>2003</td>
</tr>
<tr>
<td>Interactive phone calls, letters, birthday cards</td>
<td>2008</td>
</tr>
</tbody>
</table>

EMR = electronic medical record; HEDIS = Healthcare Effectiveness Data and Information Set; KP = Kaiser Permanente.
In 1992, the Safety Net program was proposed to reach out to women in the age range 52 to 69 years who were not receiving screening tests at recommended intervals. Rather than depend on the passive in-office marketing of the self-referral mammography program, an active outreach (out-of-office) program was designed using the computerized databases in radiology, Membership Services, and the laboratory. With scripted breast and cervical cancer screening messages, the Safety Net was launched in 1995. The Safety Net outreach in 1997 and 2000 identified 14% and 16% of all the breast cancers, respectively.

In 1994, KP leadership convened a second Breast Cancer Task Force to review our program’s progress. The Breast Cancer Task Force, using decision-analysis tools, redefined the age and frequency screening guideline and introduced a shared-decision-making process for women younger than age 50 and older than age 75 years. Also in that year, a regionwide outpatient electronic medical record (EMR) was introduced. Although the region still depended on paper charts for inpatient care, the insurance, radiology, laboratory, and scheduling databases that were operational could be used to identify and manage the at-risk populations. When the EMR was implemented, the automated ordering and charting platform permitted an expansion of preventive care activities, and other automated databases functioned to alert clinicians when guidelines were not being met. Although many prevention activities could be automated, staff was often reluctant to relinquish that responsibility.

**2002 to 2010**

By 2002, prevention and early detection programs in the region had been greatly advanced by the quality systems that had been developed. As noted in the Institute of Medicine’s *Crossing the Quality Chasm* vision for the 21st century, our systems were in place, but having a functioning infrastructure is different from demonstrating effective performance. In 2002, KP participated in the development of Healthcare Effectiveness Data and Information Set (HEDIS) metrics, and the KP Northwest Region was stimulated to focus on opportunities to demonstrate performance. With the HEDIS measures, purchasers, clinicians, and patients were able to consider a health insurer’s performance against evidence-based targets in addition to costs of care. Although guidelines were in place and performance metrics were clear, the processes established to carry out the guidelines needed to be examined to identify gaps and to streamline the system. Examination of our screening processes revealed that “all clinical contacts were an opportunity for improving care.” We knew the patients requiring screening were coming to our offices, but we needed to take the next step.

In 2006, the EMR was programmed to provide the primary clinician and office staff a patient-specific prevention profile, highlighting current care gaps. The Panel Support Tool compared a patient’s current health maintenance status with the screening guidelines. What previously required clinician time and effort was now provided easily by the computer system, and the profile was always available when the chart was opened. In May 2007, the Best Practice Alert system was added, including a provision for identifying the need for mammographic screening and providing test ordering with minimal effort. This system was supplemented by active outreach programs (Safety Net, letters, phone calls, follow-up reminder system), as shown in Table 1. Throughout these phases, organizational support was critical to the program’s success.

**Methods**

The KP Northwest Region provides medical care to more than 470,000 members in southwest Washington and in Oregon, the Portland metropolitan area and south to Salem. Features of the program that were helpful in developing self-referral mammography included a historic prevention mission, a unique individual health record number, a unified medical record, organizational databases for membership, laboratory and radiology services, an accredited tumor registry with additional high-risk tracking capability, and a strong collaboration between the medical and Health Plan leadership.

From the KP Northwest tumor registry, the database provided age, stage, and treatment information on the 8752 new cancers diagnosed during the study period. In 1989, the tumor registry added an additional data field to all new cases abstracted that defined the case as symptomatic or screen-detected. A symptomatic malignancy was defined as one diagnosed after a clinical examination finding or breast complaint. Cases lacking these features were considered screen-detected. The tumor registry included documentation about the self-referral mammography ordering process. These designations have been used to assess the evolution of screening effectiveness, including the influence of the in-office and outreach activities.

**Results**

**Impact of Self-Referral Mammography**

From 1991 to 2011, a total of 8752 new breast cancers were diagnosed. There were 658 patients who received a diagnosis through the self-referral mammography program since 1991. The
number of mammography examinations ranged between 40,000 and 60,000 examinations annually.

The impact of the self-referral mammography program was small in the first decade (Figure 1), but by 2001, 1 of 7 women (15.7%) used the self-referral program for scheduling. Many patients who initially used self-referral mammography continued to choose self-referral mammography, making it their preferred option. Between 2009 and 2011, 50% of mammograms were scheduled using this pathway. By 2011, the percentage of breast cancers diagnosed through the self-referral mammography pathway had increased to more than 25% (Figure 2).

Incidence and Prevalence

The incidence rate of cancers in a regularly screened population is 1 to 3 per 1000 mammograms. Case finding above this rate usually reflects the incidence seen in an unscreened or underscreened population. Over the study period, the incidence rate encountered in the population screened by self-referral mammography was more than 4 per 1000 half the time, suggesting lack of a completely effective screening process in the population (Figure 3).

During the last two decades, the annual total number of patients with breast cancer has increased. The incidence rates reflect a moderate increase predominately in the invasive breast cancers, with minimal change in the noninvasive cancer rates (Figure 4). The intermittent peaks in incidence rates of 1991, 2002, and 2007 may reflect the initiatives introduced at those times: self-referral mammography development; adoption of HEDIS measures; and introduction of EMR-supported Panel Support Tool and Best Practice Alert, respectively.

Screen-Detected versus Symptomatic Cancer

Historically, the presence of a breast mass led to the diagnosis of cancer. With the expectation that mammography would identify cancers before they were clinically evident (ie, absence of mass, nipple discharge, pain, or skin changes), mammography screening expanded. Compared with the prescreening era, the most common breast cancer presentation now in the surgeon’s office is a patient with no palpable findings and a pathology report from a biopsy performed by radiologists. Between 1985 and 1989, the nonpalpable presentation rate increased from 22% to 58% because of mammographic screening expansion. Even though there has been a further increase in screening since 1989, the nonpalpable cancer rate has been 60% for the last 20 years (Figure 5).

Influence of Self-Referral Mammography on Stage

Screen-detected cancers in women age 40 to 80 years demonstrated a lower stage at presentation on average for all age groups compared with the unscreened patients (Figure 6). There was no stage shift noted between groups using the self-referral mammography process or clinician-initiated screening. The convenience of the self-referral mammography option has therefore allowed a larger percentage of women at risk to be screened without detracting from the desired outcome of early detection, and is now used by half of the women undergoing the screening process (Figure 7).

Overall, the stage distribution of breast cancers detected by screening in women with a family history of breast or ovarian cancer did not appear to differ significantly from that seen in the screen-detected cancers in women of average risk (Figure 8). However, in our data for Stage IIA (T2, N0-N1, MO) a statistically significant difference (p < 0.05) was noted with a greater number of high-risk patients presenting at this stage compared with women of average risk. This finding may suggest the need for an enhanced screening process for high-risk women, or possibly reflect a difference in underlying biology and time course of disease.

Discussion

Since 1983, screening for preclinical breast cancers has been the domain of mammography. The opportunity to identify a cancer years before it is a palpable mass has transformed treatment and improved survival. Detection of cancers at an early preclinical stage is dependent on having a sensitive and specific screening test that is acceptable to patients, has reasonable cost, is convenient, and can be performed on an identifiable population at risk. Over the years since 1983, many women have felt unsure how to proceed, because different recommendations...

have been made over time by specialty societies, cancer management organizations, and guideline expert panels.

Early attempts to increase mammography screening in the community relied on mobile mammography units and small self-referral programs. For decades, these efforts only reached a small segment of the population or served only limited geographic areas. Concerns about patient selection, patient compliance, follow-up, clinical breast examination, legal exposure, and costs have hampered the mobile community outreach efforts, making them impractical for the population at large.

Overcoming these challenges was also required in the managed care population served by KPNW as we integrated a self-referral mammography process throughout our facilities. How does an organization make population-based screening more effective? Our first effort through the self-referral mammography program in 1991 was designed to reach inward to allow women who were coming to our clinics for other reasons to initiate screening without having to go through a process initiated by their primary care providers. This step proved to be convenient for women and helped our overburdened primary care physicians meet the need for preventive care more efficiently. The addition of the Safety Net program in 1995 supported an outreach program to women who were not being screened through self-referral mammography or clinician office-based care. The goal of our effort was to reach the underserved by identifying their risk status and inviting participation. The combination of these processes proved to be popular with women, and an ever-increasing number used the self-referral mammography option for their care.

Further substantial increases in self-referral mammography use corresponded to initiatives subsequently implemented: HEDIS (2002); Panel Support Tool (2006); Best Practice Alert (2008); and interactive phone calls, letters, and birthday cards (2008). The use of performance metrics associated with HEDIS provided a clear impetus for the delivery infrastructure to improve in the second decade. Corresponding to the increasing use of self-referral mammography for scheduling, the percentage of cancers detected through the self-referral mammography process has increased substantially.

The HEDIS measures continue to show that an increasing number of screening examinations are being done. It is unclear why the percentage of cases found through screening does not show a corresponding increase in screen-detected cases. We have previously reported on our screening program for colon cancer. In that report, we found that an increasing number of endoscopic screening examinations did not correlate with more effective detection of asymptomatic cancers. Population effectiveness appeared to correlate with high rates of screening in the population at risk, not the number of tests performed per se. With the screen-detection rate being steady at 60% for 20 years, we could improve screening effectiveness by examining the screening patterns of the patients presenting with symptomatic disease.

Most patients who have a family history of breast or ovarian cancer do not have a genetic abnormality and are frequently reluctant to consider a genetics assessment. The identification, education, and counseling of this group is frequently complicated by emotional reluctance about the “knowing.” Although radiologists have taken the patient’s family history into consideration when interpreting breast images and have consistently recommended annual mammography, an in-office process with genetic risk information in the mammography suites may be useful. On closer inspection, the in-office and outreach efforts for the patients with a family history are predominately passive. Given their current workloads, expecting the primary care providers to add another responsibility by adding this dimension to their workload is impractical.

Conclusion
During the last 20 years, more than 995,000 mammograms have been completed in the KPNW Region, with more than 8752 new breast cancers diagnosed. Experience with self-referral mammography in a large prepaid health care program has not been previously described, to our knowledge. Our efforts to provide breast cancer screening to our “unattached” patients has been...
successful. Over time, the self-referral mammography process has transitioned into the preferred scheduling process for half of our population.

With an understanding of the whole process, planners introduced a series of in-office and outreach programs to ensure greater screening. Continuous reengineering of the care process has been the most important element of our history, demonstrating how an increasingly complex set of patient care needs and clinical situations can be integrated and tracked to ensure optimal outcomes, freeing clinicians from overwhelming demands on their time. The role and impact of the self-referral mammography program on the overall breast cancer diagnostic process has been reviewed, including the impact on breast cancer stage. It is clear by the lack of change in the screen-detection rate that further targeting may improve outcomes. We have previously reported the KPNW experience of system innovation in colon cancer screening during a 30-year period and have appreciated the need for detailed examination of data to be sure the right questions are being asked, when some of the expected results are not met.

As clinicians, health insurers, and policymakers have used indirect measures to rate an organization's performance, it is critical to ask the additional questions:

- Is there a system that supports a guideline-based screening?
- Is there a system to identify high-risk patients?
- Is there a process to regularly review the outcomes we expect?
- Are we overscreening or underscreening women based on their personal risk?
- What is the screen-detection effect on the high-risk patients versus the average-risk population?
- Are there systems to support better active surveillance?
- Do we reach out to those individuals who may not be aware of their need to be screened?

We have summarized the evolution of our process from a passive clinician-controlled testing program to an active, comprehensive screening system. Our success has been because of the collaborative efforts of our leadership, providers and registry staff, and members who all became engaged in and benefited from these efforts.

**Disclosure Statement**

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

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**Superfluous Residue**

Cancerous tumors develop with greatest frequency in the breast of women .... Such unnatural tumors have their source in the black bile, a superfluous residue of the body.

—Galen of Pergamon, 130 AD-200 AD, Greek-speaking Roman physician, surgeon, and philosopher.
Relationship between Tumor Necrosis Factor-α Inhibitors and Cardiovascular Disease in Psoriasis: A Review

Thao Nguyen, MD; Jashin J Wu, MD

Abstract
Psoriasis, a cutaneous disease that is increasingly recognized as a systemic inflammatory process, is associated with an increased risk for the development of cardiovascular disease. Although use of tumor necrosis factor-α inhibitors for the treatment of psoriasis has also been associated with decreased incidence of major adverse cardiac events, the precise mechanism by which these agents lower cardiovascular risk remains uncertain. Speculated mechanisms include the suppression of systemic inflammation or improvement of cardiovascular risk factors. Here we review the evidence in support of the beneficial effects of tumor necrosis factor-α inhibitors on cardiovascular health. Larger, future studies of patients treated with biologic agents will provide data to more definitively quantify the risk reduction of these agents on major adverse cardiac events.

Introduction
Psoriasis is one of the most prevalent chronic inflammatory diseases, affecting approximately 2% or 3% of the population and more than 125 million patients worldwide.1-3 Study findings have linked autoimmune diseases, including rheumatoid arthritis (RA) and psoriasis, with chronic systemic inflammation and a subsequent increase in cardiovascular risk.4 Psoriatic arthritis, which has a prevalence rate of 7% to 26%5,6 in patients with psoriasis, shows an elevated cardiovascular risk similar to that experienced by patients with RA.7 It follows that anti-inflammatory treatment may theoretically reduce the incidence of cardiovascular risk factors and thus ultimately reduce patients’ eventual risk of cardiovascular disease-related mortality.8,9

However, the degree to which psoriasis, with its wide range of severity, is associated with major adverse cardiac events (a composite endpoint of myocardial infarction (MI), stroke, or cardiovascular death) has not been well defined. A case-control study of 3600 patients with severe psoriasis and 14,300 healthy subjects demonstrated a 53% increased incidence of major adverse cardiac events in the presence of severe psoriasis.10 A diagnosis of severe psoriasis was shown to confer an additional 6.2% 10-year risk of major adverse cardiac events.11 A limitation of this study was the focus on only severe psoriasis. Equivalent data about cardiovascular mortality in patients with mild psoriasis were not available at that time. Previous work has suggested only modest increased risk of cardiovascular events, including MI and stroke, in patients with mild psoriasis.12-14 Therefore, the 10-year risk of major adverse cardiac events attributed to mild psoriasis was anticipated to be small and unlikely to meaningfully affect 10-year risk estimates in the setting of severe disease.15,16

The effects of tumor necrosis factor (TNF)-α inhibitors on cardiovascular disease are potentially multifaceted because these drugs may promote heart failure and decrease heart compliance while controlling inflammation and decreasing risk for plaque formation.17 Because these agents were approved by the US Food and Drug Administration to treat rheumatologic diseases as a first indication, the safety data from most TNF-α inhibitors originate from clinical trials in rheumatology. Infliximab has been shown to improve endothelial function, specifically flow-mediated vasodilatation, in RA after 12 weeks of therapy.18 However, values returned to baseline 4 weeks after the infusion in patients followed for 1 year.19 In addition to providing at least a temporary improvement in endothelial cell function during treatment, infliximab also induces a transient increase in flow-mediated dilation.20 The beneficial effect of drug-induced dilation is countered by its association with vasoconstriction, increased wall shear stress, and deleterious effects on high-density lipoprotein.20 Despite these mixed effects on vessel wall remodeling, TNF-α inhibitor therapy may improve other risk factors for accelerated atherosclerosis, including decreased insulin resistance,21 decreased C-reactive protein and interleukin (IL)-6 levels, and increased high-density lipoprotein levels.17

Methods
This review was performed by searching MEDLINE and PubMed for articles published between 2000 and 2013 with English abstracts containing the following key terms: psoriasis; psoriatic arthritis; major adverse cardiac events; myocardial infarction; stroke; cardiovascular death; and diabetes. Manual searches of the bibliographies of selected articles were performed to identify additional studies.

Results and Discussion
There have been preliminary reports of an excess number of major adverse cardiac events in randomized controlled trials in patients with psoriasis treated with anti-IL-12/23 agents, and a small number of events reported from studies of anti-TNF-α agents for the treatment of psoriasis. Twenty-two randomized controlled trials of monotherapy comprising 10,183 patients
Relationship between Tumor Necrosis Factor-α Inhibitors and Cardiovascular Disease in Psoriasis: A Review

(continued from previous page)

In a study that included 121,280 patients with RA or psoriasis from North America between January 1996 and June 2008, nearly 14,000 patients were receiving a variety of disease-modifying antirheumatic drugs (DMARDs). The use of TNF-α inhibitors lowered the risk of diabetes (multivariate adjusted HR = 0.62; 95% CI = 0.42-0.91).27

Another study showed that patients with inflammatory arthropathies receiving anti-TNF-α therapy had reduced aortic stiffness at 3 months. Furthermore, TNF-α blockade leads to a partial reappearance of CD4+CD28- T cells. Peripheral blood expansion of CD4+CD28- T cells has been hypothesized to contribute to early atherosclerotic damage predisposing patients with RA to the development of more aggressive disease. However, the beneficial effects of anti-TNF-α agents on endothelial function do not appear to be sustained and are absent in the case of diabetic patients treated with etanercept.19,30 Furthermore, two case-control studies showed no reduction of cardiovascular events in RA with TNF-α inhibitor treatment.20,31 Other reports from large databases show discordant results of cardiovascular disease incidence in TNF-α inhibitors users vs nonusers.32,33

Solomon et al,34 a nested case-control study, examined the cardiovascular risk of glucocorticoids and cytotoxic agents other than methotrexate (leflunomide, cyclosporine, and azathioprine) compared with methotrexate and/or biologic agents among a group of older patients with RA. Hospital-based cardiovascular events were identified in 946 patients with RA from a Medicare cohort of 3501 patients with RA. There was no difference in cardiovascular events between patients receiving methotrexate monotherapy and those receiving biologic agents (OR = 1.0; 95% CI = 0.5-1.9), methotrexate plus biologic agents (OR = 0.8; 95% CI = 0.3-2.0), or biologic agents plus nonmethotrexate cytotoxic immunosuppressive agents (OR = 1.2; 95% CI = 0.7-2.2). A statistically significant increased risk of cardiovascular events was noted with glucocorticoid monotherapy (OR = 1.5; 95% CI = 1.1-2.1), glucocorticoid combination therapy (OR = 1.3; 95% CI = 0.8-2.0), and both monotherapy and combination therapy with nonmethotrexate cytotoxic immunosuppressive agents (OR = 1.8; 95% CI = 1.1-3.0). Noncytotoxic agents (gold, sulfasalazine, and hydroxychloroquine) did not increase the risk of cardiovascular events. Significant limitations to this observational study included the broad CIs on the risk estimates, the lack of information about out-of-hospital events and death, and the elderly patient cohort with increased comorbidity. The study findings suggest that methotrexate and/or biologic agents may be protective from a cardiovascular standpoint.

A team of Spanish researchers examining 4459 patients with RA treated with TNF-α antagonists provided evidence that all-cause mortality is 30% to 50% lower in patients treated with TNF-α antagonists. The authors also found that cardiovascular mortality (0.58; 95% CI = 0.24-1.41), particularly in women, was notably reduced. The rates of cardiovascular disease were 5 to 7 times higher in the patients with RA who were not treated with TNF-α inhibitors. The investigators acknowledged that the study’s main limitation was that it was not an internal cohort and that patients in the non-TNF-α inhibitor
registry had milder disease activity as assessed by baseline disease activity score. Patients treated with TNF-α inhibitors were also an average of 2 years younger than their untreated counterparts, which could have influenced the difference in the cardiovascular outcomes measured.

The British Society for Rheumatology conducted a large prospective epidemiologic study comparing 8670 patients with RA who were receiving anti-TNF-α inhibitors and 2170 patients treated with traditional DMARDs. After adjusting for baseline cardiovascular risk, similar rates of MI in the 2 cohorts were demonstrated. Further stratification revealed, however, that the risk of MI was markedly reduced by up to 60% in those who responded to TNF-α inhibitors by 6 months compared with nonresponders, which supports the underlying role of inflammation in cardiovascular disease.31 Different TNF-α inhibitors may have differential effects on endothelial and smooth-muscle cells and on vascular function.

An international team of researchers analyzed data from the QUEST-RA (Quantitative Patient Questionnaires in Standard Monitoring of Patients with Rheumatoid Arthritis) study, including 4365 patients from 48 sites in 15 countries.32 They examined the causes and effects of RA, as well as the potential benefits of various treatments. A lower risk of all major adverse cardiac events and MI was associated with a longer exposition-duration to TNF-α blockers (HR = 0.42; 95% CI = 0.21-0.81), although limited availability of biologics might have interfered with the results. Furthermore, patients with suspected cardiovascular disease may not have been prescribed biologic agents because of fear of possible side effects or drug interactions.

A study from Sweden33 suggested that the risk for developing an initial major adverse cardiac event in RA is lower in patients treated with TNF-α inhibitors. The investigators recruited patients from a regional registry that included more than 90% of RA patients, using age- and sex-adjusted incidence-density computations, with treatment and disease-severity markers as time-dependent covariates. This study did not control for most of the traditional and nontraditional risk factors, nonsteroidal anti-inflammatory drug use, or family history of MI. Furthermore, it was noted that patients starting anti-TNF-α inhibitor therapy had more severe disease and a higher level of disease activity compared with a community RA population. It is probable that patients who start anti-TNF-α inhibitor treatment usually have severe, refractory disease and are at a higher baseline risk of development of cardiovascular disease.

A study analyzed data from 10,156 patients with RA enrolled in the Consortium of Rheumatology Researchers of North America (CORRONA) RA Registry between October 2001 and December 2006.34 The researchers found that TNF-α inhibitor treatment was associated with a reduced risk of any cardiovascular event (HR = 0.39, 95% CI = 0.19-0.82) compared with nonbiologic DMARDs other than methotrexate.35 The primary outcome was major adverse cardiac events. During the study period, there were 88 events, including 45 strokes or transient ischemic attacks, 26 MIs, and 17 deaths. Risks for cardiovascular events were adjusted for multiple possible confounders, including age, sex, smoking, and comorbid disease such as diabetes and hypertension, as well as previous MI or stroke. These data indicate that TNF-α inhibitors may represent a therapeutic strategy to attenuate the heightened cardiovascular risk experienced by patients with RA and psoriasis. Strengths of the study included the size of the cohort and the availability of detailed data on drug exposure and potential confounders. However, as with all observational studies, there were limitations, such as potential confounding by indication and selection bias, as well as the small number of cardiovascular events that limited the study's statistical power for secondary outcomes.

In a Danish database study over a 3-year period from 2007 to 2009, Ahlehoff et al36 identified 2400 patients whose severe psoriasis was treated with phototherapy or systemic agents (including biologic agents in 693 patients and methotrexate in 799).37 In the biologic agents group, 80% received TNF-α inhibitors and approximately 20% received anti-IL-12/23. The incidence rates of major adverse cardiac event were reduced with the use of biologic agents (HR = 0.28; 95% CI = 0.12-0.64) and methotrexate (HR = 0.65; 95% CI = 0.42-1.00) compared with other therapies.

In a recent retrospective study analyzing a database of approximately 3.2 million patients in the Kaiser Permanente Southern California Health Plan, researchers found 8845 patients who received a diagnosis of psoriasis between 2004 and 2010.38 This cohort included 1673 patients treated with TNF-α inhibitors for at least 2 months, an “oral/phototherapy” (other systemic agents or phototherapy) cohort of 2097 patients who had not received TNF-α inhibitors, and a topical therapy cohort of 5075 patients. The median duration of TNF inhibitor therapy was 685 days (interquartile range, 215-1312 days). The HR of major adverse cardiac event was significantly lower in the TNF inhibitor cohort vs the topical cohort after adjustment for MI risk factors (adjusted HR = 0.50; 95% CI = 0.32-0.79). Incidence rates of major adverse cardiac event per 1000 patient-years were 3.05 in the TNF inhibitor cohort, 3.85 in the oral/phototherapy cohort, and 6.73 in the topical therapy cohort.

**Conclusion**

In the past decade, TNF-α inhibitors have revolutionized the treatment of psoriasis. It is well documented that psoriasis increases the risk of cardiovascular disease, and although there appears to be some reduction in the risk of major adverse cardiac events, it remains unclear whether TNF-α inhibitors significantly reduce that risk across the spectrum of psoriasis. Precisely how TNF-α inhibitors may lower cardiovascular...
There did not appear to be a reduced risk of MI in patients with psoriasis receiving systemic therapy compared with a group undergoing phototherapy. The risk of MI may vary by age.

Infliximab showed improvement in endothelial function. Infliximab may have beneficial effects on insulin sensitivity. No improvement of vascular or metabolic insulin sensitivity was observed, although short-term etanercept treatment had a significant beneficial effect on systemic inflammatory markers.

Confounding effects noted.

May improve MACE risk factors.

In the anti-TNF-α trials, only 1 of 3858 patients receiving biologic agents showed a reduction in MI risk in patients with RA. No change in MACE risk factors.

Mortality from all causes was 30% to 50% lower in the TNF-α inhibitors group, including CV mortality. No change in MACE risk factors.

No change in MACE risk factors.

No improvement of vascular or metabolic insulin sensitivity was observed, although short-term etanercept treatment had a significant beneficial effect on systemic inflammatory markers.

CRP = C-reactive protein; CV = cardiovascular; DMARDs = disease-modifying antirheumatic drugs; HDL = high-density lipoprotein; IL = interleukin; MACE = major adverse cardiac event; MI = myocardial infarction.
risk is uncertain, but some research has suggested that they may help prevent plaque rupture and improve endothelial function. Overall, studies of their effects on cardiovascular risk show mixed results. 26-31-33 We must take into account that patients receiving TNF-α inhibitors may be at higher overall cardiovascular risk. Patients receiving other medications may be at lower cardiovascular risk. Limitations of clinical trial safety data, including sample size, heterogeneity, and limited follow-up durations, have made postmarketing registries an invaluable source of safety information.

This article reviewed some of the major published data about the relationship between TNF-α inhibitors and cardiovascular disease in psoriasis (Table 1). Whereas some trials indicate no increased risk of major adverse cardiac events, there are increasing indications that the use of TNF-α inhibitors may decrease the risk of major adverse cardiac events. As more patients receiving TNF-α inhibitor therapy are enrolled in postmarketing registries, more long-term data will help elucidate whether these agents may benefit the risk reduction for major adverse cardiac events. 

Disclosure Statement
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Acknowledgment
Kathleen Louden, ELS, of Louden Health Communications provided editorial assistance.

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4. McDonald CJ, Calabresi P. Psoriasis and occlusive vascular dis-...
REVIEW ARTICLE

Relationship between Tumor Necrosis Factor-α Inhibitors and Cardiovascular Disease in Psoriasis: A Review


Proceeding From The Heart

All the veins and arteries proceed from the heart; and the reason is that the maximum thickness that is found in the veins and arteries is at the junction that they make with the heart; and the farther away they are from the heart the thinner they become and they are divided into more minute ramifications.

Investigation of Women with Postmenopausal Uterine Bleeding: Clinical Practice Recommendations

Malcolm G Munro, MD, FRCS(c), FACOG, The Southern California Permanente Medical Group’s Abnormal Uterine Bleeding Working Group

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Abstract

Postmenopausal uterine bleeding is defined as uterine bleeding after permanent cessation of menstruation resulting from loss of ovarian follicular activity. Bleeding can be spontaneous or related to ovarian hormone replacement therapy or to use of selective estrogen receptor modulators (eg, tamoxifen adjuvant therapy for breast carcinoma). Because anovulatory “cycles” with episodes of multiphase amenorrhea frequently preceed menopause, no consensus exists regarding the appropriate interval of amenorrhea before an episode of bleeding that allows for the definition of postmenopausal bleeding. The clinician faces the possibility that an underlying malignancy exists, knowing that most often the bleeding comes from a benign source. Formerly, the gold-standard clinical investigation of postmenopausal uterine bleeding was institution-based dilation and curettage, but there now exist office-based methods for the evaluation of women with this complaint. Strategies designed to implement these diagnostic methods must be applied in a balanced way considering the resource utilization issues of overinvestigation and the risk of missing a malignancy with underinvestigation. Consequently, guidelines and recommendations were developed to consider these issues and the diverse spectrum of practitioners who evaluate women with postmenopausal bleeding. The guideline development group determined that, for initial management of spontaneous postmenopausal bleeding, primary assessment may be with either endometrial sampling or transvaginal ultrasonography, allowing patients with an endometrial echo complex thickness of 4 mm or less to be managed expectantly. Guidelines are also provided for patients receiving selective estrogen receptor modulators or hormone replacement therapy, and for an endometrial echo complex with findings consistent with fluid in the endometrial cavity.

Guideline History and Scope

The Abnormal Uterine Bleeding Working Group (AUBWG) was originally created in 2004 to develop evidence-based, consensus guidelines for the management of abnormal uterine bleeding for women in Kaiser Permanente’s Southern California (KPSC) Region (see Sidebar: Members of the Abnormal Uterine Bleeding Working Group). The Southern California Permanente Medical Group (SCPMG) is the only Medical Group contracted to provide care for the more than three million members of the Kaiser Foundation Health Plan in the Southern California Region. The AUBWG determined that the scope of these guidelines included the investigation and initial management of women with postmenopausal bleeding thought or known to emanate from the vagina. The first version of these guidelines, based on evidence published to December 2004, was completed in 2005 and published in an abbreviated format on the Guideline Clearinghouse Web site of the Agency for Healthcare Research and Quality, with the full text made available on request. This version of the guidelines includes the result of a major systematic review of the evidence published since January 2005.

Postmenopausal uterine bleeding, either spontaneous or that related to ovarian hormone replacement therapy (HRT) or selective estrogen receptor modulator (SERM) use (eg, tamoxifen adjuvant therapy for breast carcinoma) collectively results in a substantial number of patient encounters. These encounters directly involve physicians and other clinicians in the Departments of Family Medicine, Internal Medicine, Obstetrics and Gynecology, and Oncology and include physicians, nurse practitioners, and other midlevel clinicians. The clinical problem also indirectly affects medical clinicians and resources in the Departments of Radiology and Pathology, particularly because of the use of endometrial sampling and imaging of the uterus. Consequently, recommendations have been developed considering this diverse spectrum of practitioners and departments.

Methods

The Chair of the AUBWG was selected by the Regional Chief of Obstetrics and Gynecology for SCPMG. The remaining members of the AUBWG were selected by the chairs of each of the 12 KPSC Medical Centers on the basis of their interest in abnormal uterine bleeding and ability to contribute to guideline development. After an introductory discussion on the general and SCPMG-specific issues involved in the investigation of postmeno-

Members of the Abnormal Uterine Bleeding Working Group

Malcolm G Munro, MD (Chair)
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Seth Kivnick, MD
Murali H Kamath, MD
Boatriz R Lauria, MD
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Paula D Richter, MD
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The Southern California Permanente Medical Group’s Abnormal Uterine Bleeding Working Group
Table 1. Definitions of terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postmenopausal bleeding</td>
<td>Spontaneous uterine bleeding that occurs more than one year after the date of the last menstrual period</td>
</tr>
<tr>
<td>Breakthrough bleeding</td>
<td>Unscheduled uterine bleeding encountered in any postmenopausal woman using hormone replacement therapy</td>
</tr>
<tr>
<td>Satisfactory endometrial biopsy</td>
<td>Comprises perceptible passage of the sampling device through the cervical canal into the endometrial cavity and appropriate functioning of the aspiration mechanism. Adequacy of the specimen for histologic interpretation is determined by the pathologist.</td>
</tr>
</tbody>
</table>

Table 2. Hierarchy of evidence

<table>
<thead>
<tr>
<th>Class</th>
<th>Type of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a†</td>
<td>Meta-analysis of randomized clinical trials</td>
</tr>
<tr>
<td>1b</td>
<td>Randomized clinical trial</td>
</tr>
<tr>
<td>2</td>
<td>Meta-analysis of studies that are not randomized</td>
</tr>
<tr>
<td>3</td>
<td>Nonrandomized, but internally controlled trials. Controls are considered to be “internal” if they are included in the original design of the study. Post hoc or historical comparisons are not considered internal controls. Comparisons of otherwise uncontrolled clinical series are not considered internal controls.</td>
</tr>
<tr>
<td>4</td>
<td>Case-control studies</td>
</tr>
<tr>
<td>5</td>
<td>Cohort studies</td>
</tr>
<tr>
<td>6</td>
<td>Clinical series, without internal comparison</td>
</tr>
<tr>
<td>7b</td>
<td>Expert opinion without available clinical studies</td>
</tr>
</tbody>
</table>


Table 3. Support for recommendations

<table>
<thead>
<tr>
<th>Strength of Evidence</th>
<th>Language</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Guideline Development Team (GDT) strongly recommends that clinicians routinely provide the intervention to eligible patients</td>
<td>Intervention improves important health outcomes, based on good evidence, and the GDT concludes that benefits substantially outweigh harms and costs</td>
</tr>
<tr>
<td>B</td>
<td>GDT recommends that clinicians routinely provide the intervention to eligible patients</td>
<td>Intervention improves important health outcomes, based on 1) good evidence that benefits outweigh harms and costs or 2) fair evidence that benefits substantially outweigh harms and costs</td>
</tr>
<tr>
<td>C</td>
<td>GDT makes no recommendation for or against routine provision of the intervention. At the discretion of the GDT, the recommendation may use the language “option,” but must list all the equivalent options.</td>
<td>Evidence is sufficient to determine the benefits, harms, and costs of an intervention, and there is at least fair evidence that the intervention improves important health outcomes. However, the GDT concludes that the balance of the benefits, harms, and costs is too close to justify a general recommendation.</td>
</tr>
<tr>
<td>D</td>
<td>GDT recommends against routinely providing the intervention to eligible patients</td>
<td>GDT found at least fair evidence that the intervention is ineffective, or that harms or costs outweigh benefits</td>
</tr>
<tr>
<td>I</td>
<td>GDT concludes that the evidence is insufficient to recommend for or against routinely providing the intervention. At the discretion of the GDT, the recommendation may use the language “option” but must list all the equivalent options.</td>
<td>Evidence that the intervention is effective is lacking, of poor quality, or conflicting, and the balance of benefits, harms, and costs cannot be determined</td>
</tr>
</tbody>
</table>

Investigation of Women with Postmenopausal Uterine Bleeding: Clinical Practice Recommendations

Problem Formulation

Intended use of the guideline
To assist physicians and other health care professionals in the evaluation and management of uterine bleeding in postmenopausal women (postmenopausal uterine bleeding)

Health problem
Postmenopausal uterine bleeding

Health interventions
Strategies and techniques for investigation of women with postmenopausal uterine bleeding

Population
Postmenopausal women

Practitioners
Physicians, physician assistants, nurse practitioners, and other health care professionals in the Departments of Emergency Medicine, Family Medicine, Internal Medicine, and Obstetrics and Gynecology

Medical setting
Offices, clinics, Emergency Departments, and hospital inpatients

Most important health outcomes
Outcomes of condition:
• Potential sign of endometrial or other uterine malignancy or premalignant condition such as atypical endometrial hyperplasia
• May reflect benign causes (including idiopathic, endometrial polyps) and iatrogenic sources

Outcomes of intervention:
• Identification of women with atypical endometrial hyperplasia and cancer
• Identification of women with usually benign lesions such as endometrial polyps

Evidence to allow for meta-analysis of randomized controlled trials, such as a Cochrane review. An additional modification was to include the creation of a Class 7 grouping that isolated expert opinion, including that from guidelines or other consensus documents from national or international organizations or from the collective opinion of the AUBWG members. The recommendations were created and classified according to the strength of the evidence and classified according to the system used by KPSC Guideline Development teams (Table 3). The term good evidence used in the text or tables indicates that either Grade A or Grade B evidence was available to support the recommendations (Table 4). The process was designed to be a continuous one, allowing for ongoing modifications and revisions as new, higher quality or otherwise clarifying evidence becomes available.

The original consensus document was created, approved by the members of the AUBWG in October 2004, and then submitted to the SCPMG Regional Chiefs for review, comment, and approval. Specifically, the Chiefs selected the 5-mm endometrial echo complex (EEC) thickness as the evidence-based threshold above which endometrial sampling is recommended. Following the 2012 review of the available evidence, the recommended threshold was changed to 4 mm. Minor modifications of the guideline were made following presentation to the SCPMG Regional Chiefs of Obstetrics and Gynecology. The revised guidelines were unanimously approved by the Regional Chiefs of Obstetrics and Gynecology on March 20, 2013.

Rationale

Introduction
Postmenopausal bleeding is a common patient complaint that is encountered by all physicians and other clinicians of gynecologic care. The clinician faces the possibility that there exists an underlying malignancy, while knowing that, in most instances, the bleeding comes from a benign source. In years past, the gold standard of clinical investigation was the institution-based dilation and curettage (D&C), but there now exists a number of office-based methods for the evaluation of women with this complaint. The postmenopausal use of gonadal steroids for the treatment of menopausal symptoms (HRT) is often associated with endometrial bleeding. Although the number of women using these agents decreased in the first decade of the 21st century, reevaluation of the literature and the release of new studies have collectively suggested that such therapy may provide benefit in at least selected instances.3,5

As a result, clinicians will continue to be challenged by the issue of HRT-associated postmenopausal bleeding in the near future. It is known that tamoxifen and other SERMs may increase the chance of endometrial neoplasia developing. However, the proportion of postmenopausal women using such agents as adjuvant treatment of breast cancer is decreasing with the introduction of aromatase inhibitors (Grade C). Nevertheless, there will continue to exist a number of women in their late reproductive years with unknown or uncertain ovarian endocrine status who experience abnormal bleeding in association with the use of these agents. Such women may have to be considered to have postmenopausal bleeding associated with the use of a SERM.

The clinician should appreciate that although the focus of investigation of postmenopausal bleeding is on the endometrium, bleeding in the postmenopausal woman may arise from a number of extraendometrial gynecologic and nongynecologic sites, such as the cervix, vagina, and urologic and gastrointestinal tracts. As a result, it is incumbent on the clinician to consider all these possibilities when evaluating a patient with postmenopausal bleeding or apparent unscheduled (“breakthrough”) bleeding who is receiving HRT. Consequently, should the results of appropriately indicated and performed evaluation of the endometrium be normal, reevaluation for these potential causes is a prudent approach.

Definition of Postmenopausal Bleeding
The World Health Organization defines menopause as the permanent cessation of menstruation resulting from the loss of ovarian follicular activity.1 Because anovulatory “cycles” with episodes of multiomonth amenorrhea frequently precede menopause, there is no consensus regarding the appropriate interval of...
In the presence of endometrial carcinoma, hysteroscopy does not appear to affect short- or long-term prognosis. When TVUS or contrast sonography such as saline infusion sonography (SIS) are used as techniques for assessing the endometrium of women with postmenopausal bleeding, a detailed description of the evaluation should be placed in the patient record with or without representative photographs of the sagittal and transverse planes. Practitioners without adequate training in either office-based EB or TVUS should refer patients with postmenopausal bleeding or breakthrough bleeding to an individual, usually a gynecologist, appropriately trained in these techniques. Women with spontaneous postmenopausal bleeding and an EEC > 4 mm should be further evaluated with endometrial sampling. If clear endometrial fluid is identified on TVUS, the EEC is determined by subtracting the measured thickness of the fluid from the EEC measurement. In the presence of sonolucent fluid, women with a measurement of ≤ 3 mm may be managed expectantly. In the presence of postmenopausal bleeding, cervical carcinoma should be considered and evaluated appropriately. Women with persistent spontaneous postmenopausal bleeding require further evaluation of the endometrial cavity for focal lesions with one or a combination of office-based contrast sonography (eg, SIS) and hysteroscopy. Such an approach is necessary even if there is a satisfactory or adequate EB without evidence of hyperplasia, and regardless of the EEC thickness. Operating room-based dilation and curettage (D&C) of women with postmenopausal bleeding should be performed only when office-based EB is indicated, cannot be performed for patient comfort or technical reasons, or when it is inconclusive and results of sonographic techniques (TVUS, SIS) are not reassuring. Women taken to the operating room for D&C should have concomitant hysteroscopy with ancillary instruments that allow for the removal of focal lesions such as endometrial polyps. In the presence of endometrial carcinoma, hysteroscopy does not appear to affect short- or long-term prognosis. Consequently, hysteroscopy is not contraindicated in the evaluation of women with postmenopausal bleeding, including cases suggestive of cancer. Only selected women with bleeding associated with estrogen and progestin-containing hormone replacement therapy (HRT) require assessment of the endometrium. Uterine bleeding or spotting may be expected depending in part on the dose of HRT administered, in part on the schedule of progestin administration, and in part on the duration of therapy. It is not necessary to routinely evaluate the endometrium of women with uterine spotting or light uterine bleeding in the first six months of continuous estrogen and progestin HRT. Endometrial assessment of such women is recommended if spotting or bleeding persists beyond six months, although there is a very low incidence of endometrial hyperplasia or neoplasia. Women receiving doses of unopposed estrogen have a much higher incidence of endometrial hyperplasia and carcinoma, and require appropriate investigation of the endometrium. Women receiving estrogen and cyclical progestins can be expected to have indefinite progestin withdrawal bleeding and require no further investigation provided that the dose and duration of cyclical progestins is adequate. For women using cyclic progestins, bleeding outside the time of progestin withdrawal is considered abnormal and requires appropriate investigation. It is apparent that EEC thresholds used for spontaneous bleeding can be applied to patients with HRT-related bleeding, but with a higher incidence of false-positive findings. Women experiencing uterine bleeding while receiving tamoxifen (usually used as an adjuvant therapy for breast cancer) should be assessed primarily with endometrial sampling because, in such patients, TVUS is neither sensitive nor specific for neoplasia. Women with persistent bleeding during tamoxifen therapy, and who have already undergone endometrial sampling, should be assessed with one or a combination of contrast sonography (such as SIS) and hysteroscopy with appropriate sampling or excision of polyps if found. Women with repeated bleeding during tamoxifen therapy, and who have been demonstrated to have normal histologic findings and a structurally normal endometrial cavity, should have EB repeated annually. Postmenopausal bleeding can be a presenting symptom of cancer in the cervical canal. Consequently, if there is no endometrial explanation for postmenopausal bleeding, appropriate steps to evaluate patients for cervical cancer should be undertaken considering the results of a Papanicolaou test, colposcopy, and curettage of the endocervical canal.

### Table 4. Summary of recommendations

<table>
<thead>
<tr>
<th>No.</th>
<th>Recommendation</th>
<th>Method</th>
<th>Strength of evidence(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Women with spontaneous postmenopausal bleeding should be primarily evaluated with either endometrial biopsy (EB), or transvaginal ultrasound (TVUS) to measure the thickness of the endometrial echo complex (EEC)</td>
<td>E</td>
<td>A</td>
</tr>
<tr>
<td>2</td>
<td>When TVUS or contrast sonography such as saline infusion sonography (SIS) are used as techniques for assessing the endometrium of women with postmenopausal bleeding, a detailed description of the evaluation should be placed in the patient record with or without representative photographs of the sagittal and transverse planes</td>
<td>C</td>
<td>N/A</td>
</tr>
<tr>
<td>3</td>
<td>Practitioners without adequate training in either office-based EB or TVUS should refer patients with postmenopausal bleeding or breakthrough bleeding to an individual, usually a gynecologist, appropriately trained in these techniques</td>
<td>C</td>
<td>N/A</td>
</tr>
<tr>
<td>4</td>
<td>Women with spontaneous postmenopausal bleeding and an EEC &gt; 4 mm should be further evaluated with endometrial sampling</td>
<td>E</td>
<td>A</td>
</tr>
<tr>
<td>5</td>
<td>If clear endometrial fluid is identified on TVUS, the EEC is determined by subtracting the measured thickness of the fluid from the EEC measurement</td>
<td>E</td>
<td>B</td>
</tr>
<tr>
<td>6</td>
<td>In the presence of sonolucent fluid, women with a measurement of ≤ 3 mm may be managed expectantly. In the presence of postmenopausal bleeding, cervical carcinoma should be considered and evaluated appropriately</td>
<td>E</td>
<td>B</td>
</tr>
<tr>
<td>7</td>
<td>Women with persistent spontaneous postmenopausal bleeding require further evaluation of the endometrial cavity for focal lesions with one or a combination of office-based contrast sonography (eg, SIS) and hysteroscopy. Such an approach is necessary even if there is a satisfactory or adequate EB without evidence of hyperplasia, and regardless of the EEC thickness</td>
<td>E</td>
<td>B</td>
</tr>
<tr>
<td>8</td>
<td>Operating room-based dilation and curettage (D&amp;C) of women with postmenopausal bleeding should be performed only when office-based EB is indicated, cannot be performed for patient comfort or technical reasons, or when it is inconclusive and results of sonographic techniques (TVUS, SIS) are not reassuring</td>
<td>E</td>
<td>B</td>
</tr>
<tr>
<td>9</td>
<td>Women taken to the operating room for D&amp;C should have concomitant hysteroscopy with ancillary instruments that allow for the removal of focal lesions such as endometrial polyps</td>
<td>C</td>
<td>N/A</td>
</tr>
<tr>
<td>10</td>
<td>In the presence of endometrial carcinoma, hysteroscopy does not appear to affect short- or long-term prognosis. Consequently, hysteroscopy is not contraindicated in the evaluation of women with postmenopausal bleeding, including cases suggestive of cancer</td>
<td>E</td>
<td>A</td>
</tr>
<tr>
<td>11</td>
<td>Only selected women with bleeding associated with estrogen and progestin-containing hormone replacement therapy (HRT) require assessment of the endometrium. Uterine bleeding or spotting may be expected depending in part on the dose of HRT administered, in part on the schedule of progestin administration, and in part on the duration of therapy</td>
<td>E</td>
<td>B</td>
</tr>
<tr>
<td>12</td>
<td>It is not necessary to routinely evaluate the endometrium of women with uterine spotting or light uterine bleeding in the first six months of continuous estrogen and progestin HRT. Endometrial assessment of such women is recommended if spotting or bleeding persists beyond six months, although there is a very low incidence of endometrial hyperplasia or neoplasia</td>
<td>E</td>
<td>B</td>
</tr>
<tr>
<td>13</td>
<td>Women receiving doses of unopposed estrogen have a much higher incidence of endometrial hyperplasia and carcinoma, and require appropriate investigation of the endometrium</td>
<td>E</td>
<td>A</td>
</tr>
<tr>
<td>14</td>
<td>Women receiving estrogen and cyclical progestins can be expected to have indefinite progestin withdrawal bleeding and require no further investigation provided that the dose and duration of cyclical progestins is adequate</td>
<td>E</td>
<td>A</td>
</tr>
<tr>
<td>15</td>
<td>For women using cyclic progestins, bleeding outside the time of progestin withdrawal is considered abnormal and requires appropriate investigation</td>
<td>E</td>
<td>B</td>
</tr>
<tr>
<td>16</td>
<td>It is apparent that EEC thresholds used for spontaneous bleeding can be applied to patients with HRT-related bleeding, but with a higher incidence of false-positive findings</td>
<td>E</td>
<td>B</td>
</tr>
<tr>
<td>17</td>
<td>Women experiencing uterine bleeding while receiving tamoxifen (usually used as an adjuvant therapy for breast cancer) should be assessed primarily with endometrial sampling because, in such patients, TVUS is neither sensitive nor specific for neoplasia</td>
<td>E</td>
<td>A</td>
</tr>
<tr>
<td>18</td>
<td>Women with persistent bleeding during tamoxifen therapy, and who have already undergone endometrial sampling, should be assessed with one or a combination of contrast sonography (such as SIS) and hysteroscopy with appropriate sampling or excision of polyps if found</td>
<td>C</td>
<td>N/A</td>
</tr>
<tr>
<td>19</td>
<td>Women with repeated bleeding during tamoxifen therapy, and who have been demonstrated to have normal histologic findings and a structurally normal endometrial cavity, should have EB repeated annually</td>
<td>E</td>
<td>B</td>
</tr>
<tr>
<td>20</td>
<td>Postmenopausal bleeding can be a presenting symptom of cancer in the cervical canal. Consequently, if there is no endometrial explanation for postmenopausal bleeding, appropriate steps to evaluate patients for cervical cancer should be undertaken considering the results of a Papanicolaou test, colposcopy, and curettage of the endocervical canal</td>
<td>C</td>
<td>N/A</td>
</tr>
</tbody>
</table>

\(^a\) Recommendations are evidence based (E) unless sufficient evidence is not available and consensus-based (C) recommendations are provided.
\(^b\) See Table 2; strength of evidence is not applicable (N/A) to consensus-based recommendations.
amenorrhea preceding an episode of bleeding that would allow for the definition of postmenopausal uterine bleeding. For the purposes of this guideline, an episode of bleeding 12 months after the last menstrual period will be deemed to constitute postmenopausal bleeding. However, and especially in the perimenopausal years, the definition of “last period” may be difficult to ascertain, so liberal use of assays for estradiol and follicle stimulating hormone will help to determine when bleeding is occurring absent measurable ovarian function.

For women receiving HRT, bleeding is common, and its frequency and timing depends in part on the scheduling of the gonadal steroids used, particularly the progestational agent (Class 5). Breakthrough bleeding is unscheduled uterine bleeding that occurs in women receiving either estrogen alone or both estrogen and progestin therapy, which does not include the withdrawal bleeding that occurs following the cyclic withdrawal of progestin treatment. About 50% of women using continuous estrogen-progestin combined replacement regimens experience breakthrough bleeding, with most cases resolving 6 months after initiation of therapy (Class 4). The following definitions of abnormal bleeding during HRT are suggested:

- For women using cyclically administered progestins in combination with a cyclical or continuous estrogen: 1) occurs at an unscheduled time or 2) occurs at the anticipated time after progestin withdrawal but is heavy or prolonged.
- For women using continuous combined estrogen and progestin-containing regimens: 1) commences six months or more after initiation or 2) commences after amenorrhea has been established.

### Risk of Endometrial Cancer

In the US, endometrial cancer is the most commonly diagnosed reproductive tract malignancy and is the fourth most common cancer among women, trailing only cancers of the breast, lung, and colorectal origin (Class 5). Although endometrial cancer accounts for 6% of all female cancers, a number of intrinsic clinical features, including a propensity for early diagnosis (because of investigation of abnormal or postmenopausal bleeding) and the prompt use of effective therapy, it causes only about 3% of all cancer-related deaths.

There are 2 distinct types of endometrial cancer; most are Type 1, which develops secondary to unopposed estrogen-induced endometrial hyperplasia with an endometrioid appearance on histopathologic evaluation. Type 2 lesions comprise the minority, are of serous or clear cell origin, are not related to estrogen exposure, and are associated with a relatively poor prognosis. Older literature would suggest that Type 2 endometrial cancers comprise between 16% and 35% of endometrial cancer cases (Class 5), but more recent data from the US reveal that approximately 90% are Type 1 and about 10% are Type 2 lesions (Class 5).

For women with postmenopausal bleeding who do not use HRT, the incidence of endometrial cancer ranges from 4.9% to 11.5% (Class 5). There appears to be a greater risk of endometrial cancer in women who present with postmenopausal bleeding 10 or more years following menopause. One relatively large study found that postmenopausal bleeding over the age of 60 years was associated with a 13% risk of endometrial cancer (Class 5). Another large cohort study of slightly more than 3000 women with postmenopausal bleeding identified a peak in the age group from 60 through 64 years, of whom 7% were found to have endometrial cancer; the risk was lower for those in the younger and older age groups (Class 5).

There are no reliable data regarding the incidence of endometrial carcinoma in women using estrogen and progestin-containing HRT regimens. However, the estimated proportions range from 0.02% to 0.05% per annum (Class 5). For women receiving tamoxifen, the risk of endometrial cancer is likely above 10% depending in part on the dose and in part on the duration of therapy (Class 4).

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### Suggested Contents for Report of Endometrial Echo Complex (EEC) Evaluation

#### Normally Configured Uterus, EEC well seen

The uterus measures ___ . ___ cm in length; the corpus ___ . ___ cm in width, and ___ . ___ cm in anterior-posterior thickness. The EEC is seen in its entirety in both the sagittal and transverse planes, is consistent in thickness and echogenicity, and measures ___ . ___ mm throughout.

Comment: ____________________________

#### Uterus with EEC well seen, endometrial cavity containing sonolucent fluid

The uterus measures ___ . ___ cm in length; the corpus ___ . ___ cm in width, and ___ . ___ cm in anterior-posterior thickness. The EEC is seen in its entirety in both the sagittal and transverse planes, and contains sonolucent fluid. The endometrium on both sides of this fluid is consistent in thickness. The two-layer endometrial thickness calculated by subtracting the thickness of the fluid from the total endometrial echo complex thickness is ___ . ___ mm.

Comment: ____________________________

#### Generic

- **Uterine length:** ___ . ___ cm
- **Corpus width:** ___ . ___ cm
- **Corpus thickness:** ___ . ___ cm

**Endometrial fluid:**
- [ ] Yes
- [ ] No
- **If Yes: Sonolucent?**
- [ ] Yes
- [ ] No
- **Thickness of sonolucent fluid (sagittal):** ___ . ___ mm
- **Thickness of sonolucent fluid (transverse):** ___ . ___ mm

**Entire EEC seen:**
- [ ] Yes
- [ ] No

**EEC consistent throughout:**
- [ ] Yes
- [ ] No

**Double-layer endometrial thickness:**
- **Sagittal plane:** ___ . ___ mm
- **Transverse plane:** ___ . ___ mm

**Net endometrial thickness if sonolucent fluid subtracted:**
- **Sagittal plane:** ___ . ___ mm
- **Transverse plane:** ___ . ___ mm

**Comment: ____________________________**
Relationship to Age

The national registries of nations with government-supported health care programs provide information regarding demographic variables associated with the risk of endometrial carcinoma. The incidence of endometrial cancer is very low below the age of 50 years, and especially before 40 years. The Scottish national data suggest that the incidence of endometrial carcinoma is about 6 to 8/100,000 women each year after the age of 50 years²² (Class 4). However, these data do not describe the risk of endometrial cancer in women presenting with postmenopausal bleeding. Swedish data demonstrate that the incidence of postmenopausal bleeding declines with succeeding years after menopause and that the incidence of endometrial carcinoma increases as the age of the patient with postmenopausal bleeding increases²² (Class 4).

Hormone Replacement Therapy

The relative risk of development of endometrial cancer for a woman receiving unopposed estrogen preparations in historically typical doses is about 5 times that for nonusers²⁷ (Class 4). This increased risk is almost, if not totally, eliminated if appropriate cyclic or continuous progestins are added to the regimen²³ (Class 4),²⁴ (Class 1a),²¹ (Class 1b). However, a number of features may affect these risks, including the dose of the estrogen, and the dose, route, and regimen used to administer the progestin.

Most of the high-quality evidence relating to estrogen and progestin type and dosing and the risks of endometrial neoplasia has been obtained from randomized trials using endometrial hyperplasia as a surrogate outcome, studies that are well summarized in The Cochrane Database of Systematic Reviews⁵ (Class 1a). Unopposed estrogen, compared with placebo, is associated with an odds ratio (OR) for the short-term (18- to 24-months) development of endometrial hyperplasia that is 2.42 (95% confidence interval [CI], 1.19-4.92), 11.86 (CI, 7.76-18.14), and 13.06 (CI, 8.88-29.02) for low-, moderate-, and high-dose formulations, respectively. A substantial reduction in the rate of recurrent breast cancer, but there is also a 3 to 6 times increase in the incidence of endometrial carcinoma⁴⁴ (Class 4). This risk is proportional both to the dose of the drug and the duration of therapy, with those patients treated for 5 or more years experiencing a fourfold risk⁶ (Class 4). Some evidence exists that, for women in whom endometrial carcinoma develops following prolonged tamoxifen use, both the grade and stage of the tumor may be

When the progestin of a combined HRT regimen is administered cyclically, optimal results are obtained with 10 to 14 days/month because there is evidence that for women who use cyclic progestin therapy for less than 10 days per cycle, the risk of endometrial cancer is raised (OR, 2.9; CI, 1.8-4.6)³⁷ (Class 4). The minimum cycle duration has generally been considered to be 1 month. However, there is fair evidence that quarterly or even semiannual cycling for 14 days of medroxyprogesterone acetate (10 mg/day) is adequate to prevent most cases of endometrial hyperplasia or neoplasia, at least with conjugated equine estrogen (or equivalent) doses up to 0.625 mg/day⁶ (Class 1b),²⁹ (Class 3). Nevertheless, in the best available case-control study evaluating the role of cyclical therapy, long-cycle progestin replacement was associated with a 1.63 OR (CI, 1.12-2.38) at 5 to 10 years and a 2.95 OR (CI, 2.42-3.62) at 10 or more years compared with women not receiving HRT²⁹ (Class 4). These increases were not seen with continuous progestin regimens, including the use of the intrauterine progestin releasing system. There is relatively recent evidence that ultralow doses of unopposed estrogen may not increase the incidence of endometrial carcinoma, but these preparations are not yet in widespread use³⁵ (Class 3). Furthermore, there is good evidence that even doses as low as 0.3 mg/day of unopposed equine estrogens are associated with an increased risk of endometrial hyperplasia³⁵ (Class 1a).

The addition of a progestin to an estrogen-based HRT regimen is frequently associated with bleeding—generally predictable with cyclic progestin therapy and unpredictable for women receiving continuous treatment with progestin preparations³⁶ (Class 4). As a result, the proportion of women having underlying endometrial carcinoma can be expected to be much lower in women using combined HRT regimens than it is for those using estrogen alone or, depending on the formulation and schedule, for those receiving no HRT at all¹⁴ (Class 4).

Endometrial Cancer and Tamoxifen

Tamoxifen is a nonsteroidal compound in the family of SERM³³ that possesses weak estrogen activity similar to clomiphene citrate. Each of these agents is used to flood estrogen receptors with relatively inactive hormones, an approach designed to diminish estrogen-related cellular function. For those women using tamoxifen as adjuvant therapy for breast cancer, there is a substantial reduction in the rate of recurrence of breast cancer, but there is also a 3 to 6 times increase in the incidence of endometrial carcinoma⁴² (Class 4). This risk is proportional both to the dose of the drug and the duration of therapy, with those women treated for 5 or more years experiencing a fourfold risk³⁷ (Class 4). Some evidence exists that, for women in whom endometrial carcinoma develops following prolonged tamoxifen use, both the grade and stage of the tumor may be
higher, thereby potentially compromising survival\textsuperscript{38} (Class 4). Formerly there was controversy regarding the most appropriate approach to monitoring the endometrium in women using tamoxifen, with some investigators suggesting that routine endometrial sampling be performed on an annual basis. However, current evidence suggests that such an approach consumes resources without improving survival rates\textsuperscript{39,40} (Class 3). Consequently, and at least for the present, only women receiving tamoxifen who experience uterine bleeding should be investigated.

Although not strictly within the scope of this guideline, the management of nonbleeding women with a thickened endometrium (thick EEC) who are receiving tamoxifen is a potential issue. Evidence from studies evaluating this issue fails to support the notion of routine sonographic screening\textsuperscript{41} (Class 5), at least in part because there is no evidence for a clinically useful EEC threshold in tamoxifen-treated patients\textsuperscript{42} (Class 3). These findings, often cystic in nature, represent a unique, reversible, tamoxifen-induced change\textsuperscript{42} (Class 5).

\textbf{Relationship to Hereditary Nonpolyposis Colonic Cancer}

A number of other factors are associated with an increased risk of endometrial cancer. Hereditary nonpolyposis colorectal cancer is a relatively common, autosomal dominant syndrome originally described by Henry Lynch, and it is still known in some quarters by the name Lynch syndrome, particularly if there is a known DNA mismatch pair. Endometrial cancer is the most common extracolonic cancer found in women with this syndrome. The estimated lifetime risk of endometrial cancer in women with Lynch syndrome is 42\% to 60\%\textsuperscript{14} (Class 5) and, unlike spontaneous endometrial cancer, these malignancies often present in the premenopausal years\textsuperscript{45} (Class 4).

\textbf{Other Risk Factors for Endometrial Cancer}

The evidence linking other risk factors to the development of endometrial cancer is relatively weak. These include obesity, hypertension, and a history of either endogenous or exogenous hyperestrogenism\textsuperscript{46} (Class 5).  

\textbf{Clinical Investigation of Women with Postmenopausal Vaginal Bleeding}

\textbf{Physical Examination}

Pelvic examination should be performed searching for visual evidence of lesions or bleeding from gynecologic (eg, vulva, vagina, exocervix) and non-gynecologic (eg, perineum, periurethral, perianal) sources.

\textbf{Evaluation of the Endometrium Histologic Assessment}

Sampling of the endometrium can be accomplished by devices designed for office use, by D&C, or under hysteroscopic direction. Office-based sampling is usually performed with disposable catheters that allow for the application of suction to obtain a specimen. Any method of sampling the endometrial cavity misses a proportion of endometrial cancers\textsuperscript{47} (Class 1b),\textsuperscript{48} (Class 3),\textsuperscript{49} (Class 5).

\textbf{Dilation and Curettage}

D&C should no longer be the first method of sampling the endometrium in most cases. Comparison of office-based endometrial sampling with the Pipelle (CooperSurgical Inc; Trumbull, CT; USA) device with combined curettage and hysteroscopy reveals that each blind procedure is an acceptable screening tool but does miss usually benign lesions such as endometrial polyps\textsuperscript{50} (Class 2). However, it is not completely clear that D&C is equivalent to endometrial sampling with a suction catheter. One group of investigators from Sweden demonstrated that D&C was slightly superior to the Endorette endometrial sampler (CooperSurgical Inc; Trumbull, CT; USA), a suction catheter device similar to the Pipelle, for diagnosing endometrial cancer when the EEC measured 7 mm or more\textsuperscript{51} (Class 1b).

\textbf{Procedure and Tissue Yield Failure Rates of Office-Based Endometrial Sampling}

When inadequate tissue is obtained to allow histologic assessment, the specimen is typically called “nondiagnostic.” Evidence suggests that such patients may have underlying intrauterine lesions, including malignancy, especially if results of transvaginal ultrasonography (TVUS) are nondiagnostic or in excess of an acceptable threshold value such as 5 mm\textsuperscript{52} (Class 5). Office-based sampling of the endometrium is associated with a procedure failure rate of approximately 10\% and a tissue yield failure rate that is historically approximately also 10\%\textsuperscript{34,40,53} (Class 3).

Collectively, these data would suggest that women with “nondiagnostic” endometrial biopsy specimens should have additional uterine evaluations with TVUS, contrast sonography, hysteroscopy, or a combination of any of these procedures.

\textbf{Comparison of Office-Based Sampling Systems}

There are a number of issues to consider when comparing office-based endometrial sampling catheters, including ease of use, procedure-associated pain, frequency of obtaining adequate samples, number of passes required to obtain those samples, and cost. The Pipelle device has been shown, in the context of a randomized trial, to be superior to the Vabra aspirator (Berkeley Medevices Inc; Richmond, CA; USA), with adequate tissue being found in 73.3\% vs 52.4\% of cases\textsuperscript{54} (Class 1b). The Pipelle device has also been compared with the Explora catheter (CooperSurgical Inc; Trumbull, CT; USA) in a randomized trial.
irregularities, or if the EEC cannot be
should be uniform and, if there are
subtracted from the measurement from
ing—the thickness of the fluid echo is
generally a nonconcerning find
This double-thickness layer is called the
women not receiving HRT (Figure 2).
should be thinner in postmenopausal
layer in the midsagittal view; Figure 1)
endometrium (by convention a double
combination of the following: TVUS,
should be performed with one or a com-
note to determine the optimum
combination of effectiveness, cost, and
procedure-related pain.
**Blind Endometrial Sampling**
Blind methods of endometrial sampling
frequently fail to identify focal pathol-
ology of the endometrium. Although blind
sampling, either by endometrial biopsy or
D&C, is a satisfactory first-line technique
for the detection of endometrial neoplasia
that affects the entire endometrial surface,
it is inadequate at detecting localized le-
sions such as endometrial polyps, which
may be malignant (Class 3). Indeed,
a well-designed prospective study dem-
strated that even D&C performed in
the operating room missed endometrial
cysts about half the time (Class 3). This
information would suggest that in the
presence of symptoms or evidence of a
focal lesion, or, following blind sampling,
if symptoms of postmenopausal bleeding
persist, imaging of the endometrial cavity
should be performed with one or a com-
bination of the following: TVUS, contrast
sonography, or hysteroscopy.

**Transvaginal Ultrasonography**
Compared with premenopausal
women, the measured thickness of the
endometrium (by convention a double
layer in the midsagittal view; Figure 1)
should be thinner in postmenopausal
women not receiving HRT (Figure 2).
This double-thickness layer is called the
EEC. If there is uniformly sonolucent
fluid—generally a nonconcerning find-
ing—the thickness of the fluid echo is
subtracted from the measurement from
baseline to baseline to obtain the EEC
(Figure 3). The morphologic features
should be uniform and, if there are
irregularities, or if the EEC cannot be
adequately evaluated (Figure 4), other
investigations are warranted, such as
contrast sonography, hysteroscopy, and/or
endometrial sampling. At this time,
available evidence suggests that there
are no advantages offered by the use
of 3-dimensional ultrasonography, as
compared with standard 2-dimensional
ultrasonography (Class 3).

In general, thicker ECCs are associated
with a greater likelihood of endometrial or
intracavitary pathology, including endo-
metrial polyps, hyperplasia, and cancer
(Class 3). On the other hand, the reliability
of TVUS allows the clinician to identify a
group of women with postmenopausal
bleeding who have a thin endometrium and
thus a very low likelihood of hyper-
plasia or neoplasia. Unless there is
a recurrence of bleeding, this group of
women with postmenopausal bleeding
and a thin EEC generally require no more
investigation (Class 2). There is some
evidence that TVUS may be less sensitive
for the detection of Type 2 endometrial
carcinomas regardless of the EEC thresh-
hold. A cohort study demonstrated that 17%
of patients with postmenopausal bleeding
and Type 2 endometrial cancer had an
EEC of less than 4 mm (Class 5).

A number of EEC thickness thresholds
have been published to guide clinicians in
discriminating between women who
require endometrial sampling and those
who do not, at least for the first episode
of postmenopausal bleeding (Table 5). The
thinner the threshold, the fewer cases of
hyperplasia and cancer missed, but with
higher sensitivity, specificity is reduced
and more endometrial sampling must be
performed. Furthermore, the use of
HRT can have a variable impact on the
measurements depending on the use of a
progestin. Continuous estrogen-progestin
regimens tend to cause a hypertrophic and
sonographically thin endometrium, whereas
the ECC in women receiving
regimens of continuous estrogen and
 cyclically administered progestins will vary
according to the date of the TVUS
and the cycle date in the HRT regimen.
Available evidence suggests that women
with postmenopausal bleeding and a
thickened endometrium are less likely to
have endometrial pathology when they are
receiving HRT than when they are not
(Class 2). Presumably, the endometrial
thickness in women receiving estrogen and
cylic progestin therapy would be lowest
shortly after the cessation of the proges-
tins, a time that might be best suited for
measurement of EEC thickness in women
who experience unscheduled bleeding.

**Normal Thickness of
Endometrial Echo Complex**
Meta-analytic research using “sum-
mary data” has been performed using
high-quality studies evaluating the utility
of TVUS-obtained EEC thickness for the
assessment of women with postmeno-
pausal bleeding. The authors of the larg-
est meta-analysis to date, with just more

![Figure 3. Measurement of endometrial echo complex (EEC) when there is fluid in the cavity.](image)

Thickness of fluid (B) is subtracted from distance between base of opposing layers of endometrium (A). These should be in the same plane; they are separated slightly here for demonstration purposes.
than 9000 patients, demonstrated that an EEC of 3 mm or less would provide a posttest probability of 0.4% for endometrial cancer; a 4-mm threshold, 1.2%; and a 5-mm threshold, 2.3% (Class 2). In this study, the best quality evidence was that for the 5-mm threshold. The authors of a second large meta-analysis of nearly 6000 women reported that an EEC of 5 mm or less was associated with a 4% chance of endometrial cancer. This sensitivity did not vary in women using HRT (Class 2).

Meta-analysis using the original datasets is thought to provide more accurate conclusions than using the summary data provided in the published manuscript because of a number of factors, including publication bias, method of analysis, and length of follow-up (technical descriptions). One such analysis employed this technique but, rather than using fixed cut-offs for EEC, used multiples of the mean for each different study and determined that if the median EEC thickness was used, the sensitivity would be approximately 96% and specificity would be 50%. However, such an approach is difficult to evaluate and implement because it does not provide guidance about EEC thickness overall (Class 2). Consequently, Timmermans et al (Class 2) performed a re-analysis of the data using original datasets, rather than summary data, and were able to evaluate 2896 cases from 13 authors (259 with endometrial carcinoma), only 2 of which were from the original 90-author group reported in the publication by Smith-Bindman et al (Class 2). The conclusions from this analysis suggested that a threshold of 5 mm for the EEC would have sensitivity for endometrial cancer of only 90%; 4 mm, a sensitivity of 95%; and 3 mm, a sensitivity of 98%—thresholds that are different from those found in the previously published meta-analyses.

Table 5. Meta-analyses of sensitivity and specificity of endometrial echo complex for detection of endometrial cancer in women with postmenopausal bleeding

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Method</th>
<th>Number of included studies</th>
<th>Number of subjects</th>
<th>Number with EEC</th>
<th>Sensitivity by EEC thickness (95% CI)</th>
<th>Specificity by EEC thickness (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3 mm</td>
<td>4 mm</td>
<td>5 mm</td>
</tr>
<tr>
<td>Timmermans et al, 2010</td>
<td>Original dataset</td>
<td>13</td>
<td>2896</td>
<td>259</td>
<td>97.3 (90.1-99.6)</td>
<td>94.8 (86.1-98.2)</td>
</tr>
<tr>
<td>Gupta et al, 2002</td>
<td>Summary data</td>
<td>57</td>
<td>8890</td>
<td>1243</td>
<td>99.3 (96.8-99.8)</td>
<td>98.9 (97.1-99.6)</td>
</tr>
<tr>
<td>Smith-Bindman et al, 1998</td>
<td>Summary data</td>
<td>35</td>
<td>5892</td>
<td>759</td>
<td>100 (89-100)</td>
<td>96 (93-98)</td>
</tr>
</tbody>
</table>

CI = confidence interval; EEC = endometrial echo complex.
permanent studies are remarkably consistent demonstrating that if the fluid is sonoluent and if the EEC, which is the combined thickness of the 2 separated endometrial layers, is 3 mm or less (see Figure 3), the finding is highly likely to be benign55 (Class 3). On the other hand, if the EEC is greater than threshold (3.0-4.5 mm depending on the study) or if the fluid is echogenic69 (Class 3), there is a risk of malignancy and immediate further investigation aimed at obtaining a tissue sample is warranted80 (Class 3). Women with postmenopausal bleeding, intrauterine sonoluent fluid, and an EEC of 3 mm or less could still harbor a carcinoma in the cervical canal, so such a diagnosis should be considered29 (Class 3).

Documentation

If TVUS or contrast sonography is used to evaluate women with postmenopausal bleeding or unscheduled bleeding who are receiving HRT, documentation ideally comprises both a midline sagittal image and a transverse fundal image documenting the thickest measurement of the EEC. A suitable note describing the findings should be included in the patient record25 (Class 7). The addition to the record of selected images is desirable but not considered mandatory provided that the note describes the endometrial findings in sufficient detail.

Contrast Sonography

Transcervical instillation of saline (saline infusion sonography), or other sonographic contrast media such as gel, into the endometrial cavity allows for contrast-enhanced sonographic evaluation that is designed to improve diagnostic utility for lesions involving the endometrial cavity such as polyps or submucous leiomyomas68 (Class 5). The procedure is performed in an office setting with a small-caliber catheter positioned in the endometrial cavity while imaging is performed with simultaneous TVUS. In addition to saline infusion sonography, such fluid contrast-enhanced ultrasonography of the endometrial cavity is known as sonohysterography and hysterosonography, although the latter two terms may create confusion with the contrast-enhanced radiographic evaluation of the endometrial cavity and fallopian tubes that is called a hysterosalpingogram. Consequently, for purposes of this document, the term contrast sonography or saline infusion sonography will be used.

The procedure appears to accurately evaluate the endometrial cavity and can be successfully performed in more than 85% of postmenopausal women in an office setting58 (Class 2). Saline infusion sonography seems superior to TVUS in defining intrauterine lesions in women with postmenopausal bleeding and a measured EEC greater than 5 mm, particularly for the delineation of endometrial polyps, for which it seems as accurate as hysteroscopy59 (Class 2). Another observer-blinded comparison demonstrated that saline infusion sonography was essentially equivalent to hysteroscopy and superior to TVUS for the diagnosis of endometrial cavity abnormalities in women with postmenopausal bleeding64 (Class 3). There is no current evidence suggesting that saline infusion sonography enhances the diagnosis of malignancy. However, by virtue of its ability to identify postmenopausal women with endometrial polyps, saline infusion sonography may facilitate diagnosis, targeted removal, and resolution of symptoms, thereby reducing resource utilization and improving patient satisfaction with the overall process (Class 7).

Hysteroscopy with Curettage and Directed Biopsy

Hysteroscopy is an endoscopic technique that allows direct visualization of the endometrial cavity. It can be performed in an office setting with local or no anesthesia, with or without sedation, or in a procedure room or operating room. To accomplish the procedure, it is often necessary to first dilate the cervix adequately to accommodate the external diameter of the outer sheath of the hysteroscope assembly, which generally ranges from 4.0 to 5.5 mm. A number of small-caliber fiberoptic devices exist that are approximately the diameter of some biopsy catheters (3-4 mm). With such instrumentation, dilation of the cervix may not be necessary. One inherent advantage of hysteroscopy is that endoscopically guided removal of lesions may be performed immediately after diagnosis, during the same procedure. Provided that the lesions are relatively small, such excisions may even be performed in an office setting. Despite the seemingly obvious advantages of the technique, the data supporting the use of hysteroscopy for management of women with postmeno-

pausal bleeding are relatively sparse and generally of relatively poor quality.

As described previously, hysteroscopy is superior to endometrial biopsy90,91,92 (Class 3), D&C94 (Class 3), and ultrasonography95,96 (Class 3) for the identification of structural lesions of the endometrium such as endometrial polyps. Hysteroscopy has good diagnostic accuracy for structural lesions, such as polyps and leiomyomas, whether or not performed in an office setting, and good patient acceptability in either setting97 (Class 1b). Indeed, in a study designed to determine the desires of women regarding a primary assessment tool for evaluation of postmenopausal bleeding, 95% preferred to undergo office hysterectomy rather than experience a 5% chance that a lesion could be missed98 (Class 6). However, it should be noted that hysteroscopic visualization alone is relatively inaccurate in the diagnosis of atypical hyperplasia and carcinoma99,100,101 (Class 3). Consequently, hysteroscopy should not be performed in women with postmenopausal bleeding who have not undergone antecedent or concurrent endometrial sampling by suction or sharp curettage.

In the past, there were concerns that the pressurized distending media used with hysteroscopy could result in retrograde dissemination of malignant cells into the peritoneal cavity sufficient to alter the prognosis of endometrial carcinoma102,103 (Class 5). However, although some investigators have shown a low incidence of peritoneal washings testing positive for endometrial cells104 (Class 5), others have compared the incidence of positive peritoneal cytologic findings associated with hysteroscopy to that associated with D&C and have found the frequency to be similar—about 9% to 10%105 (Class 1b),106 (Class 4). Overall, there seems to be a slightly increased risk of positive peritoneal cytologic findings associated with the use of hysteroscopy (OR, 1.78; CI, 1.13-2.79)107 (Class 1b). However, available high-quality evidence suggests that the prognosis associated with a hysteroscopic diagnosis of endometrial cancer is not different from that with other diagnostic methods108,109 (Class 1b),110,111,112 (Class 3).

Sequencing of Investigations

The exact sequencing of investigations for women with postmenopausal bleeding will necessarily vary somewhat depending
on the local resources and expertise, the judgment of the clinician, and patient preference. There is evidence that resource utilization is reduced if the practitioner is able to perform the TVUS examination in the office without adding additional changes as opposed to having the procedure performed by a radiologist (Class 3), and this would be presumably true for contrast sonography as well. The same can be said for hysteroscopy, for which in-office performance using local anesthesia is logically cheaper than any hospital or surgical center-based procedure.

**Primary Assessment of Spontaneous Postmenopausal Bleeding**

For women with spontaneous bleeding 12 or more months following the last menstrual period, the endometrium can be primarily assessed by either office-based endometrial biopsy (Figure 5) or TVUS (Figure 6). For those who undergo TVUS and have an EEC greater than 4 mm, localized thickening, or an indistinct or nonvisible EEC, endometrial sampling is a reasonable next step.

These approaches were compared by Weber et al (Class 3) from the Cleveland Clinic in a cost-modeling exercise, with primary TVUS predicted as being slightly less expensive. However, in that study, the assumptions were based on a charge model and included performance of the TVUS in a Radiology Department. In another study, Medverd and Dubinsky (Class 3) demonstrated that TVUS as a primary assessment modality utilized approximately 11% fewer resources than did an endometrial biopsy-initiated evaluation paradigm. It is unclear whether charges or costs were considered in their analysis, but it is presumed that the imaging was performed in a Radiology Department and was interpreted by a radiologist. A cost modeling analysis from the UK, which assumed that a gynecologist performed all procedures, suggested that endometrial biopsy- and TVUS-initiated investigational paradigms were similar regarding their cost-effectiveness when 5 mm was used as the EEC threshold (Class 3). How this analysis translates to US fee-for-service or prepaid models is unclear, and the impact of changing the EEC threshold to 4 mm was not evaluated.

**Primary Assessment of Hormone Replacement Therapy-Related Postmenopausal Bleeding (Breakthrough Bleeding)**

The increased risk of endometrial cancer for women with postmenopausal bleeding who are receiving unopposed estrogen requires assessment in all circumstances. For women with postmenopausal bleeding while receiving combined estrogen-progestin HRT regimens, the approach is less clear, as it is apparent that such women are at significantly reduced risk of endometrial carcinoma compared with women not receiving HRT (Class 5). Furthermore, women using estrogen and cyclic progestin therapy and who have cyclic bleeding near to or following the end of the progestogenic component of the regimen require no investigation. In addition, those women who use estrogen and continuous progestin regimens will frequently experience breakthrough bleeding in the first 6 months of therapy and generally require no investigation. However, women receiving cyclic progestin regimens who have unscheduled bleeding, or for those receiving continuous progestin therapy who have breakthrough bleeding beyond 6 months and especially following a period of amenorrhea, the endometrium should be assessed. Available evidence suggests that either endometrial biopsy or TVUS can be used in a fashion similar to that recommended for spontaneous bleeding using a similar EEC threshold for endometrial sampling (Class 2), (Class 5). Although it is possible that a higher EEC threshold might apply to women receiving sequential HRT, the committee could
Investigation of Women with Postmenopausal Uterine Bleeding: Clinical Practice Recommendations

Figure 7. Investigation of postmenopausal uterine bleeding in women receiving tamoxifen. Transvaginal ultrasonography is not sufficient for the evaluation of women experiencing bleeding while receiving tamoxifen. Endometrial sampling is necessary. AUB = abnormal uterine bleeding; ± = with or without.

Causes of Abnormal Uterine Bleeding

Causes of abnormal bleeding in women using HRT include the following:

- Poor compliance
- Poor gastrointestinal absorption (for oral preparations)
- Drug interactions
- Coagulation defects
- Liver disease
- Gynecologic disorders, including but not limited to endometrial cancer, endometrial polyps, and cervical or vaginal lesions
- Nonreproductive tract origins (eg, urinary tract, gastrointestinal tract).

Important Points in the Patient History

The clinician should determine if the bleeding pattern is within acceptable limits (see earlier section, Hormone Replacement Therapy). In addition, the provider should ascertain if there are any other factors or symptoms that may place the patient at increased risk of endometrial cancer. Pertinent questions to ask include the following:

- When does the bleeding occur with respect to progestin administration? Women receiving cyclical progestin therapy should have bleeding near the end of or shortly after discontinuation of the progestin component of the regimen.
- How long does the bleeding last? How heavy is it? Heavy bleeding, even when experienced in the context of a cyclically administered progestin, may suggest the presence of intrauterine pathology.
- Was there a period of amenorrhea after HRT was started? For continuous combined regimens, breakthrough bleeding is common, especially in the first six months, but should a period of amenorrhea be established initially, bleeding, even within the first six months, suggests intrauterine abnormalities.
- Is there evidence of poor compliance? The patient should understand the appropriate method for following her treatment regimen. Some women take their medications sporadically or use their progestin in an unconventional fashion.
- Is there a reason to suspect poor gastrointestinal absorption? A history of nausea, vomiting, or diarrhea is a potential explanation for incomplete absorption and resultant bleeding.
- Is there any evidence of hepato cellular disease? The liver is responsible for metabolizing estrogen. Should there be active or chronic hepatocellular disease, the circulating levels of estrogen may be higher than normal and abnormal bleeding may occur secondary to endometrial stimulation.
- Is the patient receiving any other drugs? The intentional or inadvertent use of other gonadal steroids (estrogens with or without progestins) may explain unexpected bleeding.

Discontinuation of Hormone Replacement Therapy before Clinical Investigation

There is no convincing reason to discontinue HRT before clinical investigation. If the primary physician is able to complete the required investigative steps, this issue is moot. However, if the physician will be referring the patient for clinical assessment by a gynecologist, there may be a time period between the referral and the actual consultation appointment. In such instances, women may continue their regimen (Class 7).

Recurrent Spontaneous or Breakthrough Bleeding

Spontaneous or HRT-related, recurrent postmenopausal bleeding can oc-
cur. In a prospective study of women with postmenopausal bleeding who were not receiving HRT and whose EEC measured 4 mm or less, the incidence of recurrent bleeding was 10% at a mean of 49 weeks following the original TVUS (Class 5). Of these 25 patients, 8% (n = 2) had endometrial carcinoma and 4% (n = 1) had a malignant melanoma. In another retrospective study of 1536 women with postmenopausal bleeding evaluated over a period of almost 5 years with both TVUS and endometrial biopsy, the prevalence of endometrial cancer was 3% with normal assessment. On the other hand, the prevalence was 4% in the 126 patients with normal results of the initial evaluation who presented with persistent postmenopausal bleeding (Class 5).

There is no current evidence supporting any specific recommendations for reinvestigation in the face of a normal TVUS or satisfactory and normal endometrial biopsy specimen. However, considering the false-negative rates associated with either approach, the indications for reassessment should be rather liberal considering one or a combination of repeat TVUS, repeat endometrial biopsy, and contrast sonography or hysterectomy (Class 5), (Class 6), (Class 7). Determination of the specific order and combinations of these investigations will depend on the clinical judgment of, and resources available to, the clinician.

Tamoxifen-Related Bleeding

As previously described, patients receiving tamoxifen who are postmenopausal experience an increased risk of endometrial neoplasia that is greatest after four years of exposure. Whereas there is no evidence to support the use of routine biopsy of such patients, any who present with bleeding while receiving tamoxifen should undergo office-based endometrial sampling if possible (Figure 7). If not feasible, such patients should undergo hysteroscopy and curettage.

The tamoxifen-induced impact on the endometrium frequently, if not usually, creates a thickened EEC, often with diffuse subendometrial cystic change that is in no way indicative of endometrial hyperplasia or malignancy (Class 2-4). As a result, TVUS for evaluation of EEC thickness is not useful in the evaluation of tamoxifen-related postmenopausal bleeding.

Many patients with tamoxifen-related bleeding have endometrial polyps (Class 1b). Consequently, if bleeding persists, evaluation of the endometrial cavity is indicated, generally with hysteroscopy, with hysteroscopically guided excision of any identified polyps and curettage for reassessment of the endometrium.

Contrast sonography may also be useful in this regard; however, there is evidence that saline infusion sonography is inferior to hysteroscopy in detecting focal lesions in these patients (Class 3).

For patients who are receiving tamoxifen, who have persistent episodes of postmenopausal bleeding, who have no evidence of focal lesions, and for whom both the cervical canal and endometrial cavity have been adequately evaluated with imaging and adequate endometrial sampling showing benign tissue, annual repeated sampling is indicated (Class 7).

The group also developed guidelines that apply to women with both acute and chronic abnormal uterine bleeding in the reproductive years. (Class 5).

Adapted from the Scottish Intercollegiate Guidelines Network

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REVIEW ARTICLE

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A determining point in the history of gynecology is to be found in the fact that sex plays a more important part in the life of woman than in that of man, and that she is more burdened by her sex.

—Henry E Sigerist, 1891-1957, Swiss-born American medical historian
The Role of Eye Movement Desensitization and Reprocessing (EMDR) Therapy in Medicine: Addressing the Psychological and Physical Symptoms Stemming from Adverse Life Experiences

Francine Shapiro, PhD

Abstract

Background: A substantial body of research shows that adverse life experiences contribute to both psychological and biomedical pathology. Eye movement desensitization and reprocessing (EMDR) therapy is an empirically validated treatment for trauma, including such negative life experiences as commonly present in medical practice. The positive therapeutic outcomes rapidly achieved without homework or detailed description of the disturbing event offer the medical community an efficient treatment approach with a wide range of applications.

Methods: All randomized studies and significant clinical reports related to EMDR therapy for treating the experiential basis of both psychological and somatic disorders are reviewed. Also reviewed are the recent studies evaluating the eye movement component of the therapy, which has been posited to contribute to the rapid improvement attributable to EMDR treatment.

Results: Twenty-four randomized controlled trials support the positive effects of EMDR therapy in the treatment of emotional trauma and other adverse life experiences relevant to clinical practice. Seven of 10 studies reported EMDR therapy to be more rapid and/or more effective than trauma-focused cognitive behavioral therapy. Twelve randomized studies of the eye movement component noted rapid decreases in negative emotions and/or vividness of disturbing images, with an additional 8 reporting a variety of other memory effects. Numerous other evaluations document that EMDR therapy provides relief from a variety of somatic complaints.

Conclusion: EMDR therapy provides physicians and other clinicians with an efficient approach to address psychological and physiologic symptoms stemming from adverse life experiences. Clinicians should therefore evaluate patients for experiential contributors to clinical manifestations.

Introduction

Eye movement desensitization and reprocessing (EMDR)3 is an empirically validated psychotherapy approach that medical personnel can employ to treat the sequelae of psychological trauma and other negative life experiences. Its ability to rapidly treat unprocessed memories of these adverse experiences has important implications for the medical community, as they appear to be the foundation for an array of clinical symptoms. Clinical applications of EMDR include a wide variety of psychological problems affecting patients and family members, as well as stress-induced physical disorders and medically unexplained symptoms. The frequent ability of EMDR to bring about substantial improvement in short periods of time has relevance to major current problems in medical practice such as increasing patient load and the cost of medical care. The therapy procedures can be used by qualified medical personnel to improve comfort levels and functionality in managing some of their most difficult cases in everyday practice.

EMDR therapy was introduced in 1989 with the publication of a randomized controlled trial (RCT)4 evaluating its effects with trauma victims. The same year, the first RCTs on trauma-focused cognitive behavioral therapy (CBT) and psychodynamic therapy were published.5,6 In 2008, an Institute of Medicine report7 stated that more research was needed to determine the efficacy of EMDR, cognitive therapy, and pharmacotherapy in the treatment of posttraumatic stress disorder (PTSD); psychodynamic therapy and hypnotherapy were not considered because of the paucity of relevant evidence (one study each). However, since that time additional EMDR therapy RCTs with PTSD participants have been published, and this therapy is recommended as an effective treatment for trauma victims by numerous organizations, including the American Psychiatric Association,5 Department of Defense,8 and World Health Organization.9 Although meta-analyses report comparable effect sizes for CBT and EMDR therapy5,7 and both are considered “highly efficacious in reducing PTSD symptoms,”6,25 there are significant differences between the two treatments. As noted in the World Health Organization’s 2013 Guidelines for the Management of Conditions That Are Specifically Related to Stress,9 whereas both therapies are recommended for PTSD treatment in children, adolescents, and adults, “Like CBT with a trauma focus, EMDR therapy aims to reduce subjective distress and strengthen adaptive cognitions related to the traumatic event. Unlike CBT with a trauma focus, EMDR does not involve a) detailed descriptions of the event, b) direct challenging of beliefs, c) extended exposure, or d) homework.”9

Twenty-nine RCTs have evaluated EMDR therapy as a trauma treatment. Excluding 4 RCTs determined by the International Society for Traumatic Stress Practice Guidelines Taskforce10 to...
have provided insufficient treatment doses, fidelity, or both, the remaining 25 studies have created a strong knowledge base. Twenty-four RCTs support the use of EMDR therapy with a wide range of trauma populations (see meta-analyses cited above for a comprehensive listing of most studies and critiques). Seven of 10 RCTs have indicated that EMDR therapy is more rapid or otherwise superior to CBT,21-23 and only 1 has reported superior effects for CBT on some measures.24 The latter is likewise the only RCT (of 25) to report a control condition superior to EMDR. Whereas the EMDR therapy involved only 8 standard sessions and no homework, the CBT treatment was vastly more complex and entailed 4 sessions of imaginal exposure (describing the trauma) and 4 sessions of therapist-assisted in vivo exposure (physically going to a disturbing location) plus approximately 50 hours of combined imaginal exposure and in vivo exposure homework. The EMDR therapy condition involved only 8 standard sessions and no homework. Of particular note with respect to general clinical practice is a study conducted at Kaiser Permanente21,22 that reported that 100% of single-trauma victims and 77% of multiple-trauma victims no longer had PTSD after a mean of six 50-minute EMDR therapy sessions, demonstrating a large and significant pretreatment versus posttreatment effect size (Cohen’s $\delta = 1.74$). This is consistent with 2 other RCTs that found that 84% to 90% of single-trauma victims no longer had PTSD after three 90-minute EMDR sessions.25-27 Most recently, a study funded by the National Institute of Mental Health evaluated the effects of 8 sessions of EMDR therapy compared to 8 weeks of treatment with fluoxetine.28 EMDR was superior for the amelioration of both PTSD symptoms and depression. Upon termination of therapy, the EMDR group continued to improve, whereas the fluoxetine participants who had reported as asymptomatic at posttest again became symptomatic. At follow-up, 91% of the EMDR group no longer had PTSD, compared with 72% in the fluoxetine group.

EMDR therapy is an eight-phase treatment approach composed of standardized protocols and procedures. The eight phases and three-pronged protocol facilitate a comprehensive evaluation of the clinical picture, client preparation, and processing of a) past events that set the foundation for pathology, b) current disturbing situations, and c) future challenges (Table 1).27

One of the components used during the reprocessing phases is composed of dual attention stimuli in the form of bilateral eye movements, taps, or tones. The eye movements have been the subject of great scrutiny and were called into question a decade ago by a meta-analysis30 of studies evaluating treatment effects with and without this component. However, guidelines published by the International Society for Traumatic Stress Studies31 indicated that no conclusions were possible because the studies evaluated in the meta-analyses were fatally flawed owing to the use of inappropriate populations, insufficient treatment doses, and lack of power. In contrast, since that time, 20 RCTs have indicated positive effects of the eye movement component. Twelve RCTs demonstrate an immediate decrease in arousal, negative emotions, and/or imagery vividness,20,30 and the remainder report additional memory effects, including increased attentional flexibility,31 memory retrieval,32 and recognition of true information.33 A recent meta-analysis34 has reported that significant outcomes are evident in both clinical studies, with a moderate effect size (Cohen’s $\delta = 0.41$), and laboratory experiments, with a large effect size (Cohen’s $\delta = 0.74$). Three dominant hypotheses regarding proposed mechanisms of action

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<tr>
<th>Phase</th>
<th>Purpose</th>
<th>Procedures</th>
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<tr>
<td>History taking</td>
<td>Obtain background information Identify suitability for EMDR treatment Identify processing targets from events in client's life according to standardized three-pronged protocol</td>
<td>Standard history-taking questionnaires and diagnostic psychometrics Review of selection criteria Questions and techniques to identify 1) past events that have laid the groundwork for the pathology, 2) current triggers, and 3) future needs</td>
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<tr>
<td>Preparation</td>
<td>Prepare appropriate clients for EMDR processing of targets</td>
<td>Education regarding the symptom picture Metaphors and techniques that foster stabilization and a sense of personal control</td>
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<tr>
<td>Assessment</td>
<td>Access the target for EMDR processing by stimulating primary aspects of the memory</td>
<td>Elicit the image, negative belief currently held, desired positive belief, current emotion, and physical sensation and baseline measures</td>
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<tr>
<td>Desensitization</td>
<td>Process experiences toward an adaptive resolution (no distress)</td>
<td>Standardized protocols incorporating eye movements (taps or tones) that allow the spontaneous emergence of insights, emotions, physical sensations, and other memories</td>
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<tr>
<td>Installation</td>
<td>Increase connections to positive cognitive networks</td>
<td>Enhance the validity of the desired positive belief and fully integrate the positive effects within the memory network</td>
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<td>Body Scan</td>
<td>Complete processing of any residual disturbance associated with the target</td>
<td>Concentration on and processing of any residual physical sensations</td>
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<td>Closure</td>
<td>Ensure client stability at the completion of an EMDR session and between sessions</td>
<td>Use of guided imagery or self-control techniques if needed Briefing regarding expectations and behavioral reports between sessions</td>
</tr>
<tr>
<td>Reassessment</td>
<td>Ensure maintenance of therapeutic outcomes and stability of client</td>
<td>Evaluation of treatment effects Evaluation of integration within larger social system</td>
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The Role of Eye Movement Desensitization and Reprocessing (EMDR) Therapy in Medicine: Addressing the Psychological and Physical Symptoms Stemming from Adverse Life Experiences
of EMDR therapy that have been supported by research\textsuperscript{59-67} include that the eye movements a) tax working memory, b) elicit an orienting response, and c) link into the same processes that occur during rapid eye movement sleep.

**Experiential Contributors to Pathology**

EMDR therapy is guided by the adaptive information processing (AIP) model. Developed in the early 1990s,\textsuperscript{1} this concept posts that, except for symptoms caused by organic deficits, toxicity, or injury, the primary foundations of mental health disorders are unprocessed memories of earlier life experiences. It appears that the high level of arousal engendered by distressing life events causes them to be stored in memory with the original emotions, physical sensations, and beliefs. The flashbacks, nightmares, and intrusive thoughts of PTSD are prime examples of symptoms resulting from the triggering of these memories. However, as indicated in the AIP model, a wide range of adverse life experiences can also be stored in a dysfunctional manner, providing the basis for diverse symptomology that include negative affective, cognitive, and somatic responses. Sufficient processing of those accessed memories within the standard three-pronged EMDR therapy protocol brings about adaptive resolution and functioning. It is conjectured that processing the targeted experiences transfers them from implicit and episodic memory to explicit and semantic memory systems.\textsuperscript{1,38} The originally experienced negative emotions, physical sensations, and beliefs are altered as the targeted memory is integrated with more adaptive information. What is useful is learned and stored with appropriate affective, somatic, and cognitive concomitants. Consequently, the distressing life experience becomes a source of strength and resilience.\textsuperscript{59}

Support for the AIP tenets positing the primacy of life experiences to pathology comes from research showing that general life experiences (eg, relational problems, problems with study or work) can be the source of even more posttraumatic stress symptoms than major trauma.\textsuperscript{40} Hence, patients presenting with anxiety, depression, hypervigilance, frequent anger, etc, should be evaluated for adverse experiences contributing to current dysfunction. Two RCTs have demonstrated the effectiveness of EMDR therapy in treating distressing life experiences that do not meet the criteria for traumatic events in the diagnosis of PTSD.\textsuperscript{2,4,44} Both trials reported positive treatment effects within 3 sessions. One of the studies using a mixed sample\textsuperscript{24,25} reported comparable decreases in symptoms whether or not the participant met all criteria for PTSD. The 3 sessions of EMDR therapy resulted in an 84% remission of PTSD diagnosis with a large and significant pretreatment versus posttreatment effect size (Cohen’s $\delta = 1.69$).

The ability of EMDR therapy to rapidly treat unprocessed memories of distressing life experiences has multiple applications in medical practice, as such memories have been identified as the basis for a wide variety of clinical symptoms. Research has revealed widespread mental health treatment implications. For instance, “Harm physical punishment [ie, pushing, grabbing, shoving, slapping, hitting] in the absence of [more severe] child maltreatment is associated with mood disorders, anxiety disorders, substance abuse/dependence, and personality disorders in a general population sample.”\textsuperscript{42-45} Additional research demonstrates that “Exposure to adverse, stressful events … has been linked to socioemotional behavior problems and cognitive deficits.”\textsuperscript{46-49} These studies highlight the significance of carefully evaluating patients for a history of adverse life experiences. It is particularly important in the treatment of children to identify interpersonal experiences, including household dysfunction, bullying, and humiliation, that may be contributing to problems such as anxiety, lack of focus, angry outbursts, inattention, and impulsivity issues that might otherwise be incorrectly diagnosed as attention deficit hyperactivity disorder.\textsuperscript{49-53} A course of EMDR therapy treatment can be used to alleviate the effects of experiential contributors and to evaluate whether or not medication is actually needed. Reports of insomnia, nightmares, and night terrors should be similarly evaluated, as memory processing alone can improve the quality of sleep.\textsuperscript{40}

Although these studies have contributed greatly to our knowledge base, the most important research underscoring the importance of experiential contributors to both physical and mental health problems is the Adverse Childhood Experiences (ACE) Study.\textsuperscript{57} This study examined more than 17,000 adult members in the Kaiser Permanente Medical Care Program and “… found a strong dose-response relationship between the breadth of exposure to abuse or household dysfunction during childhood and multiple risk factors for several of the leading causes of death in adults.”\textsuperscript{57-60} The implications for combined medical and psychological treatment are relevant to both prevention and remediation. In this regard, the use of EMDR therapy to treat the patient and to identify the adverse life experiences that contribute to current symptoms, and processing the memories to an adaptive resolution, can significantly contribute to efficient clinical practice.\textsuperscript{1,46,60}

**EMDR Therapy Approach**

According to the AIP model, current experiences link into already established memory networks and can trigger the unprocessed emotions, physical sensations, and beliefs inherent in earlier-stored adverse life experiences. In this way, when the past becomes present and patients react in a dysfunctional manner, it is because their perceptions of current situations are colored by their unprocessed memories. The AIP conceptualization provides the basis for a comprehensive evaluation of the clinical picture, the targets selected for treatment, and the procedures used during reprocessing.\textsuperscript{1,4,5,6} Unlike CBT, which involves extended focused attention on the disturbing event, EMDR reprocessing sessions promote an associative process that clearly reveals the intricate connections of memories that are triggered by current life experiences. The transcript of a patient who requested treatment for PTSD following an earthquake\textsuperscript{64} reveals the experiences of household dysfunction that set the foundation for her current symptoms (see Sidebar: Partial Transcript of EMDR Therapy Session, available online at: www.thepermanentejournal.org/files/Winter2014/EyeMovement.pdf). Note the spontaneous emergence of insight that ties together both past and present trauma, as well as the rapid change in affect and cognitive response. Also of note is the recognition of childhood feelings of powerlessness that provide the foundation for psychosomatic problems. Such rapid decline in subjective distress during a single EMDR therapy session has been reported in a number of
A short course of EMDR therapy has also been found to successfully treat cases of perceived neuropathy as well as stress-related dermatologic disorders such as atopic dermatitis, psoriasis, acne excorie, and generalized urticaria. Importantly, while CBT trauma treatments involve one to two hours of daily homework to achieve positive effects, EMDR therapy uses none. As reported in a controlled study funded by the National Institute of Mental Health, “An interesting potential clinical implication is that EMDR seemed to do equally well in the main despite less exposure [to the trauma memory] and no homework.”

EMDR therapy has been reported to be beneficial in the treatment of stress-related dermatologic disorders such as atopic dermatitis, to successfully treat cases of perceived neuropathy, and to amenable to physical rehabilitation services. An RCT with patients suffering from PTSD following a life-threatening cardiovascular event compared eight sessions of EMDR therapy to imaginal exposure therapy (which involves concentrating on the trauma memory and repeatedly describing it in detail). EMDR therapy resulted in greater reductions on all measures posttest, indicating a rapid decline in trauma symptoms, depression, and anxiety. Of note, significant improvement in trait anxiety was also reported and maintained. No such improvement was reported for imaginal exposure therapy. The authors reported that EMDR therapy was initially posited to be more “gentle” and therefore amenable for this debilitated population because “distancing” rather than reliving has been found to be correlated with treatment effects, and the eye movements used in EMDR appear to immediately cause parasympathetic activation, resulting in physiologic calming.

Rehabilitation services can benefit from EMDR therapy to support both patient and family members. The traumatic impact of dealing with life-threatening, incapacitating disease can be mitigated by incorporating relatively few memory-processing sessions to address distressing medical experiences, current situations, and fears of the future. As reported by Gattinara, “Using this approach in the field of neuromuscular disease is useful on three levels:

1. It can facilitate the processing of the traumatic event in the patient and the whole family.
2. It can rapidly reestablish a secure interpersonal context between the patient and his or her caregiver by reducing the high arousal level.
3. It can transform the health service into a network of support for patient and family, offering help in managing the emotional vulnerability connected with physical vulnerability, thus buffering the adverse impact of worsening clinical conditions.”

In addition, because EMDR therapy requires no homework, it can be used on consecutive days, allowing rapid completion of treatment. The cost implications are obvious.

EMDR therapy can also be used to help support family members dealing with the death of a loved one. The results of both prolonged debilitation and sudden death can involve trauma symptoms that include distressing intrusive images of the suffering patient. The family member is often unable to retrieve positive memories of the deceased, which further exacerbates and complicates the grieving process. As indicated in a nonrandomized multisite study, EMDR therapy reduced symptoms significantly more rapidly than the CBT on behavioral measures and on 4 of 5 psychosocial measures. EMDR was more efficient, inducing change at an earlier stage and requiring fewer sessions (6.2 vs 10.7 sessions). Positive recall of the deceased was significantly greater (twice the frequency) posttreatment with EMDR.

A wide range of patients suffering from debilitating medical conditions can also benefit from EMDR therapy. For instance, the utility of psychological services for burn victims has been reported, with EMDR therapy specifically recommended on the basis of both effectiveness and brevity of treatment. As indicated previously, three to six sessions are generally sufficient to alleviate symptoms from a single trauma. Of particular note is the elimination of both PTSD and somatic symptoms in a burn victim who had been severely debilitated for almost a decade. The rapid alleviation of the patient’s symptoms and return to independent functioning are consistent with the AIP model, which posits that the feelings of helplessness and hopelessness are the result of unprocessed memories of the trauma that contain the perceptions experienced at the time of the event.

These findings have important implications for the medical community in that many chronic pain patients may actually be debilitated by unprocessed memories encoded with the original somatic perceptions. As noted by Ray and Zbik, whereas CBT treatments address chronic pain through cognitive interventions that can reduce distress, EMDR therapy can result in the elimination of the pain sensations. For instance, a number of researchers have reported positive outcomes of EMDR therapy for the treatment of phantom limb pain. The 4 evaluations of patients published to date indicate an aggregate 80% success rate as defined by complete elimination or substantial reduction of pain sensations. According to the AIP model, the phantom pain is caused by the unprocessed memories of the deceased, which further exacerbates and complicates the grief process. The change in the targeted memory results in an elimination of those pain sensations that are not caused by physical nerve damage. Successful elimination and/or reduction of pain to tolerable levels has been reported after 2 to 9 EMDR therapy sessions. Therefore, when no neuropathy is observed in chronic pain patients it is often beneficial to explore the potential results of a short course of memory processing. In addition, EMDR therapy has been reported to be beneficial in the treatment of migraine headaches in an open trial and an RCT.
Potential Neurobiologic Concomitants

The different treatment outcomes and the procedural differences between EMDR therapy and CBT indicate potentially diverse underlying neurobiologic mechanisms. For instance, trauma-focused CBT exposure therapies entail extended, detailed repetitions of the disturbing event that are repeated during both sessions and homework. Research has indicated that prolonged exposures, as used in CBT, result in extinction, whereas brief exposures as used in EMDR therapy trigger memory reconsolidation.7 These differences have significant neurobiologic and clinical implications. As noted by Craske et al, "... recent work on extinction and reinstatement ... suggests that extinction does not eliminate or replace previous associations, but rather results in new learning that competes with the old information." This mechanism is posited to account for relapse. Further, "Extinction is conceptualized as the development of a second context-specific inhibitory association that, in contrast to fear acquisition, does not easily generalize to new contexts."7-12 These factors may account for differences in treatment time, with EMDR therapy reported to be more rapid than CBT in five RCTs,13-15,17-19 as well as reported positive effects obtained with EMDR treatment that have not been reported with CBT (eg, elimination of phantom limb pain, increased positive recall of the deceased). The fact that CBT exposure therapies are posited to leave the original memory intact may be the reason these beneficial results have not been reported with CBT. Likewise, a recent pilot study indicated that six sessions of EMDR therapy with patients with psychosis and PTSD also resulted in "a positive effect on auditory verbal hallucinations, delusions, anxiety symptoms, depression symptoms, and self-esteem."20-22 By contrast, successful CBT has resulted in a continuation of auditory hallucinations that the patient experiences, but with less distress. In the EMDR study, the majority of participants who had initially experienced auditory hallucinations reported that these had disappeared. The findings that "... childhood adversity is strongly associated with increased risk for psychosis"23-24 suggest the need for additional rigorous research evaluating the effects of memory processing with this population.

Future Research

The ACE Study25 conducted at Kaiser Permanente provides an ideal platform for future research to evaluate the effects of EMDR therapy for a wide range of psychological and physical problems pertinent to medical practice. Some of the conditions found in the ACE Study to be correlated with exposure to adverse life experiences in childhood are alcoholism, drug abuse, severe obesity, depression, and suicide attempts. These conditions would lend themselves well to rigorous RCTs in which integrated EMDR therapy protocols that include processing the disturbing memories are compared to current standard care. Both immediate and long-term follow-up of at least a year's duration to evaluate maintenance of treatment gains would greatly inform current medical practices.

Of equal importance is the finding in the ACE Study that ACEs result in the increased incidence of physically debilitating conditions such as ischemic heart disease, cancer, chronic lung disease, skeletal fractures, and liver disease. Rigorous longitudinal studies to evaluate the utility of EMDR therapy for preventive care would provide the medical community an important opportunity to determine whether processing the memories of adverse experiences can ameliorate these detrimental effects. The social policy and financial implications of such studies underscore their importance in providing optimal care.

For any of the suggested studies, it is vital that clinical personnel with appropriate treatment fidelity carefully assess the nature of the disturbing events in the patient’s history and allocate adequate treatment time to process a sufficient number of memories to potentially achieve asymptomatic status. As reported in the ACE Study,26 there is a "strong graded relationship between the breadth of exposure to abuse or household dysfunction during childhood and multiple risk factors for several of the leading causes of death in adults."24-25 As indicated previously, a short course of EMDR therapy may be sufficient to eliminate a variety of psychological and somatic conditions. However, patients who have been serially abused throughout childhood will generally need more treatment time to achieve comprehensive adaptive resolution.1,20 Given that EMDR treatment effects generalize to similar memories, it is unnecessary to process each disturbing event. However, sufficient time should be provided to process the relevant memories within the various categories of adverse experiences.

For all the suggested studies, the inclusion of procedures to identify epigenetic and neurophysiologic changes subsequent to treatment also opens the door to potentially important assessment possibilities. Since EMDR therapy can be provided on consecutive days, successful treatment can be accomplished over a matter of weeks, rather than months, which can reduce time confounds and provides both efficient and cost-effective research opportunities.

Conclusions

A substantial amount of research indicates that adverse life experiences may be the basis for a wide range of psychological and physiologic symptoms. EMDR therapy research has shown that processing memories of such experiences results in the rapid amelioration of negative emotions, beliefs, and physical sensations. Reports have indicated potential applications for patients with stress-related disorders, as well as those suffering from a wide range of physical conditions. The medical community can also benefit from the use of EMDR therapy for prevention and rehabilitative services to support both patients and family members. A thorough assessment of potential experiential contributors can be beneficial. If relevant, EMDR therapy can allow medical personnel to quickly determine the degree to which distressing experiences are a contributing factor and to efficiently address the problem through memory processing that can help facilitate both psychological and physical resolution. Rigorous research of the use of EMDR therapy with patients suffering from the conditions identified in the ACE Study can further contribute to our understanding of the potential for both remediation and preventive care.

Disclosure Statement

The author(s) have no conflicts of interest to disclose.
The Role of Eye Movement Desensitization and Reprocessing (EMDR) Therapy in Medicine: Addressing the Psychological and Physical Symptoms Stemming from Adverse Life Experiences


58. For the eye altering alters all.

—The Mental Traveller, William Blake, 1757-1827, English poet, painter, and printmaker
Pay for Performance for Salaried Health Care Providers: Methodology, Challenges, and Pitfalls

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Abstract
Pay for performance has been recommended by the Institute of Medicine as an incentive to improve the quality of health care. Traditional quality-improvement methods may be adapted to evaluate performance of salaried providers, but it is important to separate provider contributions from other influencing factors within the health care system. Accurate recording, extraction, and analysis of data together with careful selection and measurement of indicators of performance are crucial for meaningful assessment. If appropriate methodology is not used, much time, effort, and money may be expended gathering data that may be potentially misleading or even useless, with the possibility that good performance may go unrecognized and mediocre performance rewarded.

Introduction
Pay for performance has been recommended by the Institute of Medicine as an incentive to improve the quality of health care. It is based on the notion that financial remuneration of health care providers should be proportionate to the quality of care they provide. Implicit in this concept is the belief that improvement in provider performance will result in improvement in the overall quality of medical care, an intuitively attractive assumption that remains unproven. If this concept is correct, it is reasonable to assume that the assessment of provider performance should follow generally accepted principles of quality improvement (QI) currently used in health care settings. Although such principles usually apply to systems or microsystems within a larger system, they may be adapted to evaluate performance of individual providers or groups of providers within a discipline.

Yet, in contrast to institutional QI initiatives, pay-for-performance initiatives have two unique characteristics. First, they must measure the contribution of the providers being assessed independently of the contributions of other components of the health care system, including those of other types of providers. Second, a monetary value must be assigned to the degree of improvement measured, necessitating value judgments that may be somewhat arbitrary, especially when comparing different groups of providers in different settings or specialties.

One of the most important steps in assessing provider performance is the choice of one or more measures of that performance, often referred to as metrics or indicators. If indicators are not carefully chosen, all subsequent improvement efforts may be limited or even useless. Moreover, it must be possible to extract and analyze data relevant to the indicators in an efficient, timely manner. Therefore, much of the discussion that follows in this article will focus on indicator selection, documentation, and measurement.

An extensive literature on pay for performance and its advantages and disadvantages exists, including a number of systematic reviews and case models. That information will not be reviewed here. Rather, the methodology, challenges, and pitfalls relevant to the implementation of pay for performance for salaried health care providers within a health care organization will be presented.

Initial Selection of an Indicator
Indicators may relate to any aspect of medical care for which need for improvement is known or perceived based on past performance, variability of care, or adverse outcomes. Although indicators may be chosen for individual providers, they are more often selected by departments within a system for use by all providers within that department. Provider performance may be assessed individually or collectively within a discipline; the latter may be preferable for departments with low patient numbers or substantial shared patient management. The initial choice of an indicator is tentative and its final selection depends on defined need for improvement and feasibility concerns, discussed below.

Candidate measures may be proposed by any individual or group within a department, with subsequent review and selection through the use of focus groups or the department as a whole. Ideally, preexisting consensus-based measures would be chosen when possible, including those suggested by national groups such as the American Medical Association, Physician Consortium for Performance Improvement or the Centers for Medicare & Medicaid Services. In addition, measures should be selected for which baseline performance is low, permitting larger effect sizes (see Sample Size Considerations section). Performance indicators should not only have face validity, but improvement associated with them should also be consistent with improvement associated with other indicators that evaluate similar aspects of health care (construct validity). They should also be amenable to consistent measurement (reliability). At the same time that indicators are considered, interventions to improve performance as measured by the indicator should be formulated, together with a tentative plan for their implementation. Literature review should establish an evidence base for the indicator and, if possible, the interventions.

At times, composite indicators may be chosen that combine multiple indicators of quality into an aggregate score. This
approach is especially attractive if sample size is inadequate for an individual metric but acceptable for the aggregate. Of necessity, this requires assignment of defined weights to each component metric, a process that may be arbitrary. Such an approach may be useful for the tentative analysis of data over short periods, but it obscures the individual performance contributions of the component metrics, allowing superior performance on one component to compensate for poor performance on another.9

Structure, Process, and Outcome

Traditional quality measurements have been categorized into three domains: structure (characteristics of the health care environment), process (care administered to the patient), and outcomes (health status of the patient). These domains continue to be emphasized by the Health Resources and Services Administration of the US Department of Health and Human Services.10

Structure measures describe features of a health care organization relevant to its capacity to provide health care, usually as manifestations of the setting in which health care is administered and the policies that direct that care. Although such measures may be affected by provider performance, structural measures are poor indicators for assessing individual providers because they also reflect the net result of system factors beyond provider control (confounders).11 Structural confounders may sometimes be controlled for in analyses, but they are often multiple, vaguely defined, and difficult to quantitatively separate from one another.

Outcomes, such as medical conditions, would appear the most desirable measures of provider performance because they assess patient health status after care and are important in their own right. Yet, although outcomes may sometimes be uniquely attributable to provider performance they, like structure, usually reflect the impact of other confounding factors. In addition, random variation may contribute to outcomes, rendering sample size considerations crucial to interpretation of outcome data. Finally, many outcomes may have low incidence in the patient population studied, making statistical significance difficult to achieve. Several preconditions have been recommended for the selection of outcome indicators, including adjustment for confounders.2,5,12

In contrast to structure and outcomes, processes under direct provider control may be more sensitive indicators of individual provider performance.5,13 Processes are usually not as vulnerable to the effects of confounders and may reflect true changes in provider behavior. Moreover, process indicators are easier to extract from the medical record and interpret, such that data extraction may be less time consuming and statistical analysis more simplified, often requiring only bivariate methods. In contrast to the minimal improvements usually observed for outcome measures, process metrics generally yield better improvement rates.5,15

Improvement in an indicator requires selection of an intervention to improve performance. For process indicators, the intervention should lead to improved performance of the process. For outcome indicators, the intervention should facilitate improvement in a process (one or more specific provider behaviors) that will lead to improvement in the outcome. Clearly, analysis of a process indicator will be simpler and more direct than analysis of an outcome indicator. Characteristics of process metrics and an approach to formulating them have been outlined by Rubin et al.16,17

For a process to be of value as an indicator it must be linked to an improved outcome,14,16 and this linkage should be evidence based. This is a very important prerequisite for choice of any process metric; and in its absence, the choice of metric is unjustified.

Confounders

Confounders are factors other than provider performance that may influence the indicator being measured. Unless documented and quantified, these factors may confound measurement of the indicator with a magnitude that distorts or obscures the contribution of the providers being assessed. Examples of confounders include aspects of case mix, such as demographic and socioeconomic factors, comorbid medical conditions that may affect the indicator, and contributions of other health care providers from other disciplines. Case mix is especially relevant to QI efforts if 1) measures of improvement are related to patient characteristics and 2) the same characteristics differ in their distributions among populations being compared.19 Case mix characteristics are usually intrinsic to the patient and would not change if the patient were assigned to another population.

To dissect the provider contributions to an indicator, meticulous documentation and measurement of all other contributing factors, often referred to as risk adjustment, is required. This may be difficult, as much of this information is not routinely documented in the medical record and may be time consuming and expensive to obtain. Although direct and indirect standardization methods may correct for confounder effects on indicators, regression methods provide the best means of adjustment.20 Failure to appropriately adjust for confounders may lead to erroneous results and mistaken conclusions whenever populations are compared, whether the comparison is among clinical units, to national benchmarks, or between groups of patients within the same unit before and after an improvement initiative. If ignored, confounders may obscure good provider performance and compensate for poor provider performance.

Examples of Structural, Process, and Outcome Indicators for Assessment of Provider Performance

1. A Structural Measure with Multiple Confounders

Time to third next available appointment, the average length of time in days between the day a patient makes a request for an appointment and the third next available appointment, is a structural measure of access to care that has been recommended by the Institute for Healthcare Improvement.20 For example, a dermatology group chooses this indicator as a measure of its performance for the upcoming year after an intervention to increase the number of patients scheduled daily per physician. However, they practice in a rapidly growing health maintenance organization in which membership continues to dramatically increase. In addition, a midlevel provider that conducts group visits for acne patients at the clinic
Summary of Pay-for-Performance Methodology

**Define major data for uniform documentation within each specialty**
- Historical aspects
- Symptoms
- Signs
- Physical findings
- Laboratory data
- Radiography
- Diagnoses
- Therapies
- Outcomes

**Factors influencing outcomes (confounders/risk adjustment)**

**Data recording and analysis**
- Modify electronic medical record to facilitate ongoing discipline-specific improvement efforts
- Provide fields for structured data
- Adopt standardized phraseology for unstructured charting (semistructured)
- Allow customization/addition of new fields for structured data as needs arise
- Develop temporal tags for structured entries
- Facilitate
  - Simple, rapid query of structured and semistructured data by providers
  - Export of query results into database
  - Analysis of database data with statistical software

**Indicator selection**
- Process measures with evidence-based link to favorable outcomes
- Proposed by individuals and/or focus groups
- Applicable for provider groups/departments
- Review literature to confirm evidence base
- Measurable
- Valid
- Reliable
- Suboptimal past performance or new practice
- Confounders defined and measurable (risk adjustment)
- Sample size adequacy (number of patients, time periods for analyses)
- Define anticipated magnitude of meaningful improvement

**Implementation of practice change during interim period**

**Interventions to enhance performance**
- Continuous performance evaluation and feedback
  - Run/control charts
  - Bivariate statistics for before-and-after comparisons
  - Multivariate techniques to control for confounders

**Define relationship between magnitude of improvement and remuneration**

Other structural metrics frequently chosen to assess QI include reduction of door-to-balloon time (the interval between arrival in the emergency room and cardiac catheterization for a patient with myocardial infarction), enhanced operating room block use, reduction of hospital readmission rates, and improved Emergency Department use. These are all excellent improvement initiatives for a hospital or health care system, and in some cases it may be feasible to measure and control for nonprovider contributions to the outcome, such that provider performance can be independently assessed. However, in most cases this is very difficult if not impossible to accomplish because of multiple, poorly defined confounders, rendering these structural indicators unfavorable measures of provider performance.

2. An Outcome Indicator with Limited Confounders

Vitreous loss during cataract surgery is a complication that occurs in approximately 8% of surgeries. As an example, a group of ophthalmologists observes that their rate of vitreous loss is 16% and embarks on an initiative to improve performance during the upcoming year. After literature review, they determine that the incidence of vitreous loss is dependent on surgeon experience, patient volume, and case complexity. Patient volume in their practice has been fairly constant over several years and they project similar patient numbers for the future. In addition, they have been using a scoring system that provides for preoperative risk stratification of individual cases. They decide to continue to use this score to control for patient complexity in future measurements of surgeon performance. They undertake an educational initiative that includes group review of surgical technique and visits to another practice with a low rate of vitreous loss, after which they begin a year of measurement, with ongoing group review and discussion of each occurrence of this complication. At the end of the year, after risk adjustment, they observe a statistically significant decrease in vitreous loss, with an incidence of 11%.

This is a reliable and valid outcome indicator to which limited, definable, and measurable factors contribute. The risk scoring system provides for ongoing case analyses.
mix adjustment, allowing the contribution of surgeon performance to be evaluated with reasonable accuracy.

3. A Process Measure with Proven Links to Favorable Outcomes

Prenatal steroid treatment for threatened preterm birth has been shown to substantially reduce a variety of morbidities such as respiratory distress syndrome among very low-birth-weight infants. The rate of prenatal steroid treatment is used as a benchmark for the quality of perinatal care by the Vermont Oxford Network, an international collaborative.25 Reviewing the literature at a department meeting and recognizing that the rate of prenatal steroid treatment among their patients has been low for the past year, a group of perinatologists and obstetricians decides to embark on an initiative to improve prenatal steroid administration to eligible patients in the coming year, and a portion of their salary will be based on the degree of improvement. At the end of the year, they observe a significant increase in the rate of steroid administration. However, the incidence of morbidity among very low-birth-weight infants does not change.

Prenatal steroid treatment is a process that the literature has clearly linked to favorable outcomes among very low-birth-weight infants, and because the process is exclusively directed by the perinatologist or obstetrician, it is a reflection of physician performance. Importantly, neither case mix nor other providers substantially influence this process. Such factors may have influenced the neonatal outcomes in the above example, given that they remained unchanged. Although rapid progression of labor with delivery before steroid administration (as might occur with patients who do not seek timely care) could result in reduced apparent performance rates for steroid administration, these cases could be controlled for in analysis. In addition, available benchmark data from the Vermont Oxford Network provide an attractive added benefit.

Provider prescribing patterns are among the best process measures of performance because they are usually linked to improved outcomes, reflect the direct actions of the provider, and are relatively easy to extract from electronic medical records (EMRs). Another useful process measure of provider performance is radiologist report turnaround time, which has an impact on the efficiency of care and has been shown to be affected by pay-for-performance efforts.26 Meaningful use measures, such as maintenance of patient problem, medication, and allergy lists, might be other useful process metrics for similar reasons.7

Improvement of Past Performance: Are Relevant Data Available?

For established health care practices, choice of an indicator is often based on known or perceived suboptimal past performance for that practice. Although subjective impressions or adverse events may prompt proposed indicator candidacy, suboptimal performance should be confirmed by retrospective analysis of performance data. Unfortunately, such data are frequently unavailable and their extraction may require labor-intensive, time-consuming review of medical records. As a result, demonstration of suboptimal past performance often poses a major hurdle that must be overcome if further improvement efforts are to proceed.

Sometimes an indicator may involve the adoption of a new practice that is evidence based and holds promise to provide for potentially better care (potentially better practice).27 Because the practice is new, there are usually no data on past performance that can be used to gauge need for improvement. Often it may be possible to obtain data from other groups, such as community samples, or published performance rates as a benchmark. Calculation of the required sample size (see Sample Size Considerations section) becomes problematic, and estimates of target parameters for improvement may be arbitrary. As a result, there is great potential for either underestimating or overestimating performance targets. An advantage, however, is that with no past performance, even modest improvement may be easy to achieve.

Structured Data in Medical Records

To measure provider performance requires data, which usually must be extracted from medical records. Although such data may be extracted manually from traditional paper records, the EMR has gained increased use in hospitals and physician offices since the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.26,27 Because it is amenable to computerized query, the EMR has great potential to serve as an ongoing source of data for past and current provider performance measures.28 However, the information that can be extracted from an EMR is only as good as that which is entered.29 Consistency of data entry among providers is crucial if accurate data are to be obtained and compared.

Data are most amenable to extraction if they are entered into dedicated or “structured” fields in an EMR.30 Although data such as vital signs, demographic characteristics, medications, and diagnosis codes may be contained within such fields, much information relevant to provider performance is often embedded in unstructured, free-text notes. Information in such form may be influenced by variability in provider charting style and subjectivity of assessment.31 Because it may be positioned randomly within a note, it must be extracted manually or by sophisticated computer programs that are not in general use. At best, this is a laborious process fraught with potential error, due in part to the multiple variations in documentation style among providers. Before embarking on an initiative to improve performance, it is important to determine which variables must be extracted from the EMR to analyze performance, whether they exist in structured or unstructured form, and the degree of effort that will be required for their extraction.

For data to reflect past performance, they must already exist within the EMR. Here lies the problem: To identify areas in need of improvement we need to know past performance, but to know past performance, we need to have appropriate, prospectively recorded data to measure that performance in a consistent, easily extractable form in the EMR. This may be difficult to achieve given the current predominance of unstructured provider data...
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The Importance of Sample Size Determination: An Example

As discussed above, vitreous loss during cataract surgery is an attractive outcome measure that may reflect surgeon performance after case mix adjustment. Consider a salaried ophthalmologist, who finds that the incidence of this complication among her 250 cataract patients was 16% during the past year, much higher than the optimal value of 8% reported in the literature.42 Further analysis reveals that case mix of her patients has been stable with time. Accordingly, she pursues additional training and experience in cataract surgery and chooses this metric to assess her performance for the upcoming year. Discussions with her supervisors lead to the conclusion that she will receive a monetary bonus if she can reduce the rate to 10% during the coming year. After performing 250 cataract surgeries that year, her rate of vitreous loss is 13%, a value deemed not significantly different from the previous year by a χ² test (p = 0.13). As a result, she does not receive the bonus.

If a sample size assessment had been made at the onset of this initiative, it would have been determined that comparing the outcome in 250 patients during the “test” year (after the intervention) to that for an identically sized group during the previous year would yield a power of 0.5. This means that there was a 50% chance of not detecting an improvement even if one had truly occurred. At the ophthalmologist’s current rate of cataract surgeries, it would take 2 years to treat enough patients (500 to compare to a similar group for the previous 2 years) to attain a power of 0.80. Thus, it is entirely possible that the surgeon was performing at a higher level but that her improvement went undetected, with consequent loss of remuneration.

Databases and Statistical Programs

Ideally, data fields for quality initiatives and pay-for-performance measures would be integrated into evolving EMR systems as the latter are developed instead of retroactively, a more difficult task.32 The EMR populations should be amenable to rapid and efficient query by members of the QI team to obtain information needed for performance analysis. The results of such queries should be exportable into charting in the EMR. Quality measures based on unstructured fields are likely to be inaccurate.38 Changing provider documentation styles to achieve consistency and enhanced use of structured charting may be needed.

Within any medical specialty there is a body of discrete data for which fields could be generated within an EMR for provider use. These could take the form of separate pull-down entries or standard phrases that could be consistently used by providers within that specialty in a given patient care situation. For inpatient care, temporal linkage of structured data would be helpful for future analysis (eg, time since admission, surgery, delivery, rather than absolute date and time). If this could be achieved, retrospective data extraction for performance analysis could be easier.

Sample Size Considerations

A frequently overlooked aspect of performance analysis is adequacy of the size of the analyzed sample of a population. If sample size is inadequate, there is a substantial risk of concluding that there was no change in performance when, in reality, a change did occur.39 This phenomenon is referred to as a type II error, and its probability is symbolized by the Greek letter β. Statistical power (1 - β) is the probability of correctly rejecting a false null hypothesis and detecting an effect that truly exists. Before any measurement of performance is made, the minimum adequate sample size should be determined. It is always desirable to maximize power, and typically a value of 0.8 or greater is chosen.

Statistical power is primarily determined by four factors: α level, directionality of measurement, effect size, and sample size.35

1) The α level, traditionally symbolized by the letter p, is the probability of rejecting the null hypothesis when it is true, thereby concluding that a difference is present when it is not. Most frequently, a p value of 0.05 or less is chosen as an acceptable α level.

2) Directionality of measurement is implicit in the process of QI initiatives, given that we usually hypothesize that our interventions will improve, rather than worsen, performance metrics. As a result, we may confidently use one-tailed, rather than two-tailed, statistical tests in our analyses.

3) Effect size assesses the anticipated magnitude of change with respect to a given metric. The effect size is usually not under our direct control when we embark on an improvement initiative, because we cannot predict how much of an improvement will occur. We might estimate effect size on the basis of past changes in our population or on the basis of improvement results reported by others (benchmarking). And although effect size may be arbitrarily estimated, its magnitude will have practical implications only within a particular clinical context. Lower baseline performance may permit greater room for improvement and a greater effect size.5

4) Of the factors that influence statistical power, sample size has the greatest impact. With increasing sample size, the standard error of the distribution sampled is progressively reduced. Adequacy of sample size should always be determined before beginning any improvement initiative.

Sample size calculations will depend on the statistical test chosen for comparative analysis. Choice of an inappropriate statistical test for comparison may influence the power. For example, applying parametric rather than nonparametric tests to nonnormally distributed data reduces power and increases the probability of a type II error, a common mistake in the analysis of Emergency Department length-of-stay data.31

After choosing the appropriate statistical test to compare the outcome of interest before and after the initiative, it is reasonable to choose the one-sided version of that test and set the α and β levels to 0.05 and 0.20, respectively (80% power). Once these parameters are set, the magnitude of the observable effect will be determined by the sample size available for analysis. Generally, larger numbers of subjects are required to detect smaller changes in performance.

Several Web sites are available that permit determination of the sample size required to achieve a desired effect size.35,36 Sample size should be determined a priori, but power may also be assessed periodically during the accumulation of data, permitting termination of study when an adequate sample size is achieved.
database programs. However, this may not be possible, especially if the EMR lacks the required structured data fields or is not amenable to easy query. In cases such as this, a separate database into which data may be entered manually may be required.

After population data are entered into a database, preliminary analyses may often be performed within that database. Some database programs permit performance of elementary tasks, such as sorting, variable definition, and bivariate statistical analyses. However, more sophisticated statistical procedures, such as multivariate analyses, are best performed with a statistical program that can import data from database programs.

**Choice and Implementation of the Intervention**

The intervention is essentially a prompt to foster performance improvement. It may take many forms and will attempt to facilitate a change in provider practice that either constitutes (process) or affects (outcome) the indicator. Given that the providers will have selected the indicator as a measure of performance, they will presumably be keenly aware of the need to improve and of the financial incentives for doing so. It is assumed that this awareness will be adequate to implement the performance change. However, educational interventions in the form of formal presentations, posters, and message prompts may help to maintain this awareness. If analysis of past performance, ongoing monitoring, or both reveal suboptimal performance for certain individuals within a department, feedback could be provided to those providers. Periodic review of performance could also be presented at regular department meetings, with case review as needed. A method for implementation of practice change was previously reported.

**Ongoing Monitoring of Performance**

Performance improvement is best assessed by comparison of sequential time periods before and after the implementation of an initiative using bivariate and multivariate statistics as appropriate. In addition, control charts may be useful in determining ongoing trends during an improvement initiative, with continuous feedback to providers and ongoing review of cases. Because of the time required to implement practice changes, it may be advisable to allow for an interim period between the periods to be compared, during which time changes may be made. Use of moving averages or rolling period analysis may add precision when samples are small during individual time periods; however, this approach is insensitive to changes from one period to the next. Moreover, there is a middle-period bias, such that higher performance in the middle period will yield a higher rolling period performance rate than will performance at either end period. Thus, more recent improvements may go unrecognized.

**Incentives and Meaningful Magnitude of Improvement**

For general QI initiatives, any improvement that is statistically significant and clinically meaningful may be considered important. However, translating the magnitude of improvement into monetary compensation becomes a challenge. Inevitably, somewhat arbitrary value judgments must be made in such assignments, especially when comparing different metrics among departments or specialties. Moreover, all metrics may not be amenable to similar degrees of improvement, even with the best efforts on the part of individual providers. Providers with poor past performance have greater potential for improvement, in contrast to high-performance providers with less room for improvement.

Most frequently, improvement incentives consist of financial rewards that may be based on either a defined threshold for improvement or a continuous scale. In general, they produce a greater positive effect for low performers than for high performers. However, the relationship between incentive size and improvement effect has not been established. The frequency of incentive payment has been reported not to affect performance.

**Statistically Significant Change Versus Meaningful Change: The Example of Patient Satisfaction**

It is important to be aware that all statistically significant improvements may not be clinically meaningful because of their magnitude. A good example of this phenomenon is the measurement of patient satisfaction. Although few studies have demonstrated that patient satisfaction is associated with quality of provider care, satisfaction surveys have been recommended as a quality indicator by the Institute of Medicine and have been adopted by many hospitals and practice groups. Consider the following example: A large multidisciplinary group practice uses satisfaction surveys to assess the quality of physician care during recent office visits and hospitalizations. These surveys yield scores that range from 0% to 100%. The practice has determined that scores on the surveys will partially determine physician bonus payments within departments. During sequential 12-month periods, scores for medical subspecialty care increased from 94% to 96%. However, scores for surgical subspecialties declined from 94% to 93%. Both of these changes were statistically significant, with p < 0.01.

Studies of patient satisfaction tend to show high levels of undifferentiated satisfaction, with most respondents rating the quality of provider care very high, even when assessed across multiple categories. One consequence is that large patient samples are required to detect significant changes in performance ratings, because scores may already be near the top of the measurement scale, with little room for improvement. Even if significant changes are observed, the magnitude of change is likely to be small and of questionable practical importance, as shown in the above example. It has been suggested that satisfaction surveys should attempt to focus on dissatisfaction with care rather than satisfaction. If results of satisfaction surveys with high levels of satisfaction are chosen as a basis for provider remuneration, it might be preferable to reward sustained high performance above a chosen threshold, rather than small but statistically significant changes of questionable practical importance.
literature, modify charting methods, and set up databases to prospectively monitor improvement. In some cases it may be reasonable to provide compensation for these efforts, yet the magnitude of compensation for particular levels of progress will remain arbitrary. In addition, some initially attractive metrics may later prove impractical for unforeseen reasons, but only after the expenditure of considerable effort to explore their feasibility. The possibility of such results must be anticipated and provisions made for appropriate remuneration for efforts expended.

Even when appropriate indicators are chosen and optimal computer facilities are available for documentation and analysis, a substantial amount of time is required to complete an assessment of performance. One or more individuals comfortable with the methodology described above should be designated to coordinate these efforts, and the cost of their financial remuneration should be anticipated at the onset.

Summary and Conclusions

Most aspects of pay for performance are not unique but are shared by QI initiatives in general (see Sidebar: Summary of Pay-for-Performance Methodology). Achieving uniform consensus-based, specialty-specific documentation in the EMR is a worthy goal in its own right. An especially important aspect that has not received adequate attention in the literature is the need for EMRs that are more conducive to data collection for quality purposes, with structured charting and capacity for rapid query by improvement teams. Current EMRs are deficient in these attributes, and investment of time and resources to rectify these deficiencies would greatly enhance the capability and efficiency of all future QI efforts.

In pay for performance, process indicators with known links to favorable outcomes are preferred to outcome or structural indicators, and a priori determination of sample size adequacy is crucial if erroneous conclusions are to be avoided. Continuous evaluation of performance with ongoing feedback to providers during the initiative is also critical. Yet even if improvement can be rigorously accomplished, achievement of equitable remuneration among provider groups will remain a challenge because of the arbitrariness inherent in assigning monetary value to the degree of improvement.

The methodologic goals outlined above are neither esoteric nor complex. They are basic, achievable, and important for accurately conducting provider-specific QI initiatives. The technologies required to implement them are simple and inexpensive in any setting with EMRs and a personal computer. If this methodology is ignored, much time, effort, and money may be expended in gathering data that may be potentially misleading or even useless, such that good performance may go unrecognized and mediocre performance rewarded.

Disclosure Statement

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A Unique Service

No greater opportunity, responsibility, or obligation can fall to the lot of a human being than to become a physician. In the care of the suffering he needs technical skill, scientific knowledge, and human understanding. He who uses these with courage, with humility, and with wisdom will provide a unique service for his fellow man and will build an enduring edifice of character within himself. The physician should ask of his destiny no more than this; he should be content with no less.

—Tinsley R Harrison, 1900-1978, American physician and editor of the first five editions of Harrison’s Principles of Internal Medicine
Sukhna Lake is an artificial lake in the foothills of the Himalayas. Created in 1958, the lake is an integral part of the city of Chandigarh and in winter months becomes a sanctuary for exotic migratory birds.

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Eluding Meaninglessness: A Note to Self in Regard to Camus, Critical Care, and the Absurd

Thomas John Papadimos, MD, MPH

Abstract

Here I present a medical narrative, as a catharsis, regarding Albert Camus's The Myth of Sisyphus in an attempt to elude meaninglessness in my difficult everyday practice of critical care medicine. It is well documented that physicians who practice critical care medicine are subject to burnout. The sense of despair that occasionally overwhells me prompted my rereading of Camus's classic text and caused me to recount his arguments that life is meaningless unless one is willing to take a leap of faith to the divine or, alternately, to commit suicide. This set up the examination of his third alternative, acceptance of a life without prima facie evidence of purpose and meaning, a view that may truly have some bearing on my professional life in the intensive care unit.

Introduction

All life ends. I spend most of the hours of my days trying to delay or avoid the inevitable on behalf of my patients in the intensive care unit (ICU). At times I can put it off for days; sometimes I can help it off for decades. Physicians who practice critical care medicine (intensivists) are at the forefront of treatments that confront the complicated, the futile, the end of life, hopefulness (and hopelessness), and, at times, a search for the meaning of such efforts. As an intensivist I live in the present. I try to get my critically ill patients through the day. I formulate treatment plans with foresight, but I know that setbacks occur in the care of such patients. At the end of the day I hope that things have gone better than the day before. In effect, an intensivist cannot live anywhere but in the present, and in this "present" I contemplate the effectiveness of my efforts, and at times the futility of these efforts that I struggle with on behalf of my patients and their families. I realized that as an intensivist I am subject to burnout. I made a note to myself to locate an old text that I had read in my youth and to reread it: The Myth of Sisyphus by Albert Camus. I recalled that its content struck a bell somewhere in my remote memory in regard to my current situation.

Upon reexamination of this text I came away a little disturbed because I could see parallels in Camus's arguments that apply to my practice of critical care medicine, especially in times of despair. I truly try to elude the feelings of meaninglessness that his dialogues address. Camus claims we will never find the meaning we seek. He insists we need to make a leap of faith and place our trust in God or conclude that life has no meaning, thereby allowing ourselves no alternative but to commit suicide (because life is meaningless). Indeed, there are times when my efforts seem meaningless, especially when I cannot get a good result for my patient or if I cannot get the patient's family to understand that there will be no meaningful result for their loved one. In these cases the universe remains deafeningly silent. Even if I wish to make that leap of faith to the divine in order to help me understand that there is meaning to this existence, Camus's arguments lead me to believe that he is correct on some philosophical level (understanding that he was a novelist who had a philosophical perspective and that I am a physician who dabbles in philosophy at the edges, which makes neither one of us philosophers—me less so than him, but both have an appreciation of the fact that we need to know not so much how we do things but why). I struggle daily to fight back against Camus's perspective on these matters.

What really interested Camus was starting a discourse on his third alternative. He poses the interrogative, "Can we accept a life without purpose and meaning and continue our existence?" This is quite an intellectual quagmire for an intensivist. It may be that Camus's third alternative can come to pass, albeit not entirely on Camus's terms.

Discussion

In The Myth of Sisyphus, Camus points out that there is an absurdity that humans face in that we seek meaningfulness in the things we do but the universe remains silent in the face of our queries. Humans are not absurd, and neither is the human mind, but as we seek clarity in regard to our surroundings, actions, and existence in a world that does not seem rational to us, we encounter silence and irrationality from our universe. According to Camus, the absurdity is this conflict, or confrontation, between this search for meaning and its concealment from us. An intensivist must live with this contradiction and must struggle against it. This contradiction cannot be reconciled, being aware of it is all I can do (Camus's above-mentioned third alternative). In other words, the successful intensivist does live in the moment the vast majority of the time. Critical care medicine requires an intensity of purpose and focus. By living in the moment and by concentrating on helping my patients, I elude meaninglessness—or so I think. I am successful in doing so by acknowledging my conflict with the absurd and living my life fully in the face of it.

According to Camus, the three characteristics of the absurd life are revolt, freedom, and passion. Examples of the absurd life presented by Camus in The Myth of Sisyphus

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include the seducer, the actor, the rebel/conqueror, and the writer. Here I will confine myself to using the example of the conqueror because it seems appropriate in reference to the mission and personality type of intensivists (conquerors of disease/critical illness).

In regard to revolt, I can hope for unity and order, but I must realize that it will never come to pass. Camus tells me that I cannot accept any answer or reconciliation in my struggle, that I live in a state of perpetual conflict, a state of revolt with no hope—it is the absurd. Although this may not make sense to many, in the ICU I confront this consequence daily.

How so? First, I provide care for patients for whom I know death or disability is a probable outcome, yet their families push me to engage in maximizing futile care, and I acquiesce. I understand that this is wrong on a medical, social, ethical, and economic level, but I do not deny them that care nor deny the family their wishes. I hint, cajole, plead, and try to bring the family to an action (or inaction). I struggle against death and disability even when we know there is no hope of success.

Second, many ICUs actually lack goals of care for the patient (goals that palliative care teams can provide if used appropriately). Without goals of care, the ICU environment becomes an arena for the provision of high-intensity care. In other words, every laboratory test and every number is corrected, regardless of any apparent futility (there are low-intensity care units where goals of care take priority and the end of life is not based on a lab test, but is a failure to achieve the aforementioned goals of care). The ICU team wades in against the inevitable, waiting for a condition of unity and order that will never appear. Therefore, in regard to Camus’s view of revolt, he will find a sympathetic ear on my part.

Camus claims that men and women should be free to do anything they wish because life has no value or meaning. In other words, every minute of one’s life should be free of constraint. Camus keeps his ideas of freedom on an individual/nondivine level and forgoes imbuing his thoughts with the concepts of the divine or rational thought. Freedom, in the ICU, can be linked to a Camusesque political struggle (in many ways similar to Camus’s conqueror). These political struggles many times are between the intensivist, the family, the primary care team, and the hospital administration or any permutation thereof. This freedom and political struggle are connected. I constantly wish to act as I see fit in regard to the patient’s best interests and wish to act without constraint in their behalf. I try not to have regulations, statutes, and orders that are thrust upon me by outside forces prevailing on my practice. This is frequently not possible.

I work with many suffering patients and, at times, I am left with some level of despair, in that 45% of all patients who are dying do not realize it, 22% of patients in the US die in ICUs, and up to 58% die in hospitals.

However, the reason that I continue to persist in my curative and resuscitative efforts must be because, at some level, my self identifies the work I do as important, regardless of the fact that there is concealment of any value or meaning. Nonetheless, I struggle against this concealment. But here Camus may err to a degree. I am free to help patients because I choose to do so. There is nothing metaphysical about this. It is a rational choice, devoid of the divine. No one makes me do it. I choose on a daily basis to enter the daily critical care grind of my own volition. I am free of constraint or action. My actions have nothing to do with conformity.

The passion of the moment is very real in critical care medicine. The absurd man or woman will live only in the present, with no concern for the future or the past. The present is the only time of importance. If life has no meaning then living fully in the present is the best that I can do. The present then has more intensity. That is very appropriate in my line of work. This allows Camus to make the argument that passion occurs because of the quantity of experiences in the present. Even though I may fight this, I do indeed live in the present. An intensivist seems to need to do so. The future and the past do not preoccupy me in my daily duties. When a patient is in extremis, or on an identifiable death trajectory, I can only live in those immediate moments. An intensivist usually takes a 7- to 14-day rotation, and in that 1 to 2 weeks there is little time to look back or to look forward. If a patient dies, it is truly a most unfortunate event, but I must complete rounds, take new patients, and face the postmortem analysis at a much later date (usually at a monthly meeting). Here there is pressure to acquiesce to the arguments of Camus in his perception of passion to avoid the meaningless of absurdity. In critical care medicine there is a vast quantity of moments. These moments do serve to make me live in the present and to live my professional life to the fullest.

Even though I feel the qualitative absurdity of my quantifiable experiences, I continue to struggle with what is meaningful and doable. Is it possible for me to live with merely what I know? In most situations, even if I did hope for divine intervention, it probably would not arrive; but, of course, I would not contemplate suicide under these circumstances. My frustration does, in fact, lead to revolt (at least intellectually). The truth in regard to my freedom is that it is constrained in the arena of patient care (although maybe not in my personal life) even though I am absolutely free to think and behave as I choose. The vast majority of us do what we can in the present on the basis of our experience (quantity), which is a source of passion. With regard to the practice of medicine in the ICU environment, Camus may falter a bit on freedom, but as to revolt and passion he scores well. However, any attempt on my part as to a conclusion merely leads to more questions. Am I like Sisyphus? Do I just roll a rock up a mountain only to have it roll back down at the end of a long, hard day? Do I struggle for my patients without hope of success? Is there more for me than these daily struggles?

In this narrative I take a Camusesque look into my self, because his work *The Myth of Sisyphus* struck a chord in the deepest, most reflective portion of my self. All of us who provide health care occasionally reach down deep into our being and seek an answer or explanation only to find that the cosmos comes up wanting. Especially when it comes to an explanation to soothe our innermost frustrations and conflicts.
Conclusion

Reflection through medical narratives, particularly a disquisition of 21st century dialectics and discourses interpreted through the eyes and examination of thinkers and doers who predated us may be a source of resolution, explanation, or comfort for those of us who struggle with the ethics, conflicts, and concerns of modern-day medical situations and controversies.

Although Camus rejects the metaphysical and insists on asking me (from the grave) if I can accept a life that, from his perspective, is without purpose and meaning (the third alternative), I can only respond to him in the affirmative. I go through my long, busy workdays in the ICU without thinking about anything metaphysical, let alone divine. Whether I believe in God is essentially irrelevant in this context. People are sick. They need to be cared for. The job needs to get done. I am absolutely focused on the task at hand.

Furthermore, I am not committing suicide because my rebelliousness, freedom, and passion do indeed keep me interested, concerned, connected, and engaged. I do not expect anything or anyone divine to step up and solve my problems or to save my patients. So yes, Mr Camus, I am happy. I am not impaired or paralyzed by the thunderous silence of the cosmos. And no, Mr Camus, I am not going anywhere tonight, except to bed. I am going to get up in the morning, have my cup of coffee, and go back for another busy day of stamping out disease and pestilence—meaninglessness eluded.

A note to self can be a very good thing.

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References


What I Understand

What I know, what is certain, what I cannot deny, what I cannot reject—this is what counts. I can negate everything of that part of me that lives on vague nostalgias, except this desire for unity, this longing to solve, this need for clarity and cohesion. I can refute everything in this world surrounding me that offends or enraptures me, except this chaos, this sovereign chance and this divine equivalence, which springs from anarchy. I don’t know whether this world has a meaning that transcends it. But I know that I do not know that meaning and that it is impossible for me just now to know it. What can a meaning outside my condition mean to me? I can understand only in human terms. What I touch, what resists me—that is what I understand. And these two certainties—my appetite for the absolute and for unity and the impossibility of reducing this world to a rational and reasonable principle—I also know that I cannot reconcile them. What other truth can I admit without lying, without bringing in a hope I lack and which means nothing within the limits of my condition?

—_The Myth of Sisyphus and other essays._ Albert Camus, 1913-1960, French Nobel Prize winning author, journalist, and philosopher
Person-Focused Care at Kaiser Permanente

Jim Bellows, PhD; Scott Young, MD; Alide Chase, MS

Abstract
Patient-focused care has been described as an extension of patient-centered care, recognizing that patients’ medical needs are best understood and addressed in the context of their entire lives, including their life goals and social, economic, emotional, and spiritual functioning. Kaiser Permanente is expanding its ability to care for members as whole persons, not just as patients, with sensitivity to nonmedical factors in planning and delivering care. We describe emerging examples in several areas: interdisciplinary care planning, behavior change, social care, patient-reported outcome measures, and Total Health. Realizing the vision of person-focused care requires taking every opportunity to fully recognizing that each patient we serve is first and foremost a person.

Behavior Change
The whole person is also at the heart of new approaches to help members improve health-related lifestyle behaviors. Traditional models of behavior change focus on behaviors carrying the greatest risk, such as tobacco use or physical inactivity, and seek to motivate change by educating patients about the risks and consequences of lifestyle choices. However, substantial evidence indicates that behavior change is most effective when based on personal goals and embedded into personal routines, rather than originating from externally defined goals or instructions. Accordingly, three facets of KP’s developing person-focused approach to behavior change reflect the importance of context. First, members identify and address health-related behaviors they are most ready to improve, even if these are not their highest risks, with the understanding that success can build self-efficacy and lead to changes in higher-risk behaviors. Second, members are encouraged to link positive behaviors with “triggers” occurring in daily life, using them to prompt desired healthy behaviors. Third, members are encouraged to build “optimal defaults” into their routines; such that healthy choices become default choices and less-healthy choices require extra effort. Person-focused behavior change was featured at the 2012 annual meeting of KP’s Care Management Institute (CMI), which is working with several Regions to translate these concepts into their health education and behavior change programs.

Care Planning
Traditional treatment plans, written from a clinical perspective by a physician or nurse, document planned diagnostics or therapies. Demonstration projects in the Northwest and Colorado Regions aim to dramatically improve care for members, many elderly, with complex needs. At the center of each project are interdisciplinary, person-focused care plans including patient preferences, motivations, and goals, in addition to anticipated medical treatment. A communication tool for members, physicians, and other providers such as case managers and social workers, person-focused care plans summarize the results of shared decision making and describe how providers will work together to address patient needs. Providers considering new treatment can refer to the shared plan to ensure coordination with other care and check alignment with the person’s preferences, goals, and circumstances.

Social Care
Life circumstances provide important context in providing care for any person but can impose real constraints in caring for those with unmet needs for housing, transportation, healthy food, or personal care. Care often fails if it does not address...
life circumstances, especially among those who are frail, have dementia or mental health disorders, or are socially or economically vulnerable. KP has a long history of addressing social health needs, eg, the Northwest Region’s Social Health Maintenance Organization program that operated until Medicare discontinued funding in 2001.4 Recent awareness of the interrelationship of unmet social needs and high health care costs has led many Regions to attempt closer integration of health care and social services. Initial efforts include creating “navigator” or “integrator” roles: KP staff who help members connect with community-based social services. Institutional partnerships also reflect closer integration of health and social services. A simple example is KP medical care in assisted living facilities, improving access and allowing elders to receive care in a safe, familiar environment. Other partnerships to jointly address related health and social needs are under development.

**Patient-Reported Outcome Measures**

Measures gauging health care quality performance can influence the evolution of care delivery. In addition to measures of physiology or utilization, patient-reported outcome measures (PROMs)—patient self-reported outcomes, such as symptom management and functional status—can move care toward patient-centeredness. PROMs can also move care toward person-focus if they assess whether care is aligned with patient preferences and is yielding improved health and social function. Improvement teams in several KP Regions are implementing person-focused PROMs. For example, cancer patients in Orange County are asked, “Have you had any trouble meeting the needs of your family?” and in the Northwest and Hawaii Regions, complex care patients will soon be asked, “How often did the doctors and other staff help you with the things that worry you the most?” These steps, albeit small and early, add to our understanding of whether care supports social function, in additional to physical and behavioral function.

**Total Health**

At the broadest level, KP is enacting its commitment to person-focused care through the Total Health initiative, which explicitly addresses the interconnectedness between health, health care, individual behaviors, environments, and social determinants of health. The Total Health initiative will bring together KP’s work in health care delivery with resources and influence to mobilize programs and policies promoting health in schools, worksites, and communities; the goal is to align influences in personal behavior and environments. This approach brings the concept of “optimal defaults” to the societal level, reshaping food systems, transportation, and other services so that healthy choices are the easiest choices.

**Conclusion**

Fully realizing person-focused care by explicitly addressing members’ health-related needs, preferences, and expectations will encounter three challenges. The first is complexity, a primary challenge to highly reliable and user-friendly health care. Planning and delivering health care is already characterized by extraordinary complexity—in patients’ genetics and physiology, available treatments, technologies, data, organizational structures, payment systems, and interactions among these. Also considering patients’ family, work, and life goals multiplies the complexity involved in creating optimal care plans and could strain operational efficiency. However, person-related complexity already exists whether we address it explicitly or leave patients to sort it out on their own. If we do not explicitly address the complexity of patients’ lives, the result will likely be care plans that are not followed, behavior change efforts that fail, and the use of health care when social care might suffice.

Reimbursement mechanisms in the US, a second challenge to person-focused care, are still primarily based on fees for medically necessary services, making it harder to fund innovative efforts bridging health care and related services. Payment mechanisms in other systems provide more flexible alternatives. In the United Kingdom, for example, the National Health Service is experimenting with “integrated personal budgets” for health care and/or social care.3 Accountable care organizations in the US created under the Affordable Care Act4 may also have incentives and flexibility to provide person-focused care.

A third challenge lies in understanding how health care providers and systems can best add value for their patients. Some patients may prefer health care that is narrowly focused on health and medical issues, integrating health care with other services on their own. Others will prefer a more integrated solution, although their willingness to pay for integration is unknown. The needs and preferences of patients’ caregivers—family, friends, and paid caregivers—will also influence integration of health and social services, especially for patients who are not capable of accessing and integrating services on their own.

Realizing the vision of person-focused care requires taking every opportunity—member by member and initiative by initiative—to broaden our understanding of how health and health care intersect with other aspects of people’s lives, fully recognizing that each patient we serve is first and foremost a person. Tuso and his co-authors give us an example of how this can be done, and other examples are starting to bear fruit. These set a high new bar we can all aim to reach.

**References**

Editor's note: Mr LaBorie's artwork "The Man in the Mirror" may be seen on page 94.

*This glass has seen some strange things, sir; whispered Poole.*
*And surely none stranger than itself, echoed the lawyer.*

—Robert Louis Stevenson

My younger brother is 70 and has been diagnosed with dementia. To me, it's a baffling disease. One minute he's here in the same room with his wife and me, the next he's talking about or interacting with a situation or event that has no apparent relation to what appears to be our current reality.

Unseen visitors flicker in and out of his mind. Sometimes they come and stand next to his chair in the living room; on other occasions, they arise unbidden in the form of dreams.

Where do they come from, these mysterious apparitions? When my brother looks in a mirror, can he see them? They certainly appear in his dreams, which he sometimes finds difficult to distinguish from his waking hours. These strange events remind me that supposedly vampires can't be seen in mirrors and they cast no shadows. However, in this case, the vampires seem to be very real, but instead of drawing blood, they're stealing my brother's mind.

For a family member who cares, these visitations are very troubling and disconcerting, because they appear with absolutely no advance notice and can last from a couple of minutes to an hour or more, leaving my brother bewildered and completely exhausted.

Are his hallucinations caused by actual dementia, overmedication (he's in almost constant pain as a result of a difficult surgical history), or stress? Most likely, it's a combination of all three.

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Are his hallucinations caused by actual dementia, overmedication (he's in almost constant pain as a result of a difficult surgical history), or stress? Most likely, it's a combination of all three.

Then there's the additional side effects of dementia to deal with as well—loss of memory, confusion, frustration, anger, anxiety, and depression.

What's a guy who wants to help to do?

*You can fool the whole world down the pathway of years, but you can't fool the guy staring back from the glass.*

—Dale Wimbrow

For starters, when I look at myself in the mirror, I remind myself to be honest with my own emotions and feelings and not to make judgments. I am not some deus ex machina who has just casually dropped onto the stage to set everything straight. I continually have to remind myself that an important part of my role is to be a caregiver, not a caretaker (in the possessive sense of the word). I ask myself, though, why bother when his condition suggests a one-way ticket to Palookaville?

Well, he's my brother, we're all of our family that's left. We have to look after each other. But in addition, I try to exercise what the Tao proclaims, *When you see someone more advanced than you, try to learn from them. When you see someone less fortunate than you, express compassion.*

This is not a role I'm accustomed to playing, and I often feel as though I'm not doing a very good job of it. Instead, I want to break through during my brother's periods of hallucination and depression; tell him to snap out of it, get a grip, you're out of control. What's wrong with you? But as his wife continually reminds me, "You can't say any of those things, you'll just upset him and make it worse. He'll be all right. Just let him be."

And, difficult as that may be, that's what I try to do. Sometimes I'm successful. On other occasions, I get exasperated when I've heard the same story for the fourth or fifth time.

As I'm sitting here writing this at 4:30 am, my brother has been taken to the hospital. Because he's had 5 heart attacks and suffers from chronic obstructive pulmonary disease and numerous other ailments due to exposure to Agent Orange during his deployment in Vietnam—we take no chances.

Three hours later, it turns out, he's fine—it was a panic attack, but what lies ahead?

I have very little knowledge about the disease, so I turned to the Internet for more information.

Given my brother's symptoms, what form of dementia does he suffer from?


He replied, "They don't seem to know."

Not a very comforting diagnosis. And even if I did know what type of the disease he suffers from, what good would it do?

His condition is further exasperated by periods of acute anxiety as we frantically search the house for missing or misplaced documents, car keys, credit cards, glasses, his wallet, the list goes on. Sometimes our hunt is successful, sometimes not. However, it all contributes to the unsettling What's next? scenario.
The best part of one’s life is the working part, the creative part. Believe me, I love to succeed … However, the real spiritual and emotional excitement is in the doing.\(^\text{4p49}\)

—Garson Kanin

The good news is that all of these symptoms and stresses disappear when we’re making art together. He and his wife have been collecting and polishing beach stones for years with the idea of turning them into jewelry. The space under the house is now full of stones, some ready for polishing, some ready for drilling, some whose future is as uncertain as ours.

In addition to collecting the stones, he has designed a small wooden vise to hold them when they’re being drilled to eventually become necklaces and bracelets.

I asked him about the vise and how he came up with the idea. “It came to me in a dream,” he said.

“To me, that’s just amazing. How can he have such threatening dreams on the one hand, and such revelatory ones on the other?”

Drilling the stones by hand is difficult and very labor-intensive work and calls for patience and absolute accuracy. We work as a team. My brother handles the actual drilling, he’s the maestro; as his trainee/assistant, I hold the vice with the stone in place and replace the water surrounding the vise as needed. (Because of the intense heat that is generated, all drilling has to be done under water and executed with diamond tip drills.) I also help to select the stones to be drilled. Only certain ones will work well and they have to be culled from a huge assortment of sizes and shapes.

Production proceeds at a very slow rate—on a good day, we might get six or eight perfect specimens. But in spite of our meager output, our sense of accomplishment is wonderful when we complete an individual drilling without breaking the stone. The LaBorie brothers have done it again!

The process keeps us very much in the moment and also gives us plenty of time to talk about things including our numerous adventures in the past and what’s happening in the world today. We don’t discuss the future very often, although at times I suspect we both silently speculate about what it might hold.

Instead, I try to keep any discussion about possible outcomes as practical as possible. “Do you know where your will is? Do you have a living will? Have you given your wife power of attorney?” I’ve come to learn this is a difficult area to manage, especially with memory loss, but that it is essential information that we may eventually need, with no certainty of what the timing will be.

It’s also important for all of us to remain as positive as possible. “Don’t give in. Don’t lose hope. Enjoy every day as much as possible,” I tell him. And perhaps even more important, “When you feel pain, depression, anxiety, whatever, don’t put off seeing your doctor.” To me, it’s an absolute wonder how simply changing moods can change moods.

But then, there are those days when he has long periods of absolute clarity, penetrating insights, and boundless energy. We laugh, kid around, and reminisce: I rejoice in the connections we are still able to make and the bridges we are still able to cross together.

Some other things that help us stay in the moment:

Occasionally we walk together, but most of the time he and his wife set out at a brisk pace for parts unknown in the blistering South Carolina summer heat. I think that’s an important part of their personal time together and I stay out of it.

His wife also reminds me that I need to involve him in routine day-to-day activities. Simple things, like loading and unloading the dishwasher, taking the garbage to the landfill, all the stuff that needs doing around the house. I shouldn’t take it all on—by allowing him to participate, I empower him.

The simplest acts create opportunities for him to feel wanted and needed, and most of all, not to feel useless. Sometimes it’s not that easy to do—it’s much quicker if I do it myself, but that leaves him with nothing to do. Not a good place for him to be.

And, I need to ask for his opinion and advice about what I’m doing. “Should I restore this toy and try to sell it on eBay? What do you think about this art project I’m working on? I’ve picked up a writing assignment and would appreciate your input.”

I like a state of continually becoming, with a goal in front and not behind.\(^\text{4p56}\)

—George Bernard Shaw

Where will all this end? What will his life and his wife’s become in the future? What will become of mine? Where will the next string of events take us? I have no idea, but somehow I’m not worried. Things will work out. Why? Because I think I’ve learned more about my identity from someone who is losing his than I did throughout my life. I’ve come to realize that I’m not as nice a guy as I thought I was. I’m not as forgiving and forgetting as I might be. I’m still too selfish with my time. I can be resentful and critical. But I am slowly learning to be more charitable and understanding of the needs of others—not just my brother and his wife, but perhaps the world in general.

As dementia creeps into my brother’s life, it opens new doors for me. Some are difficult to pass through, to accept and understand. Others open new vistas—including the view of the Atlantic Ocean from the beach, watching egrets go about their business in the salt marsh, the tranquility of a quiet Southern street, sitting on our front porch reading a book or keeping an eye on the approaching huge thunderheads in the sky. All of these and much more have given me a positive perspective on life and living. They make me appreciate how important making art is to me and how helpful art can be in keeping dementia at bay, at least for the moment.

My goal nowadays when I look in the mirror is to make the most of the time my brother and I have together.

I’ve learned that people with dementia may forget many things, but those around them need to remember why we’re there. At least I do.AÇÃO

References
“The Man in the Mirror”  
18” x 24”  
mixed media  
Phillip LaBorie

The original artwork to accompany “The Man in the Mirror: Reflections On Dealing With A Family Member's Dementia” (page 92). It is composed of watercolor and acrylic paints, colored pencil highlights, paper scraps, thread, and found objects.

The artwork was three-dimensionally scanned and prepared for accurate reproduction by Photographic Solutions of Norwalk, CT.

Mr LaBorie is an Artist and Writer in Murrells Inlet, SC.
Jeffrey Weisz, MD’s book *It’s a Great Time to be a Physician: Building a Healthcare System that Works* is a blueprint to create the health care system America needs. Dr. Weisz has tremendous credibility in how to transform health care. His results speak for themselves. As Executive Medical Director, Dr. Weisz has led two Permanente Medical Groups: Southern California Permanente Medical Group (SCPMG), 2004 to 2011, and Northwest Permanente (NWP), 2012 to the present. As a physician leader and in partnership with the Kaiser Foundation Health Plan, Dr. Weisz has guided both Regions to national prominence and recognition in clinical quality. With this book, Dr. Weisz shares his philosophy, knowledge, and experience to the benefit of those who are dedicated to improving America’s health care system. In the book and in Dr. Weisz’s leadership, the most unwavering principle is a total focus on the reality and the needs of the patient. He shows us how to create a system that our patients need, want, and deserve. At this moment in time, we are learning how to function in an industry influenced by the Affordable Care Act. Legislation, at best, can be an enabler of improvement for health care. This book provides a pathway to improve health care, validated with clear and substantiated evidence.

The essential learnings and success factors Dr. Weisz outlines are:

- **Clear, Consistent Vision.** Dr. Weisz’s leadership is remarkable for its great clarity and consistent focus on the reality of the patient for all decisions. He shares the vision of building a health system that brings all its resources to bear to make patients as healthy as they can possibly be.

- **Clinical Leadership.** At both SCPMG and NWP, Dr. Weisz has emphasized building a strong senior team and extensive leadership development throughout the Medical Group. He has championed and developed leadership programs, recognizing that the nation needs thoughtful physician leaders and that leadership skills are not part of core medical training. He is an ardent believer in the shared leadership model because physicians, in particular, do not respond well to a command-and-control leadership style.

- **Deployment of Information Technology.** Access to valid information is a critical enabler for both high clinical quality and innovation in care processes. Dr. Weisz talks openly about the challenge of the aggressive implementation of Kaiser Permanente’s electronic health record (EHR). At the same time, he celebrates the EHR as a critical component of many of the best practices and results he and the Medical Group have achieved.

- **Strong Clinical Evidence and Knowledge.** Keeping up with clinical evidence and knowledge can be a challenge. Dr. Weisz points out that one of the benefits of working in a large multispecialty Medical Group within an integrated system is the ability to distill research and translate it into readily accessible information so physicians have more time to practice medicine. Having this embedded in the EHR makes it available at the point of care. He provides detailed descriptions of how clinical evidence and knowledge are shared not just within SCPMG but across Kaiser Permanente systematically.

- **Prevention, Patient Wellness, and Self-Care.** Physicians and teams have increasingly focused on education, support, empowerment, and motivation. With the growing trend of patient empowerment, Dr. Weisz believes that aggressive self-management by patients is a positive development that leads to greater adherence to healthy and health-restoring regimens. He extols ways that the organization has supported patient wellness.

- **Culture.** Developing a culture that embraces metrics and measurement is a basis for system improvement. Throughout the book, the reader is immersed in the culture of SCPMG, which values teamwork, performance, innovation, and openness. Finally, the book includes unique and powerful tools. Particularly useful are the numerous tables highlighting current trends and their implications for physicians.

This book is a must read for all of us trying to fix health care in America. It offers a clear vision and substantive evidence that provides the blueprint to create a health care system that is safe, equitable, accessible, and affordable.

**Reference**


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**Review by Jack Cochran, MD, FACS**

Jack Cochran, MD, FACS, is the Executive Director of The Permanente Federation; formerly a plastic surgeon with Kaiser Permanente Colorado and Executive Medical Director of the Colorado Permanente Medical Group. E-mail: jack.h.cochran@kp.org.
### CME Evaluation Program

#### Section A.

**Article 1. (page 33) Highly Reliable Procedural Teams: The Journey to Spread the Universal Protocol in Diagnostic Imaging**

Which of the following key elements were not included in implementing the Highly Reliable Procedural Team program?

- [ ] a. human factors training
- [ ] b. regular steering committee meetings
- [ ] c. an agreed-upon Time-Out process
- [ ] d. secret shoppers conducting audits

In implementing a Highly Reliable Procedural Teams program, the following concerns were important except:

- [ ] a. establishing baseline data with which to compare outcomes
- [ ] b. engaging radiologists in workflow changes
- [ ] c. decreasing the time needed to complete a procedure
- [ ] d. creating a culture where all feel comfortable reporting errors

**Article 2. (page 38) Complex Case Conferences Associated with Reduced Hospital Admissions for High-Risk Patients with Multiple Comorbidities**

The data reported in this paper suggest that lowest rates of readmission were associated with which of the following:

- [ ] a. follow-up with a physician
- [ ] b. home visit
- [ ] c. postdischarge phone call
- [ ] d. follow-up with a physician combined with a home health visit
- [ ] e. follow-up with a physician and a postdischarge phone call

Based on the information provided in this paper, which of the following is most true:

- [ ] a. readmission rates can be reduced by a focus only on disease management
- [ ] b. readmission rates can be reduced by a focus only on person-centered care
- [ ] c. readmission rates will not be reduced by a focus on disease or person-centered care
- [ ] d. readmission rates may be reduced by a focus both on the disease and the person with the disease

#### Section B.

**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 use evidence-based medicine to produce better patient outcomes.

**Objective 4**

Physicians may earn up to 1 AMA PRA Category 1 Credit™ per article for reading and analyzing the designated CME articles published in each edition of TPJ. Each issue has four articles available for review. Other clinicians for whom CME is acceptable in meeting educational requirements may report up to four hours of participation. Please return (fax or mail to the address listed on the bottom of this form) to The Permanente Journal by April 30, 2014. Forms may also be completed and submitted online at www.thepermanentejournal.org. You must complete all sections to receive credit. (Completed forms will be accepted until April 2015. Acknowledgment will be mailed within 2 months after receipt of form.)

To earn CME for reading each article designated for AMA PRA Category 1 Credit, you must:

- Score at least 50% in the post-test
- Complete the evaluation and provide your contact information

Please return completed form by April 30, 2014.

#### Section C.

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

<table>
<thead>
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<th>Objective 1</th>
<th>Objective 2</th>
<th>Objective 3</th>
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#### Section D. (Please print)

Name  
[ ] Physician  [ ] Non-Physician

Title

E-mail

Address

Signature

Date

The Kaiser Permanente National CME Program is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. The Kaiser Permanente National CME Program designates this journal-based CME activity for 4 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.
The Economic Impact of Hospitalization for Diabetic Foot Infections in a Caribbean Nation

Shamir O Cawich, MBBS, DM; Shariful Islam, MBBS; Seetharaman Hariharan, MBBS, FRCA; Patrick Harnarayan, MBBS, FRCS; Steve Budhooram, MBBS, FRCA; Shivaa Ramsewak, MBBS; Vijay Naraynsingh, MBBS, FRCS

Abstract

Context: Foot infection is the most common complication of diabetes mellitus in the Caribbean. Diabetic foot infections place a heavy burden on health care resources in the Caribbean.

Objective: To evaluate the treatment-related costs for diabetic foot infections in a Caribbean nation.

Methods: We identified all patients with diabetic foot infections in a 730-bed hospital serving a catchment population of approximately 400,000 persons from June 1, 2011 through July 31, 2012. The following data were collected: details of infection, antibiotic usage, investigations performed, number of physician consultations, details of operative treatment, and duration of hospitalization. Total charges were tallied to determine the final cost for inpatient treatment of diabetic foot infections.

Results: There were 446 patients hospitalized with diabetic foot infections, yielding approximately 0.75% annual risk for patients with diabetes to develop foot infections. The mean duration of hospitalization was 22.5 days. Sixteen patients (3.6%) were treated conservatively without an operative procedure and 430 (96.4%) required some form of operative intervention. There were 885 debridements, 193 minor amputations and 60 major amputations, 7102 wound dressings, 2763 wound cultures, and 27,015 glucometer measurements. When the hospital charges were tallied, a total of US $13,922,178 (mean, US $31,216) were spent to treat diabetic foot infections in these 446 patients during 1 year at this hospital.

Conclusions: Each year, the government of Trinidad and Tobago spends US $85 million, or 0.4% of their gross domestic product, solely to treat patients hospitalized for diabetic foot infections. With this level of national expenditure and the anticipated increase in the prevalence of diabetes, it is necessary to revive the call for investment in preventive public health strategies.

Introduction

Diabetes mellitus affects between 10.9% and 20% of the general adult population in the Caribbean. These patients have 15% to 25% lifetime risk of developing foot infections, making it the most common complication of diabetes requiring surgery. In fact, diabetic foot infections account for 75% of the surgical bed occupancy in Barbados and 29% of bed occupancy in Trinidad and Tobago. When they occur, diabetic foot infections negatively affect patient health and social well-being, but the economic impact has not been thoroughly assessed in the Caribbean. We evaluated the charges accrued by patients with diabetes who required hospitalization for the treatment of diabetic foot infections in a Caribbean nation.

Methods

This study was performed at the San Fernando General Hospital in Trinidad and Tobago. This is a 730-bed hospital that serves a catchment population of approximately 400,000 persons living in and around the city of San Fernando. The local institutional review board granted ethical approval to collect data on all patients presenting with diabetic foot infections at this facility from June 1, 2011 through July 31, 2012.

The patients were identified on admission registers and their data recorded prospectively on a form designed for the study purpose. The following data were collected: details of infection, antibiotic usage, investigations performed, number of physician consultations, details of operative treatment, and duration of hospitalization. All data were entered into a spreadsheet (Microsoft Excel v14, Redmond, WA) and analyzed with the Statistical Package for Social Sciences (SPSS v 12. SPSS Inc, Chicago, IL), version 12.0. Descriptive statistics were generated as appropriate.

In all cases, the services provided were codified using current procedural terminology where available. The charges associated with inpatient treatment of all patients with diabetic foot infections were tallied over the study period, and the mean charge per admission per patient was calculated.

We estimated the yearly national expenditure using the following equation: [expected number of persons with diabetes] × [annual risk for a patient with diabetes to develop foot infections] × [mean number of admissions per patient per year] × [mean charge per admission].

Results

Approximately 60,000 patients with diabetes are served by the San Fernando General Hospital, representing 15% of the Caribbean population. E-mail: socawich@hotmail.com. Shariful Islam, MBBS, is a Senior Resident in the Department of Surgery at San Fernando General Hospital in Trinidad and Tobago. E-mail: socawich@hotmail.com. Shariful Islam, MBBS, is a Senior Lecturer in the Department of Clinical Surgical Sciences at the University of West Indies St Augustine Campus in Trinidad and Tobago. E-mail: sxsl201198@yahoo.com. Seetharaman Hariharan, MBBS, FRCA, is a Professor of Anesthesia in the Department of Clinical Surgical Sciences at the University of West Indies St Augustine Campus in Trinidad and Tobago. E-mail: uwhar@gmail.com. Patrick Harnarayan, MBBS, FRCS, is a Lecturer in the Department of Surgery at the University of West Indies in Port of Spain, Trinidad and Tobago. E-mail: pharnara@tstt.net.tt. Shivaa Ramsewak, MBBS, is a Senior Lecturer in the Department of Clinical Surgical Sciences at the University of West Indies St Augustine Campus in Trinidad and Tobago. E-mail: sramsewak@hotmail.com. Vijay Naraynsingh, MBBS, FRCS, is a Professor of Surgery in the Department of Surgery at the University of West Indies in Port of Spain, Trinidad and Tobago. E-mail: vnaraysingh@gmail.com.
patients hospitalized with diabetic foot infections, yielding approximately 0.75% annual risk for patients with diabetes to develop foot infections.

The study population included 205 women and 241 men at a mean age of 57 years (standard deviation [SD] = 12 years, median = 56 years, range = 24 to 93 years). There were 416 persons with type 2 diabetes and 30 with type 1 diabetes. These patients lived with diabetes for a mean duration of 14 years (SD = 8 years, median = 13 years, range = 1 month to 55 years). In the outpatient setting, these patients received insulin in 157 cases (35.2%), oral medication in 204 (45.7%), and combinations of insulin with oral therapy in 85 (19.1%).

Although 271 patients (60.8%) reported compliance with their outpatient medications at the time they were hospitalized, there was poor correlation with objective HbA1c measurements. Three hundred thirty-four patients (74.9%) had HbA1c levels of 7.1% or greater to suggest inadequate glycemic control in the prehospitalization period.

At the time of presentation, 129 patients (28.9%) admitted to regular use of tobacco products and 212 (47.5%) had preexisting complications of diabetes apart from foot infections: 98 (22.0%) had retinopathy, 135 (30.3%) had ischemic heart disease, and 63 (14.1%) had renal impairment.

Three hundred twenty-seven patients (73.3%) had a history of hospitalizations for foot infections, with 288 (64.6%) of these occurring within a year of the current hospitalization. During previous hospitalizations, 72 patients (16.1%) had an amputation. The mean number of hospitalizations in the 12-month period before the current admission was 1.85 hospitalizations per patient (SD = 0.74 hospitalization, range = 1 to 4 hospitalizations). Each hospitalization lasted for a mean duration of 22.5 days (SD = 15 days, range = 2 to 60 days).

Sixteen patients (3.6%) presented early and were treated conservatively without the need for an operative procedure. They were treated with wound dressings, antibiotics, hypoglycemic medications, and clinical observation.

The remaining 450 patients (96.4%) required some form of operative intervention, with 885 debridements in 418 (93.7%), 193 minor amputations in 176 (39.7%), and 60 major amputations in 60 (13.5%).

Overall, there were 7102 wound dressings performed (mean = 15.9, SD = 3.17); 2763 wound cultures (mean = 4.97, SD = 0.48); 8885 blood investigations for white cell count, electrolytes, and HbA1c level (mean = 19.93, SD = 1.5); and 27,015 glomerular measurements (mean = 60.57, SD = 9.96).

When the charges were tallied, a total of US $13,922,178 (mean = $31,216, SD = $14,830, range = $3,763-$89,516) in charges were accumulated to treat diabetic foot infections in these 416 patients during 1 year at this hospital.

The most recent population census documented 1,317,714 persons living in Trinidad and Tobago and approximately 197,657 persons (15% of the general population) have diabetes.12 With approximately 0.75% annual risk, 1482 persons with diabetes will develop serious foot infections requiring hospitalization every year.

Using these findings, we calculated the national expenditure: annual risk to develop foot infections (0.75%) × [number of persons with diabetes in Trinidad and Tobago (197,657) × [mean number of admissions per patient per year (1.85) × [mean charge per patient per admission ($31,216)]]. Inhospital treatment of this condition demanded an estimated national expenditure of US $85,701,185 per year in Trinidad and Tobago.

**Discussion**

Trinidad and Tobago is the largest Anglophone island nation in the Eastern Caribbean, with a population of 1,317,714 persons at the most recent national census. The World Bank estimated the islands’ gross domestic product among the highest in the region at US $23,99 billion.7

The Government of Trinidad and Tobago provides free health care to all legal residents through a network of public health care facilities, which are managed by Regional Health Authorities (RHA) under the auspices of the Ministry of Health.8 There are no user fees generated at the point of service for patients who access the health care system. Instead the RHAs are responsible for all charges accrued during health care delivery, and these are funded from a yearly budget allocated to each RHA by the Ministry of Health.

The San Fernando General Hospital, which serves approximately 60,000 patients with diabetes, is one such public hospital. This population places a significant demand on the health care delivery system. This is highlighted by the high prevalence of diabetic complications in our patients at the time of presentation: renal impairment in 14.1%, limb loss in 16.1%, retinopathy in 22.0%, and ischemic heart disease in 30.3%.

These patients are also predisposed to diabetic foot infections that lead to significant morbidity and premature mortality in the Caribbean.36-39 In Trinidad and Tobago, there was approximately 0.75% annual risk for patients with diabetes to develop foot infections that required hospitalization. This is lower than the 2% annual risk reported by Richard and Schuldiner in 2008, but in that study the risk was reported for all foot complications whereas we report the annual risk only for serious foot infections requiring hospitalization.

Many patients experience amputations and permanent disability or functional dependence after recovering from severe infections. Apart from the negative consequences on individual patient health, there is negative impact on social, economic, and health care sectors that remains to be accurately quantified in Caribbean nations.

The overall cost to treat unselected complications of diabetes has been estimated to range from US $218 million4 to US $467 million13 across the Caribbean per year. However, it is important for each country to have objective data on their national expenditure because this information will significantly affect policymakers’ decisions when formulating their own national health care policies. To our knowledge, there has been no previous accurate assessment of the specific costs incurred when treating diabetic foot infections in Trinidad and Tobago.

The charges accrued during the treatment of patients with diabetic foot infections at this city hospital was US $13,922,178 in a single year or US $31,216 per patient for each admission. This is actually a conservative estimate because we did not count patients who were man-
aged as outpatients and/or discharged from the Emergency Department without being hospitalized.

The figures were comparable with reports from other countries where the average charge (US dollars) per patient to treat diabetic foot infections was reported to be: $24,710 in Great Britain,11 $26,509 in Sweden,15 $27,930 in the US,16 $33,540 in Sweden,16 and $41,984 in Belgium.16 It is difficult to compare charges directly because there is significant variation in the cost of supplies, availability and use of investigations, physician remuneration, facility reimbursements, and treatment protocols in each country. It is clear, however, that each country is burdened by high costs to treat this disease.

We calculated a national expenditure of US $85,701,185 per year to treat patients who are hospitalized with diabetic foot infections in Trinidad and Tobago. This is a significant demand on the national budget of Trinidad and Tobago, accounting for 0.4% of the national gross domestic product.1 Considering that the prevalence of diabetes and its complications are anticipated to increase across the region,10-12 there is an urgent need to strengthen preventive public health measures.

There are already several well-developed primary care initiatives aimed at preventing complications of diabetes in Trinidad and Tobago. In 2006, the Ministry of Health introduced dedicated diabetic clinics that were placed strategically at high-traffic areas within the community.13 Dedicated personnel were specially trained to staff the diabetic foot clinics (eg, primary care clinicians, counselors, podiatrists, diabetes educators, physiotherapists), hosting regular foot care workshops and public educational lectures aimed at persons with diabetes.14 The intention was to give patients with diabetes unimpeded and convenient access to these services in the community. It was also hoped that patients who developed foot infections would present early with the absence of user fees at the point of care.

One year after the diabetic clinics were implemented, Singh et al19 followed 361 patients enrolled in the clinics who were deemed to be at high risk for foot infections. They reported only 4% ulceration rate in high-risk patients, and when infections did develop, 54% healed without operative intervention.20 However, when we evaluated the efficacy of these preventive strategies 6 years after their introduction to Trinidad and Tobago, it was evident that the services were not being used effectively because none of the patients we encountered with severe diabetic foot infections were enrolled in diabetes clinics.21 Additionally, 52% of patients led unhealthy lifestyles with sustained high-risk practices and 43% were never counseled on foot care by a health professional.21

Additionally, Islam et al19 followed 257 patients with severe diabetic foot infections in Trinidad and Tobago and reported that 30% of them opted to use home remedies instead of seeking medical attention. This accounted for an unacceptably long delay of 6.2 days between detection of the foot infection and commencement of medical care.19 Several high-risk behaviors were also observed, with 37% regularly walking barefoot and 43% not performing regular foot inspections.19 Although much has been invested into the preventive measures for complications of diabetes and diabetic foot infections, there is room for improvement. Unless the existing preventive strategies are optimized, the nation will continue to spend 0.4% of its gross domestic product on this solitary disease process.

Some strategies the nation should consider are an increased use of educational campaigns focusing on healthy lifestyle practices,22-25 regular foot inspection,26-28 the dangers of home remedies29 and of walking barefoot,30 the use of proper fitting footwear,26-30 and avoidance of high-risk behavior.19

**Conclusion**

Each year, the Government of Trinidad and Tobago spends US $85,701,185, or 0.4% of their gross domestic product, solely to treat patients hospitalized with diabetic foot infections. With this level of national expenditure and the anticipated increase in the prevalence of diabetes, it is necessary to revive the call for investment in preventive public health strategies. 

**Disclosure Statement**

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

**Acknowledgment**

Mary Corrado, ELS, provided editorial assistance.

**References**


20. Singh H, Rahaman MA, Ramcharitar Maharaj A, Armour B, County St George Central, North West Regional Health Authority (NWRA).


Abstract

One challenge in the treatment of plantar fasciitis is that very few high-quality studies exist comparing different treatment modalities to guide evidence-based management. Current literature suggests a change to the way that plantar fasciitis is managed. This article reviews the most current literature on plantar fasciitis and showcases recommended treatment guidelines. This serves to assist physicians in diagnosing and treating heel pain with plantar fasciitis.

Introduction

Plantar fasciitis is one of the most common causes of heel pain and has been estimated to affect about two million people in the US, resulting in more than one million visits to both primary care physicians and foot specialists. Plantar fasciitis affects both sedentary and athletic people and is thought to result from chronic overload either from lifestyle or exercise. Current literature suggests that plantar fasciitis is more correctly termed fasciosis because of the chronicity of the disease and the evidence of degeneration rather than inflammation. Treatment is often difficult because of the poorly understood mechanism by which the body heals chronic degeneration as opposed to acute inflammation. This article lays out current recommendations for diagnosis and treatment so as to better guide any physician who encounters a patient with plantar pain.

Case Report

A 48-year-old obese but otherwise healthy woman presents to her primary care physician complaining of bilateral foot pain. She states that she has had the pain daily for months. The pain is located on the bottom of her feet at the heel and is severe, especially on the first step out of bed in the morning and after a long day at work. She works at a warehouse handing out samples to customers and stands for approximately 7 hours a day. The pain does not radiate anywhere, and there is no associated numbness, tingling, leg swelling, or weakness. She denies any history of trauma or falls. She exercises by walking 3 times a week for 30 minutes and is able to complete the walk without problems. In fact, the walking seems to make her feet feel better. She has tried changing shoes and ibuprofen but has had no relief.

On physical examination, her lower legs and feet have no apparent abnormalities. There is no edema, ecchymoses, skin changes, or evidence of cyanosis. She has no tenderness to palpation over the tibia, fibula, malleoli, tarsals, metatarsals, metacarpophalangeal joints, or digits. She has exquisite tenderness to palpation just medial to the midline of her heel and just superior to the calcaneal bone. She also has tenderness, but less so, along the plantar aspect of the midfoot. She has normal strength of dorsiflexors and plantar flexors. She has normal range of motion with inversion, eversion, and plantar flexion. She is just able to get to neutral position on dorsiflexion. Sensation is intact and pedal pulses are present and equal bilaterally. When she is standing, it is apparent that she has pes planus. She is able to walk on her toes and heels and has a normal gait with mild pronation.

The patient receives a diagnosis of plantar fasciitis and instructions on conservative management to facilitate recovery, including appropriate footwear at work, stretching, and massage. She is encouraged to start a low-impact exercise program to aid in weight loss.

Discussion

The plantar fascia is a thick fibrous aponeurosis that originates at the medial calcaneal tubercle and helps support the arch of the foot (Figure 1). It is thought that repetitive tensile overload from standing for long periods of time or running causes changes in the aponeurosis that can be either acute or chronic. More recently, the term plantar fasciosis has

Table 1: Risk factors for plantar fasciitis.1-4

<table>
<thead>
<tr>
<th>Intrinsic risk factors</th>
<th>Extrinsic risk factors</th>
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<tr>
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<td>Environmental</td>
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<td>Obesity</td>
<td>Poor biomechanics or alignment</td>
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<td>Pes planus (flat feet)</td>
<td>Deconditioning</td>
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<td>Pes cavus (high-arched feet)</td>
<td>Hard surface</td>
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<tr>
<td>Shortened Achilles tendon</td>
<td>Walking barefoot</td>
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<td>Weak intrinsic muscles of the foot</td>
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<tr>
<td>Weak plantar flexor muscles</td>
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been introduced to de-emphasize the idea that inflammation is the cause of pain. Histopathologic studies have shown that patients with diagnosed plantar fasciitis have more disorganization of fibrous tissue similar to degenerative tendinosis rather than inflammation.

Classic symptoms include severe pain in the morning or after a rest period that improves with movement but is aggravated by long periods of weight bearing. Physical examination findings are typically tenderness to palpation over the medical calcaneal tubercle and discomfort with passive dorsiflexion of the first toe.

Several risk factors, both intrinsic and extrinsic, are listed in Table 1.

All of the risk factors can be assessed on the basis of history and physical alone and help to guide appropriate treatment. Imaging is typically not necessary for the diagnosis but may be helpful if there are other likely reasons for heel pain included in the differential diagnosis (Table 2).

Treatment mechanisms have been wide ranging, from ice, nonsteroidal anti-inflammatory medications, stretching, formal physical therapy, night splints, custom orthotics, over-the-counter heel cups, LowDye taping, corticosteroid injections, platelet-rich plasma injections, botulinum toxin injections, iontophoresis, extracorporeal shock wave therapy, and fasciotomy.

It is understood that in general practice, first-line treatment may include a corticosteroid injection. This may relieve symptoms, especially during an acute flare or even with chronic pain, but recent studies are suggesting that less-invasive techniques may be more effective at providing long-term relief.

A current treatment pathway is provided in Figure 2 to aid in the formulation of a treatment plan. All patients should be counseled that with any conservative treatment option, they should not expect to see significant improvement before six to eight weeks.

Results of a 2008 query of orthopedic surgeons who are foot-and-ankle specialists showed that for patients with more than 4 months of pain, 74 out of 116 surgeons preferred plantar fascia-specific stretching and supervised physical therapy over anti-inflammatories or corticosteroid injections.

A 2008 Cochrane Review showed that custom orthotics may not reduce foot pain any more than sham orthotics, noncustomized orthotics, or no orthotics.

### Table 2: Differential diagnosis for heel pain.

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<td></td>
<td>Neuropathy such as from diabetes</td>
<td>Paresthesias in plantar region</td>
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<td>Skeletal</td>
<td>Acute calcaneal fracture</td>
<td>Likely after hard landing on heel</td>
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<td>Calcaneal stress fracture</td>
<td>Most likely seen in runners</td>
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<td></td>
<td>Sever disease: calcaneal apophysitis</td>
<td>Seen in pediatric patients with open physes</td>
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<td></td>
<td>Systemic arthritides such as rheumatoid</td>
<td>Expect pain in multiple joints along with heel pain</td>
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<td>Soft tissue</td>
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<td>More likely associated with hard landing on heel</td>
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<td>Pain in retrocalcaneal bursa</td>
</tr>
<tr>
<td></td>
<td>Posterior tibial tendinitis</td>
<td>Pain along posterior tibial tendon and at insertion mid foot at the arch</td>
</tr>
</tbody>
</table>

Initial Treatment: Patient Directed
- Relative rest and activity modification
- Stretching
- Over-the-counter heel cups
- LowDye taping
- Corticosteroid injections
- Platelet-rich plasma injections
- Botulinum toxin injections
- Iontophoresis
- Extracorporeal shock wave therapy
- Fasciotomy

Secondary Treatment: Physician Directed
- Referral to physical therapy: eccentric stretches, iontophoresis, deep myofascial massage injections: corticosteroid, dextrose (peelortherapy), botulinum toxin
- Percutaneous needling
- Anterior night splints

Tertiary Treatment: Specialist Directed
- Consider referral to a foot and ankle specialist
- Consider speaking with a specialist about any suggested imaging prior to referral

**Figure 2. Treatment algorithm**

**Figure 3. Calf and arch stretch using a towel.** Consider keeping the towel near the bedside and performing before going to sleep and before taking first steps in the morning. Pull back on foot for 30 seconds 3 times with 30 seconds of rest in between.

**Figure 4. Manual plantar fascia stretch with cross-friction massage.** Stretch and massage before taking first steps for 1 minute 3 times with 30 seconds of rest in between.
more than sham orthotics, over-the-counter orthotics, or night splints and were not any better than stretching alone. Night splints are associated with statistically significant improvement, but the cumbersome splints limit patient adherence and, therefore, potential benefits. Fasciectomy may be effective for recalcitrant plantar fasciitis that has not responded to any other conservative treatments. Less well-studied treatments, such as extracorporeal shock wave therapy, iontophoresis, botulinum toxin injections, and platelet-rich plasma injections, have had favorable outcomes but have not yet been tested with randomized, double-blind, placebo-controlled studies.

In all of the literature reviewed, plantar fascia-specific stretching had the best statistically significant long-term results (Figures 3-5). The figures show some of the most widely used and evidence-supported stretches that patients can do at home.

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

Acknowledgment
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References
Self-Reported Activities and Outcomes of Ambulatory Care Staff Registered Nurses: An Exploration

June L Rondinelli, RN, MSN, CNS; Anna K Omery, RN, DNSc, NEA-BC; Cecelia L Crawford, RN, DNP; Joyce A Johnson, PhD, RN-BC

Introduction

The ambulatory setting is where most individuals in the US receive health care. Consequently, ambulatory care is a growing field of nursing practice. Employment of registered nurses (RNs) is projected to rise dramatically in physician offices and medical center outpatient clinics from 2010 to 2020. As ambulatory care RN practice grows, there has been an ongoing effort to identify the desired role of the staff RN in outpatient care and to provide linkages to preferred outcomes.

Objective: This study sought to describe the perceived impact of components of the staff RN role on specific activities and outcomes, as guided by the structures, processes, and outcomes of the Nursing Role Effectiveness Model.

Design: This exploratory research study used a descriptive, self-report survey design.

Results: Survey respondents were ambulatory care staff RNs from various primary and specialty care clinics (n = 187) in an integrated health care organization in Southern California. The most frequently reported activities included patient assessment, nurse advice during message management, and completion of patient triage. Reported patient outcomes most frequently affected by RN activities were patient satisfaction, normalization of laboratory values, receiving the correct level of medical treatment, and prevention of complications. Respondents expressed that “emergency situations” periodically occur in the ambulatory setting.

Conclusions: This research study supports what ambulatory care RNs say they are doing: daily, diverse, and complex patient care activities that influence multiple relevant patient outcomes. Future research studies could reveal best practices related to message management, in addition to activities and outcomes unique to specialty care populations.

Abstract

Context: Ambulatory care is a growing field of nursing practice. As ambulatory registered nurse (RN) practice grows, there has been an ongoing effort to identify the desired role of the staff RN in outpatient care and to provide linkages to preferred outcomes.

Objective: This study sought to describe the perceived impact of components of the staff RN role on specific activities and outcomes, as guided by the structures, processes, and outcomes of the Nursing Role Effectiveness Model.

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Conclusions: This research study supports what ambulatory care RNs say they are doing: daily, diverse, and complex patient care activities that influence multiple relevant patient outcomes. Future research studies could reveal best practices related to message management, in addition to activities and outcomes unique to specialty care populations.
Self-Reported Activities and Outcomes of Ambulatory Care Staff Registered Nurses: An Exploration

be completed within effective structures leading to the desired outcomes. In the Nursing Role Effectiveness Model, the nurse is considered a structure. That is, structures are constituted as nurse demographics, education, settings, and skill mix. Processes in the model are the activities of the nurse’s role, as illustrated by nurse-initiated independent processes such as self-care facilitation, exercise enhancement, and nutritional support. Outcomes in the Nursing Role Effectiveness Model are clinical outcomes, prevention of complications, knowledge of disease and treatment, functional status, and patient satisfaction. 25

Methods
This study employed a descriptive, self-report survey design. Because of the exploratory nature of the survey, both quantitative and qualitative data were obtained from participants. After obtaining approval from the institutional review board, the researchers considered all ambulatory care RNs (N = 4124) working in a large integrated health care organization in the Southern California Region as potential participants. These nurses provide care in 40 unique clinical settings that are primary care clinics/medical offices, specialty clinics, and Emergency Departments at 14 medical centers with outpatient clinics/units and 405 medical office buildings.

A power analysis indicated that a final sample of 352 was necessary to generalize results to the overall ambulatory care nursing population. In the absence of a sufficient sample size to achieve power, a sample of approximately 188 was deemed sufficient for reporting the findings because it would yield results with an acceptable ± 7% margin of error at a confidence level of 95%.

The Web-based survey was launched in Fall 2011. The survey questionnaire was adapted from a previously validated Clinical Nurse Specialist instrument that captured Clinical Nurse Specialist activities and outcomes. 26 However, because ambulatory care staff RNs are a separate and different population, study investigators tailored the survey to include activities and outcomes unique to ambulatory care practice. Activities and outcomes in this survey were drawn from several sources:

1) a review of the literature, 27,28 2) the 2010 American Academy of Ambulatory Care Nursing professional practice standards, 29 3) an internal organizational job description, 4) the National Quality Forum 2008 and 2010 proposed outcome measures, 30,31 and 5) ambulatory care expert clinicians. Seventeen ambulatory care practice nurse leaders in the health care organization validated the survey content.

The final survey had 30 questions related to activities and 18 questions about outcomes. Respondents selected from the following categories of times per shift that they perceived an activity was completed or an outcome was influenced: 0 or not applicable; 1 to 5; 6 to 10; 11 to 15; or more than 15 times a shift. Nurses were not asked to track the time required to complete activities in this study. Open-ended questions included the request to describe any activities and outcomes not listed in the survey, in addition to an area for free-text comments from participants.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Responses, % (n)</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, b years (n = 186)</td>
<td>49 (9.49)</td>
<td></td>
</tr>
<tr>
<td>Sex&lt;sup&gt;a&lt;/sup&gt; (n = 184)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>89.1 (164)</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>10.9 (20)</td>
<td></td>
</tr>
<tr>
<td>Race/ethnicity&lt;sup&gt;a&lt;/sup&gt; (n = 176)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>46.0 (81)</td>
<td></td>
</tr>
<tr>
<td>Asian/Pacific Islander/Filipino</td>
<td>24.0 (43)</td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino/Spanish origin</td>
<td>14.0 (25)</td>
<td></td>
</tr>
<tr>
<td>Black/African American</td>
<td>9.7 (17)</td>
<td></td>
</tr>
<tr>
<td>American Indian/Native American</td>
<td>0.6 (1)</td>
<td></td>
</tr>
<tr>
<td>≥ 2 races</td>
<td>2.8 (5)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>2.3 (4)</td>
<td></td>
</tr>
<tr>
<td>Experience</td>
<td>Total years as RN (n = 187)</td>
<td>20.68 (11.30)</td>
</tr>
<tr>
<td>Years as staff RN in ambulatory care (n = 185)</td>
<td>9.45 (8.54)</td>
<td></td>
</tr>
<tr>
<td>Highest degree of education (n = 187)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Associate</td>
<td>40.6 (76)</td>
<td></td>
</tr>
<tr>
<td>BS/BA in nursing</td>
<td>32 (60)</td>
<td></td>
</tr>
<tr>
<td>BS/BA in another field</td>
<td>8 (15)</td>
<td></td>
</tr>
<tr>
<td>MSN</td>
<td>8.8 (16)</td>
<td></td>
</tr>
<tr>
<td>MS in another field</td>
<td>2.7 (5)</td>
<td></td>
</tr>
<tr>
<td>Joint MSN plus degree in another field</td>
<td>2.7 (5)</td>
<td></td>
</tr>
<tr>
<td>Doctorate in another field</td>
<td>2 (4)</td>
<td></td>
</tr>
<tr>
<td>Diploma</td>
<td>3 (6)</td>
<td></td>
</tr>
<tr>
<td>Work hours&lt;sup&gt;a&lt;/sup&gt; per week (n = 179)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 20</td>
<td>1.6 (3)</td>
<td></td>
</tr>
<tr>
<td>20-30</td>
<td>12.3 (22)</td>
<td></td>
</tr>
<tr>
<td>31-40</td>
<td>77.7 (139)</td>
<td></td>
</tr>
<tr>
<td>&gt; 40</td>
<td>8.4 (15)</td>
<td></td>
</tr>
<tr>
<td>Average hours per shift&lt;sup&gt;a&lt;/sup&gt; (n = 158)</td>
<td>8.20 (1.37)</td>
<td></td>
</tr>
<tr>
<td>Staff mix&lt;sup&gt;a&lt;/sup&gt; (n = 182)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RN, LVN, MA, with clinicians</td>
<td>84 (153)</td>
<td></td>
</tr>
<tr>
<td>RN, LVN, with clinicians</td>
<td>11.5 (21)</td>
<td></td>
</tr>
<tr>
<td>RN, LVN, in a nurse-run clinic</td>
<td>4.4 (8)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Because of rounding, some percentages do not total to 100.
<sup>b</sup> Some responses are missing.

BA = bachelor of arts; BS = bachelor of science; LVN = licensed vocational nurse; MA = medical assistants; MS = master of science; MSN = master of science in nursing; RN = registered nurse; SD = standard deviation.
Data Analysis

Data were analyzed using statistical analysis software (SPSS Version 18, IBM SPSS, Armonk, NY). The Cronbach α scores confirmed the reliability of the survey for this population (0.94 for activities section; 0.93 for outcomes section). Descriptive statistics, including percentages, frequencies, means, and standard deviations (SDs), were used to generate the findings. Wording from answered open-ended questions and the comments section were coded using content analysis.

Results

After surveys from advanced practice nurses and managers were deleted, a total of 187 designated staff ambulatory care RNs completed usable survey questionnaires. Although these eliminated roles are important to the health care team in ambulatory care, the investigators’ goal was to capture the staff RN’s perceived activities and outcomes.

Table 2. Characteristics of ambulatory practice environment

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Percentage (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total respondents (N = 187)</td>
<td></td>
</tr>
<tr>
<td>Primary care (includes Family Medicine, Adult Medicine)</td>
<td>39.6 (74)</td>
</tr>
<tr>
<td>Specialty care</td>
<td>39.6 (74)</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>4.3 (8)</td>
</tr>
<tr>
<td>Other or did not answer</td>
<td>16.0 (31)</td>
</tr>
</tbody>
</table>

Patient encounters: “Yes, I see patients in person”

<table>
<thead>
<tr>
<th>Primary care (total) (n = 72)</th>
<th>Yes</th>
<th>67.5 (63)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>12.5 (9)</td>
</tr>
<tr>
<td>Specialty care (total) (n = 69)</td>
<td>Yes</td>
<td>92.8 (64)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>7.2 (5)</td>
</tr>
</tbody>
</table>

Walk-in patients: number of walk-in patients I assess for care

<table>
<thead>
<tr>
<th>Primary care (total) (n = 58)</th>
<th>0-10</th>
<th>63.8 (37)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11-20</td>
<td>29.3 (17)</td>
</tr>
<tr>
<td></td>
<td>21-30</td>
<td>6.9 (4)</td>
</tr>
<tr>
<td>Specialty care (total) (n = 46)</td>
<td>0-10</td>
<td>76.1 (35)</td>
</tr>
<tr>
<td></td>
<td>11-20</td>
<td>15.2 (7)</td>
</tr>
<tr>
<td></td>
<td>21-30</td>
<td>2.2 (1)</td>
</tr>
<tr>
<td></td>
<td>31-100</td>
<td>2.2 (1)</td>
</tr>
<tr>
<td></td>
<td>&gt; 100</td>
<td>4.3 (2)</td>
</tr>
</tbody>
</table>

Table 3. Message management (answered “Yes, I manage messages”)

<table>
<thead>
<tr>
<th>Characteristic (n = number of respondents)</th>
<th>Mean of all reported daily range averages (SD)</th>
<th>Daily range of managed messages per shift</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary care (n = 59)</td>
<td>32.86 (23.52)</td>
<td>9-56</td>
</tr>
<tr>
<td>Specialty care (n = 49)</td>
<td>19.29 (20.01)</td>
<td>0-39</td>
</tr>
</tbody>
</table>

SD = standard deviation.
The same activity less than 5 times a shift, are displayed across the row. Ranking accompanied each percentage. Lastly, the percentage of nurses who reported “zero/not applicable” for each activity is listed. The top 5 activities completed at least 15 times per shift were 1) assessment of the patient’s health history, 2) chief complaint/subjective history, 3) nurse advice during message management, 4) assessing laboratory test results, and 5) triage/access. Moving across Table 4, one sees that these same activities were reported and ranked last as infrequent daily activities (defined as 5 or fewer times per shift).

The following activities ranked among those at the bottom of Table 4: 1) assist while a clinician completes treatments or diagnostic procedures, 2) teaching patients and/or family daily self-monitoring techniques, or 3) arranging for appropriate at-home equipment. For these activities, there was also a high rate of zero/not applicable responses. Therefore, when high zero/not applicable percentages appear for activities in addition to low frequency, said activities may not be relevant to the staff RN role in ambulatory care for these respondents.

Activities of interest for further examination are those in the middle of activity rankings (Table 4). Examples such as 1) initiating and managing treatments (as orders or preset standardized procedures), 2) evaluation of treatment and/or procedures, and 3) teaching the patient and/or

### Table 4. Reported frequency of activities of ambulatory care staff registered nurses

<table>
<thead>
<tr>
<th>Self-reported frequency of activities*</th>
<th>Completed 15 times a shift or more</th>
<th>Rank for 1-5 times a shift</th>
<th>Completed 1-5 times or more</th>
<th>Rank for 1-5 times</th>
<th>Marked zero or not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessing the patient’s health history</td>
<td>47.7 (82)</td>
<td>1</td>
<td>14.5 (25)</td>
<td>30</td>
<td>6.4 (11)</td>
</tr>
<tr>
<td>Assessing the patient’s chief complaint and subjective history</td>
<td>40.5 (70)</td>
<td>2</td>
<td>19.7 (34)</td>
<td>28</td>
<td>7.5 (13)</td>
</tr>
<tr>
<td>Conducting nurse advice during message management</td>
<td>39.7 (69)</td>
<td>3</td>
<td>19.5 (34)</td>
<td>29</td>
<td>14.4 (25)</td>
</tr>
<tr>
<td>Assessing laboratory test results</td>
<td>32.6 (57)</td>
<td>4</td>
<td>28.0 (49)</td>
<td>26</td>
<td>10.9 (19)</td>
</tr>
<tr>
<td>Triaging and arranging access to appropriate level of care on the basis of assessment</td>
<td>32.2 (56)</td>
<td>5</td>
<td>29.3 (51)</td>
<td>24</td>
<td>14.4 (25)</td>
</tr>
<tr>
<td>Developing immediate plan of nursing care</td>
<td>26.0 (45)</td>
<td>6</td>
<td>28.9 (50)</td>
<td>25</td>
<td>16.8 (29)</td>
</tr>
<tr>
<td>Evaluation of patient/family education</td>
<td>20.9 (36)</td>
<td>7</td>
<td>33.7 (58)</td>
<td>18</td>
<td>20.3 (35)</td>
</tr>
<tr>
<td>Coordinating next clinician visit</td>
<td>19.8 (33)</td>
<td>8</td>
<td>35.3 (59)</td>
<td>15</td>
<td>13.8 (23)</td>
</tr>
<tr>
<td>Evaluation of treatment or procedure</td>
<td>19.2 (33)</td>
<td>9</td>
<td>32.6 (56)</td>
<td>21</td>
<td>15.1 (26)</td>
</tr>
<tr>
<td>Coordinating next laboratory test</td>
<td>19.2 (32)</td>
<td>10</td>
<td>37.1 (62)</td>
<td>17</td>
<td>19.8 (33)</td>
</tr>
<tr>
<td>Initiating and managing treatments (as orders or preset standardized procedures)</td>
<td>18.3 (30)</td>
<td>11</td>
<td>32.3 (53)</td>
<td>22</td>
<td>23.2 (38)</td>
</tr>
<tr>
<td>Establishing with the patient the long-term outcome goal</td>
<td>17.1 (29)</td>
<td>12</td>
<td>27.6 (47)</td>
<td>27</td>
<td>30.0 (51)</td>
</tr>
<tr>
<td>Teaching patients and/or family health nutrition</td>
<td>16.2 (28)</td>
<td>13</td>
<td>44.5 (77)</td>
<td>6</td>
<td>18.5 (32)</td>
</tr>
<tr>
<td>Consultation with clinicians on plan of care</td>
<td>15.7 (26)</td>
<td>14</td>
<td>51.2 (85)</td>
<td>1</td>
<td>11.4 (19)</td>
</tr>
<tr>
<td>Teaching patients and/or family physical activity guidelines</td>
<td>15.5 (27)</td>
<td>15</td>
<td>39.1 (68)</td>
<td>10</td>
<td>23.6 (41)</td>
</tr>
<tr>
<td>Conducting nursing physical assessments</td>
<td>14.9 (26)</td>
<td>16</td>
<td>32.8 (57)</td>
<td>20</td>
<td>32.2 (56)</td>
</tr>
<tr>
<td>Teaching the patient and/or family medication administration</td>
<td>14.5 (25)</td>
<td>17</td>
<td>43.6 (75)</td>
<td>7</td>
<td>12.8 (22)</td>
</tr>
<tr>
<td>Teaching patients and/or family safety measures</td>
<td>14.5 (25)</td>
<td>18</td>
<td>46.2 (80)</td>
<td>5</td>
<td>20.8 (36)</td>
</tr>
<tr>
<td>Evaluation of patient readiness for release/discharge from the ambulatory setting</td>
<td>14.5 (25)</td>
<td>19</td>
<td>33.7 (58)</td>
<td>19</td>
<td>33.1 (57)</td>
</tr>
<tr>
<td>Completing/reviewing discharge instructions with the patient or family</td>
<td>14.4 (25)</td>
<td>20</td>
<td>29.9 (52)</td>
<td>23</td>
<td>28.7 (50)</td>
</tr>
<tr>
<td>Initiating and managing medications (as orders or preset standardized procedures)</td>
<td>13.9 (23)</td>
<td>21</td>
<td>36.4 (60)</td>
<td>16</td>
<td>27.9 (46)</td>
</tr>
<tr>
<td>Goal setting with the patient/family</td>
<td>12.4 (21)</td>
<td>22</td>
<td>37.1 (63)</td>
<td>14</td>
<td>28.8 (49)</td>
</tr>
<tr>
<td>Evaluation of medication effect</td>
<td>11.5 (20)</td>
<td>23</td>
<td>38.5 (67)</td>
<td>11</td>
<td>26.4 (46)</td>
</tr>
<tr>
<td>Coordinating/pending radiograph (x-ray) or diagnostic procedure</td>
<td>9.7 (16)</td>
<td>24</td>
<td>38.2 (63)</td>
<td>12</td>
<td>33.9 (56)</td>
</tr>
<tr>
<td>Teaching the patient and/or family administration of treatments/procedures for self-care</td>
<td>9.3 (16)</td>
<td>25</td>
<td>47.7 (82)</td>
<td>4</td>
<td>24.4 (42)</td>
</tr>
<tr>
<td>Assist while a clinician completes treatments or diagnostic procedures</td>
<td>7.9 (13)</td>
<td>26</td>
<td>40.2 (66)</td>
<td>9</td>
<td>40.2 (66)</td>
</tr>
<tr>
<td>Teaching the patient and/or family operation of equipment or products</td>
<td>6.9 (12)</td>
<td>27</td>
<td>50.9 (88)</td>
<td>2</td>
<td>29.5 (51)</td>
</tr>
<tr>
<td>Teaching patients and/or family daily self-monitoring techniques (eg, blood glucose, daily weigh-in)</td>
<td>6.9 (12)</td>
<td>28</td>
<td>40.8 (71)</td>
<td>8</td>
<td>32.2 (56)</td>
</tr>
<tr>
<td>Coordinating patient care with other departments (eg, Pharmacy or Social Services)</td>
<td>6.0 (10)</td>
<td>29</td>
<td>50.9 (85)</td>
<td>3</td>
<td>22.8 (38)</td>
</tr>
<tr>
<td>Arranging for appropriate at-home equipment</td>
<td>2.4 (4)</td>
<td>30</td>
<td>37.2 (61)</td>
<td>13</td>
<td>52.4 (86)</td>
</tr>
</tbody>
</table>

* Total number of respondents varied per question and did not equal 187. The responses listed are from the most frequently reported and less frequently reported categories only. Results are reported by sample percentage and number of respondents in parentheses.
Family medication administration are reported as completed infrequently, yet not reported as zero/not applicable. Results appear to reflect potential opportunities for consideration that are within the ambulatory care staff RN’s scope of practice.

**Outcomes: Perceived Influence by Ambulatory Care Staff Registered Nurses**

Respondents were asked to choose the perceived frequency in which they influenced select patient outcomes during one shift. Survey questions addressed outcomes related to patient clinical care and symptom control, self-care, complications, disease knowledge, and satisfaction. Again, responses of primary and specialty care nurses were combined for data analysis. Eighteen separate outcomes were listed on the survey. The top 5 patient outcomes the nurses felt they influenced at least 15 times per shift were 1) patient satisfaction, 2) normal laboratory values, 3) prevention of complications, 4) correct level of medical treatment, and 5) decreased anxiety levels (Table 5). These same 5 outcomes also received low percentages as zero/not applicable.

Analogous to activities, a few outcomes were marked high as infrequent and high percentages as zero/not applicable. Examples include 1) body mass index improvement, 2) normalization of blood glucose levels, 3) decrease in medication for the patient, and 4) appropriate care products for the patient. For outcomes, this may reflect irrelevance to the role or that the outcome is considered too long term to achieve in relation to a worked shift.

However, there were outcomes reported as highly infrequent, yet with a low percentage of zero/not applicable scores. Examples are improved patient and/or family knowledge of disease process and medication adherence. Another opportunity within the scope of practice of the ambulatory care staff RN is influencing patient self-care ability with both highly infrequent, yet low percentage of zero/not applicable scores.

**Content Analysis of Open-Ended Questions**

Many respondents took the opportunity to articulate any additional outcomes and activities related to their role. Content analysis of these comments resulted in the formation of two overarching themes: “Acute Aspects of Ambulatory Care” and “Daily Diverse and Complex Activities.” These themes cut across both primary and specialty care settings.

**Acute Aspects of Ambulatory Care**

Respondents discussed emergency situations that could happen anywhere and anytime in ambulatory care practice. Examples included assisting patients during syncopal episodes and patient assessment/monitoring while waiting for paramedic transport to an Emergency Department. Emergency response skills included starting intravenous fluid administration, oxygen therapy, and “whatever was needed” for patient stabilization and transfer. Code blue situations and 911 calls were repeatedly discussed. One respondent eloquently articulated this major theme in the following quote: “Ambulatory care is more acute than we thought; it requires a whole range of different kinds of skills, [and] our care impacts people of all stages and ages. Ambulatory care and education should have its own body of evidence to establish it as a specialty.”

---

**Table 5. Outcomes: Reported frequency of influence**

<table>
<thead>
<tr>
<th>Outcomes: Reported frequency of outcomes influenced</th>
<th>Influenced 15 times a shift or more</th>
<th>Rank for 15 times or more</th>
<th>Influenced 1-5 times a shift</th>
<th>Rank for 1-5 times</th>
<th>Marked zero or not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall patient satisfaction</td>
<td>36.8 (60)</td>
<td>1</td>
<td>19.6 (32)</td>
<td>18</td>
<td>4.9 (8)</td>
</tr>
<tr>
<td>Normal laboratory values for the patient</td>
<td>22.8 (37)</td>
<td>2</td>
<td>38.3 (62)</td>
<td>8</td>
<td>11.7 (19)</td>
</tr>
<tr>
<td>Prevention of complications</td>
<td>20.5 (33)</td>
<td>3</td>
<td>36.6 (59)</td>
<td>13</td>
<td>13.0 (21)</td>
</tr>
<tr>
<td>Patient receiving the correct level of medical treatment in relation to presenting need</td>
<td>17.9 (29)</td>
<td>4</td>
<td>35.8 (58)</td>
<td>14</td>
<td>18.5 (30)</td>
</tr>
<tr>
<td>Decreased patient anxiety level</td>
<td>17.8 (29)</td>
<td>5</td>
<td>39.3 (64)</td>
<td>5</td>
<td>8.6 (14)</td>
</tr>
<tr>
<td>Medication adherence</td>
<td>16.8 (27)</td>
<td>6</td>
<td>41.0 (66)</td>
<td>3</td>
<td>16.8 (27)</td>
</tr>
<tr>
<td>Appropriate medication reconciliation</td>
<td>15.0 (24)</td>
<td>7</td>
<td>30.0 (48)</td>
<td>16</td>
<td>35.6 (57)</td>
</tr>
<tr>
<td>Improved patient and/or family knowledge of disease process</td>
<td>14.7 (24)</td>
<td>8</td>
<td>44.8 (73)</td>
<td>1</td>
<td>15.3 (25)</td>
</tr>
<tr>
<td>Prevention of admission to acute care unit</td>
<td>13.5 (22)</td>
<td>9</td>
<td>39.3 (64)</td>
<td>6</td>
<td>30.7 (50)</td>
</tr>
<tr>
<td>Increased patient self-care ability</td>
<td>12.5 (20)</td>
<td>10</td>
<td>36.9 (59)</td>
<td>12</td>
<td>27.5 (44)</td>
</tr>
<tr>
<td>Increased family/significant other’s ability to participate in the patient’s care</td>
<td>12.3 (20)</td>
<td>11</td>
<td>38.7 (63)</td>
<td>7</td>
<td>28.2 (46)</td>
</tr>
<tr>
<td>Decreased excessive wait time for the patient</td>
<td>11.7 (19)</td>
<td>12</td>
<td>37.4 (61)</td>
<td>10</td>
<td>29.4 (48)</td>
</tr>
<tr>
<td>Normalization of blood pressure measurements</td>
<td>10.5 (17)</td>
<td>13</td>
<td>33.3 (54)</td>
<td>15</td>
<td>30.2 (49)</td>
</tr>
<tr>
<td>Decreased number of office visits for the patient</td>
<td>10.5 (17)</td>
<td>14</td>
<td>38.3 (62)</td>
<td>9</td>
<td>38.3 (62)</td>
</tr>
<tr>
<td>Decrease in needed medication for the patient</td>
<td>9.3 (15)</td>
<td>15</td>
<td>37.0 (60)</td>
<td>11</td>
<td>42.6 (69)</td>
</tr>
<tr>
<td>Normalization of blood glucose levels</td>
<td>7.4 (12)</td>
<td>16</td>
<td>39.5 (64)</td>
<td>4</td>
<td>37.7 (61)</td>
</tr>
<tr>
<td>Appropriate care products for the patient</td>
<td>6.2 (10)</td>
<td>17</td>
<td>43.5 (70)</td>
<td>2</td>
<td>35.4 (57)</td>
</tr>
<tr>
<td>Body mass index improvement</td>
<td>5.6 (10)</td>
<td>18</td>
<td>29.4 (47)</td>
<td>17</td>
<td>53.8 (86)</td>
</tr>
</tbody>
</table>

*a Total number of respondents varied per question and did not equal 187. The responses listed above are from the most frequently reported and less frequently reported categories only. Results are reported by sample percentage and number of respondents in parentheses.*
Daily Diverse and Complex Activities
Numerous comments were made concerning additional activities not covered by the survey. Examples included staff education, case management, complex wound care, and conscious sedation procedures. A key comment was that respondents found it difficult to quantify activities and outcomes per shift. The nurses suggested future surveys that examine activities every week or per month. A staff RN reported: The Ambulatory Practice RN role is so varied and wide it is difficult on a day-to-day level to try to frame it in numbers.

Discussion
In 2010, the Institute of Medicine published its report, The Future of Nursing: Leading Change, Advancing Health. Included in that report’s key messages was that nurses should practice to the full extent of their education and training. In 2014, principal provisions of the Affordable Care Act that will mandate individual health care coverage will be implemented as US law. Given these social drivers, the nursing profession will be asked to deliver on its social contract. There is and will be an urgent need for nurses to understand and to grow their practice if they are to adequately respond to these significant social changes.

Data from this exploratory survey are specific to the scope of practice of ambulatory care RNs as identified by the nurses in one health care system in Southern California. Objective measures of activities and outcomes were not part of the study. Although the instrument was newly designed for this exploration, results provide timely and compelling baseline information for improvement of internal organizational practice and recent external influences for the RN scope of practice examination, as seen in the Institute of Medicine report.

The activities that most ambulatory care nurses reported as occurring most frequently were related to assessment. Only one other most frequent activity, conducting advice during message management, was an intervention. Assessment and triage activities reflect the nursing process, with message management aligning with telephone communication. The evidence from this exploratory study supports the relevance of RN assessment and surveillance to daily practice. It also helps define the unique contributions of the RN, as assessment and surveillance are not part of the scope of practice for a nursing assistant or medical assistant.

However, assessment is only the first step of the nursing process. Nursing intervention and evaluation completes the process for RN practice. The findings in this group of nurses generate the formation of additional questions: Do ambulatory care staff RNs have the knowledge and/or support of the systems where they work to initiate nursing interventions? If the tradition in nursing practice in ambulatory care has been to hand off to another clinician such as an advanced practice nurse, a physician assistant, or a physician, how are nurse and operational leaders going to assist staff RNs in practicing to the full scope of regulatory activities?

Movement in health care to chronic care models and the team approach requires that all team members practice collaboratively. One reported activity identified as “consultation” could be inferred as falling under the American Academy of Ambulatory Care Nursing 2010 standards of collegiality and collaboration. Most activities described in this study also align with the American Nurses Credentialing Center certification for ambulatory care nursing for the conceptual domains of clinical practice and communication. Nursing brings unique and critical knowledge to both a patient with a new diagnosis and patients and families receiving long-term episodic ambulatory care as they integrate a chronic illness into their lives. Chronic disease management, therefore, is an opportunity to expand areas for collaboration as ambulatory care staff RNs become integrated in the health care team.

Outcomes reported in this study reflect the cited literature on patient satisfaction, increased patient knowledge, and prevention of complications or admissions. Perceived effect on patient outcomes of receiving the correct level of treatment or appropriate care products mirror effective care coordination previously described by Swan et al for performance measurement. Nurses’ self-reported effect on the outcome of normalizing general patient laboratory values reflects many population-specific targets for ambulatory care performance measures. Although the findings from this study align with previous literature that articulates a multitude of domains that is the current state of ambulatory care nursing practice and its varied dimensions, it does not reflect specific regulated outcome indicators such as Healthcare Effectiveness Data and Information Set (HEDIS) measures. Further research on outcomes for ambulatory care nurses should reflect those measures in primary and specialty care that are established as critical or even regulatory. If nursing is not seen as having an impact on those measures, the members of the discipline will not be seen as important to the outcomes achieved in their practice setting. Given the dynamic state of health care, nursing’s contribution to outcomes must be clearly visible.

Noteworthy findings for the structural characteristics include those regarding sex and education. The sample was composed of 10% male respondents, which is slightly lower than a 2008 California survey reporting 14% of all RNs as male. Nevertheless, the visibility of male nurses in the ambulatory care setting is encouraging. Slightly more than 40% of participants had a highest education level at an associate degree in nursing, which reflects the initial education of most California RNs. However, a striking survey finding was that 16% of staff nurse respondents had obtained a master’s degree level or higher. If one circles back to the activities-related findings, in which it was identified that most of these nurses spend the majority of their time in assessment activities, one disconcerting conclusion might be that, indeed, these nurses are not being used to their fullest capacity. Patients and families who often are struggling in the complex ambulatory care environment require the presence of and care provided by these highly educated clinical professionals.

Results regarding message management align with the literature related to the telephone advice nurse (Tables 3 and 4). The advent of e-mail messaging systems has introduced an added dimension to nurse-clinician-patient communications. Both primary and specialty care nurses reported a high percentage of message management as part of their role as an am-
The sharing of common activities, processes, and outcomes unique to specialty care populations. Overall, this evidence provides support for the piloting of clinical improvement initiatives to demonstrate the complex role of ambulatory care staff RNs in an evolving health care system that needs every one of its practitioners practicing at the full scope of his/her knowledge and abilities.

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

Acknowledgment
The authors would like to acknowledge the research study’s sponsors, the members of the Southern California Permanente Medical Group Regional Ambulatory Clinical Practice Committee, Terry Bream, RN, MN, as well as Jan Boller, RN, PhD, Regina Valdez, MA, Gloria Redden, RN, MSN, and Jennifer Biseno, RN, BSN. The authors also thank the nurses who participated in the survey. Their willingness to voice their perceptions made this research study and subsequent article possible.

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

References


NURSING RESEARCH & PRACTICE

Self-Reported Activities and Outcomes of Ambulatory Care Staff Registered Nurses: An Exploration


A 79-year-old woman with a medical history of hypertension and cardiac surgery for mitral valve repair was transported to the Emergency Department by ambulance service after falling to the floor of her bedroom. She complained of weakness in her legs and was unable to move them. The initial evaluation excluded vertebral-medullary trauma. A neurologic assessment revealed paraplegia, with a loss of sensation at the level of T12 and absent reflexes in the legs. There were no palpable pulses in the legs, and Doppler examination confirmed no blood flow. A computed tomography with angiographic study of the thoracoabdominal aorta (Figure 1) revealed almost complete thrombosis of the distal aorta (Figure 2) and common iliac arteries. Spontaneous reperfusion of the internal and external iliac arteries was observed distally (Figure 3). The patient was started on anticoagulants (4000 units intravenous bolus of unfractionated heparin) and immediately transferred to a center for emergency revascularization. Unfortunately, this patient did not survive efforts at revascularization.

Acute aortic abdominal occlusion is an uncommon condition and potentially life threatening, frequently resulting from saddle embolism or from thrombosis of an atherosclerotic plaque.\(^1\) Although rare, sudden neurologic symptoms (namely paraplegia) without prominent vascular symptomatology, can occur.\(^2\) A high level of suspicion must be maintained so a prompt diagnosis can be made and appropriate treatment implemented.\(^3\)

References


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CLINICAL MEDICINE

Case Study

A 58-year-old alcoholic man presented with pain, swelling, and bruising of his right leg. He had no history of trauma or injury. His medical history was significant for frequent spontaneous hematomas in his legs (Figure 1), the first and most dramatic of which was a large thigh hematoma occurring 4 years earlier. This area became infected, developing necrotizing fasciitis that required emergency surgery.

On physical examination, he had hyperplastic gums and no teeth. He had no body hair below his head. The calf of his right leg was enlarged and tender, with more swelling medially than laterally. Dependent bruising was noted in the popliteal fossa initially as his leg was elevated; several days later, when he started ambulating, bruising became apparent around his ankle.

His initial blood alcohol level was 0.28%, and his Aspartate Aminotransferase and Alanine Aminotransferase levels were 90 and 61 international units/microliter, respectively. His platelet count and coagulation studies were normal. His body mass index was 30 kg/m².

Color flow Doppler ultrasound of his right leg was performed, and no deep venous thrombosis was identified. Imaging of his leg by a contrast-enhanced computerized tomography scan (Figure 2) showed a large hematoma in the right calf (white arrows), measuring 7.5 x 3.5 x 12.6 cm (anterior-posterior, transverse, and caudal-cranial dimensions, respectively). Extravasation of intravenous contrast was seen, indicating active bleeding (black arrowhead). There were no aneurysms or other vascular malformations in or near the hematoma.

This patient drank a 1.75-liter bottle of vodka daily and smoked cigarettes. He ate mostly precooked hash brown potatoes, pasta, and occasional canned tuna. He did not eat fresh vegetables and rarely ate fruit.

Discussion

The diagnosis of scurvy (vitamin C deficiency) is based largely on clinical evidence and requires a high index of suspicion. The dietary history of the patient should be obtained. Laboratory testing for ascorbic acid (vitamin C) levels to corroborate the diagnosis is possible but is seldom useful because of the frequent use of intravenous fluids with vitamins, commonly referred to as banana bags, which contain 200 milligrams of vitamin C per liter. Testing the leukocyte level of vitamin C is more accurate than testing serum or plasma levels to evaluate total body stores. Initial symptoms of scurvy involve skin changes, which are more likely to occur in the lower extremities, including corkscrew hairs, perifollicular hemorrhages, and perifollicular keratosis.

Malaise, loose teeth, gum abnormalities, edema, hematomas, and musculoskeletal pain are frequent symptoms. Wound healing is impaired, and well-healed wounds can become painful and reopen. Cutaneous hemorrhages frequently become palpable, and with the presence of rheumatologic symptoms, scurvy can mimic vasculitis as well as bleeding disorders.

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Most animals are able to synthesize ascorbic acid. Humans, apes, fruit-eating bats, and guinea pigs are missing the enzyme L-gulonolactone oxidase and require vitamin C in the diet. Vitamin C is required for a number of enzymatic processes, including the hydroxylation of the proline and lysine residues serving to cross-link collagen fibers. The hematomas and other bleeding seen in scurvy are a result of abnormal collagen.

Scurvy is a historically prominent disease, causing many deaths during long sea voyages and wars. Although scurvy is now rare in industrialized countries, it still occurs in people who do not eat sufficient fresh fruits or vegetables.

Acknowledgment

The authors thank Jane Smith, RN, BSN, JD, for taking the photograph and Laura McNeill, RD, CNSC, for the dietary consult.

References

CLINICAL MEDICINE

ECG Diagnosis: The Effect of Ionized Serum Calcium Levels on Electrocardiogram

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Abstract

High and low levels of ionized serum calcium concentration can produce characteristic changes on the electrocardiogram. These changes are almost entirely limited to the duration of the ST segment, with no change in the QRS complexes or T waves. High ionized serum calcium shortens the ST segment, and low ionized serum calcium prolongs the ST segment. Two common clinical scenarios are presented.

Case 1 – Hypocalcemia

A 17-year-old woman with severe chronic renal failure and atrophic kidneys had an electrocardiogram (ECG) (Figure 1) with a prolonged QT interval of 0.44 seconds and a corrected QT interval (QTc) of 0.533 seconds. Her total serum calcium was 5.0 mg/dL (normal 8.6-10.6 mg/dL). Repeat analysis showed a total serum calcium of 5.8 mg/dL and an ionized serum calcium of 2.73 mg/dL (normal 4.73-5.21 mg/dL).

Case 2 – Hypercalcemia

A 37-year-old man previously had 6 kidney stones, which either spontaneously passed or were surgically removed. His preoperative ECG before surgical repair of an uncomplicated inguinal hernia had an abnormally short QT interval of 0.320 seconds and a QTc of 0.341 seconds (Figure 2). His total serum calcium was 12.0 mg/dL (normal 8.6-10.6 mg/dL), and his ionized serum calcium was 6.64 mg/dL (normal 4.73-5.21 mg/dL). This patient had primary hyperparathyroidism and had surgical removal of the parathyroid adenoma followed promptly by a rapid decrease in his serum calcium.

Figure 1. Electrocardiogram demonstrates prolonged QTc and QT segment in a patient with hypocalcemia.

Figure 2. Electrocardiogram demonstrates shortened QTc and QT segment in a patient with hypercalcemia.

Figure 3. Electrocardiogram demonstrates the absence of an ST segment in a 59-year-old woman with marked elevation in ionized serum calcium secondary to chronic and severe hyperparathyroidism. The T wave starts immediately at the end of the QRS complex.
Discussion
Variations in the ionized serum calcium concentration produce the characteristic ECG changes that occur with hypercalcemia and hypocalcemia.\(^1\)\(^2\) These changes are almost entirely limited to the duration of the ST segment with no change in the QRS complexes or T waves. High levels of ionized serum calcium shorten the ST segment on the ECG. Conversely, low levels of ionized serum calcium prolong the ST segment. Variations in the QT interval and the QTc duration are caused by variations in the duration of the ST segment.\(^1\)\(^2\) In marked elevation of the ionized serum calcium, no ST segment is present and the T wave starts immediately at the end of the QRS complex (Figure 3).

Bazett's Formula (Figure 4) is used to calculate the QTc. A QTc greater than 500 milliseconds is associated with an increased risk for developing life-threatening cardiac arrhythmias. ♦

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

Acknowledgment
We would like to thank Sandra Wilson, Graphic Designer and Illustrator, for designing Figure 4.

References

Figure 4. Comparison of a normal ST segment and QT interval with a prolonged ST segment and QT interval. Bazett's Formula is used to calculate the corrected QT interval (QTc).
Dear Editor,

The review by Aimee Lee, MD, and associates mentions various risks for falls in the elderly population. However, an important point is missing. Emerging literature shows that chronic hyponatremia increases the adjusted odds ratio for falls and is now recognized as an important factor for increased falls and fractures in the elderly.\(^1\,^2\) This is true even for mild hyponatremia, which is sometimes considered to be “asymptomatic” with serum sodium levels of 130 meq/L to 134 meq/L. The mechanism proposed includes mild impairment in cognitive abilities leading to unsteadiness in gait. At least in some cases, hyponatremia may contribute to osteoporosis and increased bone fragility by causing higher rate of bone resorption to mobilize sodium.

Earlier reports had shown that mild hyponatremia is associated with falls, but the first prospective study came from Rotterdam. In this study of 5208 patients, subjects with mild hyponatremia had more recent falls (23.8% vs 16.4%, \(p < 0.001\)).\(^2\) Adjustments for disability index and diuretics, along with other factors, did not modify the risks.

Also, hyponatremia has been shown to be a novel risk factor for hip fracture in the elderly.\(^1\,^2\) Even without osteoporosis, even mild serum sodium levels of < 135 meq/L have been associated with fracture occurrence.\(^2\) In the Rotterdam study, hyponatremia was not associated with lower bone mineral density but was associated with increased risk of incident nonvertebral fractures (hazard ratio = 1.39) independent of comorbidities and diuretics.\(^2\)

Hyponatremia can cause more attention deficit than a serum alcohol level of 0.6 g/L.\(^4\) Even mild hyponatremia can be a cause of major morbidity and mortality in elderly patients.\(^5\) Physicians should look for hyponatremia during assessment of new falls as well as check it on an intermittent basis for elderly patients who may be at risk for future falls. Mild hyponatremia merits new well-deserved attention in the elderly population.\(\text{v}\)

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References

Dear Editor,

We read with great interest the work by Masek and Levis published in a recent issue of The Permanente Journal.1 They describe a classical electrocardiographic evolution of acute pericarditis. In the presented first electrocardiogram (ECG) of Stage 1 acute pericarditis, we would like to bring to the readers’ attention an interesting ECG finding: Spodick’s sign (Figure 1).2 This sign has been named after our University professor David Spodick, MD, a world-famous physician for his work on the pericardial diseases. It signifies to a downsloping TP segment in patients with acute pericarditis and is present in about 80% of the patients affected with acute pericarditis. The sign is often best visualized in lead II and lateral precordial leads. In addition, Spodick’s sign may also serve as an important distinguishing electrocardiographic tool between the acute pericarditis and acute coronary syndrome.3 PR-segment depression when used alone can sometimes be a masquerader, as it can be seen in both acute pericarditis and acute coronary syndrome. However, the presence of PR depression and Spodick’s sign is often a giveaway to the diagnosis.4,5

In Masek and Levis’s Figure 1 ECG (www.thepermanentejournal.org/issues/2013/fall/5537-acute-pericarditis.html), TP-segment downsloping is clearly apparent especially in leads II, V4-6 with near complete resolution after treatment with nonsteroidal anti-inflammatory drugs (Masek and Levis’s Figure 2 [www.thepermanentejournal.org/issues/2013/fall/5537-acute-pericarditis.html]).

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References
Assessment of Quality of Life in Patients with Chronic Oral Mucosal Diseases: A Questionnaire-Based Study

Bijina Rajan, BDS; Junaid Ahmed, BDS, MDS; Nandita Shenoy, BDS, MDS; Ceena Denny, BDS, MDS; Ravikiran Ongole, BDS, MDS; Almas Binnal, BDS, MDS

Abstract

Context: A validated discipline-specific questionnaire has been developed recently to assess the quality of life (QOL) in patients with chronic oral mucosal diseases.

Objective: Use the Chronic Oral Mucosal Diseases Questionnaire for evaluating a diverse group of patients with chronic oral mucosal disease after therapy.

Design: Prospective convenience sample.

Main Outcome Measure: Quality of life.

Methods: Seventy patients seen in the Department of Oral Medicine and Radiology with oral lichen planus, recurrent aphthous ulcers, pemphigus, and other chronic oral mucosal diseases were included in the study. Patients completed the questionnaire after undergoing treatment of their oral mucosal disease to assess their QOL.

Results: Patients older than age 35 years reported significantly lower QOL (p = 0.015) in the domain of social and emotional status. Significant age-related differences in QOL were not observed in other domains. Older individuals also reported a significantly lower overall QOL. Men reported significantly better oral health-related QOL than women did in pain and functional limitation: 16.14 ± 8.94 vs 21.44 ± 7.696, respectively (p = 0.010). Significant differences were not observed between sexes for other domains. Significant differences were observed between the disease groups only for recurrent aphthous ulcers and pemphigus (p = 0.005). Patients with pemphigus had the worst overall QOL (73.6 ± 5.6).

Conclusion: Even after treatment, chronic oral mucosal diseases negatively affect patients’ QOL. Use of the Chronic Oral Mucosal Diseases Questionnaire may allow physicians to more effectively care for their patients with these diseases.

Introduction

Chronic oral mucosal diseases (COMD) are a diverse group of autoimmune, inflammatory, and infectious conditions that can affect the soft tissues of the mouth. These conditions, like other diseases of the mouth, can result in considerable morbidity with physical, social, and psychological consequences for patients. Some of the most commonly encountered COMD in dental practice include recurrent aphthous ulcers, oral lichen planus, and pemphigus. Both the clinical manifestations and the treatment options available in the management of these can affect quality of life (QOL). Although most COMD are currently managed symptomatically, not much importance has been given to QOL.

According to the World Health Organization, QOL is defined as an individual’s perception of his/her position in life in the context of the culture and value system in which s/he lives and in relation to his/her goals, expectations, standards, and concerns. A number of patient-centered oral health status measurement instruments have been developed over the last decade to assess the physical, social, and psychological consequences of oral health and the impact of oral health status on QOL. The QOL measurement instruments can be divided into generic, disease-specific, and discipline-specific questionnaires. Generic QOL questionnaires cannot detect small but clinically important changes associated with a particular disease, but they allow comparisons to be made across different diseases. Disease-specific questionnaires accurately predict clinical changes associated with a particular disease but do not allow comparison to be made across diseases. Discipline-specific questionnaires combine the increased accuracy and sensitivity to disease-specific changes with the ability to compare the QOL of patients with related diseases.

The 2 most commonly used QOL measures in oral medicine are the Oral Health Impact Profile-14 and the 36-item Short Form Health Survey. They have certain disadvantages, such as poor responsiveness and lack of suitability for certain patients. The Chronic Oral Mucosal Diseases Questionnaire (COMDQ) is a discipline-specific questionnaire developed for the field of oral medicine and radiology. The questionnaire was developed on a patient-centered approach and has demonstrated acceptable validity and reliability to support its use.

QOL questionnaires can provide an important role in therapy, because they can help patients communicate with their physicians in an objective fashion about the subjective conditions associated with their illness. Clinicians may be considered experts at observation of disease activity, and with effective QOL questionnaires, patients can help make decisions about their treatment.

The aim of the study was to measure the QOL after therapy in patients with COMD using the COMDQ. We sought to assess the role of pain and functional limitation, efficacy of the medication...
Table 1. Patient demographics by disease group

<table>
<thead>
<tr>
<th>Sex</th>
<th>Number</th>
<th>Mean age (SD), years</th>
<th>Mean disease duration (SD), months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral lichen planus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>18</td>
<td>46.33 (13.53)</td>
<td>17.11 (9.4)</td>
</tr>
<tr>
<td>Men</td>
<td>14</td>
<td>44.8 (15.03)</td>
<td>16.3 (5.39)</td>
</tr>
<tr>
<td>Recurrent aphthous ulcers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>4</td>
<td>27.0 (7.87)</td>
<td>10.25 (2.75)</td>
</tr>
<tr>
<td>Men</td>
<td>9</td>
<td>38.78 (17.58)</td>
<td>13.5556 (5.39)</td>
</tr>
<tr>
<td>Pemphigus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>5</td>
<td>44.80 (13.39)</td>
<td>9.40 (8.35)</td>
</tr>
<tr>
<td>Men</td>
<td>4</td>
<td>39.25 (6.50)</td>
<td>4.5 (2.08)</td>
</tr>
<tr>
<td>Others*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>7</td>
<td>57.71 (16.78)</td>
<td>10.2857 (10.48)</td>
</tr>
<tr>
<td>Men</td>
<td>9</td>
<td>35.33 (12.75)</td>
<td>11.7778 (9.78)</td>
</tr>
</tbody>
</table>

* Included candidiasis, Stevens-Johnson syndrome, oral submucous fibrosis, leukoplakia, radiation-induced mucositis, and bullous pemphigoid.

SD = standard deviation.

Assessment of Quality of Life in Patients with Chronic Oral Mucosal Diseases: A Questionnaire-Based Study

Chronic Oral Mucosal Diseases Questionnaire

Pain and functional limitation
1. How much do certain types of food/drink cause you discomfort (spicy food, acidic food)?
2. How much does your oral condition cause you to limit the types of food/drinks you consume?
3. How much do certain food textures cause you discomfort (rough food, crusty food)?
4. How much does your oral condition cause you to limit the textures of the food you consume?
5. How much does the temperatures of certain foods/dinks cause you discomfort?
6. How much does your oral condition cause you to limit the temperature of the foods/drinks you consume?
7. How much does your oral condition lead to discomfort when carrying out your daily oral hygiene routine (brushing, flossing, mouthwash usage)?
8. How much does your oral condition cause you to limit your daily oral hygiene routine (brushing, flossing, mouthwash usage)?
9. How much does your oral condition lead to discomfort when wearing a denture (false teeth)?

Medication and treatment (including mouthwashes, gels, creams, ointments, injections, tablets, infusions)
1. How much do you feel you need medication to help you with activities of daily life (talking, eating, etc)?
2. How satisfied are you with the medication being used to treat your oral condition?
3. How concerned are you about the possible side effects of the medications used to treat your oral condition?
4. How much does it frustrate you that there is no single standard medication to be used in your oral condition?
5. How much does the use of the medication limit you in your everyday life (routine/the way you apply or take your medications)?
6. How much does it bother you that there is no cure for your oral condition?

Social and emotional
1. How much does your oral condition get your down?
2. How much does your oral condition cause you anxiety?
3. How much does your oral condition cause you stress?
4. How much does the unpredictability of your oral condition bother you?
5. How much does your oral condition cause you to worry about the future (spread of the condition, possible cancer risk)?
6. How much does your oral condition make you pessimistic about the future?
7. How much does your oral condition disrupt social activities in your life (social gatherings, eating out, parties)?

Patient support
1. How satisfactory do you consider the information available to you regarding your oral condition?
2. How satisfied are you with the level of support and understanding shown to you by family regarding this oral condition?
3. How satisfied are you with the level of support and understanding shown to you by friends/work colleagues regarding your oral condition?
4. How isolated do you feel as a result of this oral condition?

Response options and scale rating code
Not at all = 0
Slightly = 1
Moderately = 2
Considerably = 3
Extremely = 4

* Questions in which the response scale was reversed: Not at all = 4; Slightly = 3; Modestely = 2; Considerably = 1; Extremely = 0.
Results

Patient demographics are displayed in Table 1. Patients were divided into 4 disease categories: oral lichen planus, recurrent aphthous ulcers, pemphigus, and others. The latter category included candidiasis, Stevens-Johnson syndrome, oral submucous fibrosis, leukoplakia, radiation-induced mucositis, and bullous pemphigoid. We observed that chronic oral mucosal diseases affected a wide range of ages. The 2 decades with the most study subjects were those age 31 to 40 years and those age 51 to 60 years, which consisted of 26% and 20% of subjects, respectively. There were equal numbers of men and women in our study.

The overall COMDQ scores by domain are displayed in Table 2. Patients had a moderate overall QOL when physical disability, medications and side effects, and social and emotional status were considered. However, patients had a good QOL when support from family members and friends was considered. We observed a significant correlation between medication and treatment and social and emotional status with pain and functional limitation using Pearson correlation (Table 3). Social and emotional status also correlated with patient support, indicating that all four variables affected the patients' QOL. Improvement in any or all of these variables could positively affect the QOL.

Disease group-specific scores on the COMDQ are reported in Tables 4 and 5. Recurrent aphthous ulcers and pemphigus adversely affected the QOL more than the other COMD subgroups did. Among different disease groups, patients with pemphigus had the worst QOL: 73.67 ± 5.68.

Age- and sex-related questionnaire scores are reported in Tables 6 and 7, respectively. Older patients—those older than age 35 years—reported significantly lower QOL (p = 0.015). There was also a significantly lower overall QOL in older individuals (Table 6). Further comparison of age with different domains revealed a significantly lower QOL in the domain of social and emotional status (Table 8). Significant age-related differences in QOL were not observed in the other domains. Men reported significantly better oral health-related QOL than women in pain and functional limitation: mean (standard deviation) 16.14 ± 8.94 vs 21.44 ± 7.70 (p = 0.010; Table 8). Significant differences were not observed between the sexes for the other domains. Significant differences in QOL were not observed between the disease groups apart from recurrent aphthous ulcers and pemphigus (p = 0.005).

Discussion

In this study, we found that COMD significantly affected the patients' QOL, which was influenced by pain and functional limitation, medication and treatment, social and emotional status of the patient, and patient support. Llewellyn and Warnakulasuriya evaluated oral diseases such as recurrent aphthous ulcers, oral lichen planus, oral candidiasis, dry mouth, burning mouth, and other temporomandibular joint disorders using the Oral Health Impact Profile-14 and observed that COMD can have a serious impact on patients' oral health-related QOL.

Mumcu et al evaluated the effect of disease activity in Behçet’s disease and recurrent aphthous ulcers using an oral health-related QOL. Those patients with active oral ulcers reported poorer oral health-related QOL compared with ulcer-free patients.

Table 2. Overall scores on Chronic Oral Mucosal Diseases Questionnaire

<table>
<thead>
<tr>
<th>Domain</th>
<th>Mean</th>
<th>SD</th>
<th>Mean percentage of total score</th>
<th>Range of score obtained</th>
<th>Maximum possible score</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain and functional limitation</td>
<td>18.71</td>
<td>8.71</td>
<td>51.98</td>
<td>1 - 36</td>
<td>36</td>
<td>Moderate</td>
</tr>
<tr>
<td>Medication and treatment</td>
<td>14.57</td>
<td>4.91</td>
<td>60.71</td>
<td>2 - 22</td>
<td>24</td>
<td>Moderate</td>
</tr>
<tr>
<td>Social and emotional</td>
<td>16.04</td>
<td>7.53</td>
<td>57.30</td>
<td>0 - 28</td>
<td>28</td>
<td>Moderate</td>
</tr>
<tr>
<td>Patient support</td>
<td>7.93</td>
<td>3.20</td>
<td>49.55</td>
<td>1 - 14</td>
<td>16</td>
<td>Good</td>
</tr>
<tr>
<td>Overall QOL</td>
<td>57.26</td>
<td>19.73</td>
<td>55.05</td>
<td>13 - 85</td>
<td>104</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

QOL = quality of life; SD = standard deviation.

Table 3. Karl Pearson correlation between different domains of Chronic Oral Mucosal Diseases Questionnaire

<table>
<thead>
<tr>
<th>Karl Pearson correlation coefficient</th>
<th>Pain and functional limitation</th>
<th>Medication and treatment</th>
<th>Social and emotional</th>
<th>Patient support</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>r value</td>
<td>0.604*</td>
<td>0.693*</td>
<td>0.176</td>
<td>0.885*</td>
<td></td>
</tr>
<tr>
<td>p value</td>
<td>0.000</td>
<td>0.000</td>
<td>0.146</td>
<td>0.000</td>
<td></td>
</tr>
<tr>
<td>r value</td>
<td>0.604*</td>
<td>0.667*</td>
<td>0.180</td>
<td>0.800*</td>
<td></td>
</tr>
<tr>
<td>p value</td>
<td>0.000</td>
<td>0.000</td>
<td>0.135</td>
<td>0.000</td>
<td></td>
</tr>
<tr>
<td>r value</td>
<td>0.693*</td>
<td>0.667*</td>
<td>0.308*</td>
<td>0.904*</td>
<td></td>
</tr>
<tr>
<td>p value</td>
<td>0.000</td>
<td>0.000</td>
<td>0.010</td>
<td>0.000</td>
<td></td>
</tr>
<tr>
<td>r value</td>
<td>0.176</td>
<td>0.180</td>
<td>0.308*</td>
<td>0.402*</td>
<td></td>
</tr>
<tr>
<td>p value</td>
<td>0.146</td>
<td>0.135</td>
<td>0.010</td>
<td>0.001</td>
<td></td>
</tr>
</tbody>
</table>

* Correlation is significant at the 0.01 level (2-tailed).
The existing literature shows that oral health problems can result in pain and discomfort and can lead to problems in eating, interpersonal relationships, appearance, and self-image.\textsuperscript{17,18} Therefore, pain and functional limitation secondary to disease should be properly evaluated and treated when possible to help improve the patient’s QOL. Tabolli et al\textsuperscript{19} found that administration of specific and generic questionnaires provided a detailed picture of the impact of oral diseases on patients, which adds information that may be useful in clinical practice. The COMDQ, being a single discipline-specific questionnaire, could help in the analysis of both physical and psychological evaluation of QOL. The use of this questionnaire for the evaluation of QOL may help give a greater focus to the limited time available at follow-up appointments. These outpatient visits have often concentrated on the symptomatic exacerbation of COMD to the exclusion of other aspects of a patient’s health. The COMDQ may allow the patient to assist in the evaluation and assessment of treatment effectiveness. It could supply valuable information regarding the patient’s perspective on his/her disease. However, included the patient’s own perception of his/her disease. However, our study looking at the specific domains of the COMDQ, we observed that pain, physical status, and patient’s psychological status were equally affected in patients with oral lichen planus.\textsuperscript{20}

With increasing age, we observed a worse QOL that was attributed mainly to the worsening social and emotional status that included the patient’s own perception of his/her disease. However, in our opinion, giving proper education about COMD, patient counseling, and assurance about the success of available treatment modalities may help prevent worsening of QOL in patients with a poor social and emotional status.

The clinical evaluation of COMD, by including dentists and physicians, may give information about the cause, can aid in determining potential treatments, and can also provide clues about relationships, appearance, and self-image. Counseling, and assurance about the success of available treatment modalities may help prevent worsening of QOL in patients with a poor social and emotional status.

**Table 5. Post hoc analysis showing the subgroups with difference**

<table>
<thead>
<tr>
<th>Multiple comparisons</th>
<th>Dependent variable, p value</th>
<th>Pain and functional limitation</th>
<th>Medication and treatment</th>
<th>Social and emotional</th>
<th>Patient support</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OLP</td>
<td>RAU</td>
<td>1.00</td>
<td>0.238</td>
<td>0.276</td>
<td>1.00</td>
<td>0.414</td>
</tr>
<tr>
<td></td>
<td>Pemphigus</td>
<td>0.084</td>
<td>0.970</td>
<td>0.227</td>
<td>1.00</td>
<td>0.119</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>1.00</td>
<td>1.000</td>
<td>1.000</td>
<td>1.00</td>
<td>1.000</td>
</tr>
<tr>
<td>RAU</td>
<td>OLP</td>
<td>1.00</td>
<td>0.238</td>
<td>0.276</td>
<td>1.00</td>
<td>0.414</td>
</tr>
<tr>
<td></td>
<td>Pemphigus</td>
<td>0.017*</td>
<td>0.038*</td>
<td>0.007*</td>
<td>1.00</td>
<td>0.005*</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>0.471</td>
<td>0.987</td>
<td>1.000</td>
<td>1.00</td>
<td>0.480</td>
</tr>
<tr>
<td>Pemphigus</td>
<td>OLP</td>
<td>0.084</td>
<td>0.970</td>
<td>0.227</td>
<td>1.00</td>
<td>0.119</td>
</tr>
<tr>
<td></td>
<td>RAU</td>
<td>0.017*</td>
<td>0.038*</td>
<td>0.007*</td>
<td>1.00</td>
<td>0.005*</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>0.654</td>
<td>0.588</td>
<td>0.155</td>
<td>1.00</td>
<td>0.280</td>
</tr>
<tr>
<td>Other</td>
<td>OLP</td>
<td>1.00</td>
<td>1.000</td>
<td>1.000</td>
<td>1.00</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>RAU</td>
<td>0.471</td>
<td>0.987</td>
<td>1.000</td>
<td>1.00</td>
<td>0.480</td>
</tr>
<tr>
<td></td>
<td>Pemphigus</td>
<td>0.654</td>
<td>0.588</td>
<td>0.155</td>
<td>1.00</td>
<td>0.280</td>
</tr>
</tbody>
</table>

* The mean difference is significant at the 0.05 level.

OLP = oral lichen planus; RAU = recurrent aphthous ulcers.
the prognosis but may not directly reflect the resulting level of impairment. This is where QOL measurements can play a key role by helping evaluate the more subjective dimensions of the disease and its treatment. These measurements must be simple and practical enough for the clinician and patient to use and interpret, but at the same time include all the factors that can affect the disease burden. The COMDQ was found to be reliable, simple to use, and sensitive to clinical parameters and treatment modalities. A limitation to this report was that it was based on a sample of convenience and had no control group. The COMDQ can be successfully administered to assess the oral health-related QOL as a part of the routine management of COMD. The COMDQ may be useful in future clinical trials.

Table 6. Correlation between age and scores on Chronic Oral Mucosal Diseases Questionnaire

<table>
<thead>
<tr>
<th>Age group</th>
<th>n</th>
<th>Mean score</th>
<th>SD</th>
<th>t value</th>
<th>df</th>
<th>Significance (2-tailed p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 35 years</td>
<td>25</td>
<td>48.62</td>
<td>21.48</td>
<td>-2.17</td>
<td>68</td>
<td>0.033</td>
</tr>
<tr>
<td>&gt; 35 years</td>
<td>45</td>
<td>58.63</td>
<td>16.62</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

df = degrees of freedom; SD = standard deviation.

Table 7. Sex correlation with scores on Chronic Oral Mucosal Diseases Questionnaire

<table>
<thead>
<tr>
<th>Sex breakdown by questionnaire domain</th>
<th>Mean</th>
<th>SD</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain and functional limitation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>16.14</td>
<td>8.94</td>
<td>2.65</td>
<td>0.010*</td>
</tr>
<tr>
<td>Women</td>
<td>21.44</td>
<td>7.70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication and treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>14.17</td>
<td>4.98</td>
<td>0.71</td>
<td>0.482</td>
</tr>
<tr>
<td>Women</td>
<td>15.0</td>
<td>4.88</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social and emotional</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>14.47</td>
<td>8.28</td>
<td>1.83</td>
<td>0.072</td>
</tr>
<tr>
<td>Women</td>
<td>17.71</td>
<td>6.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient support</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>8.22</td>
<td>3.23</td>
<td>0.79</td>
<td>0.434</td>
</tr>
<tr>
<td>Women</td>
<td>7.62</td>
<td>3.20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>53.0</td>
<td>21.33</td>
<td>1.89</td>
<td>0.063</td>
</tr>
<tr>
<td>Women</td>
<td>61.76</td>
<td>17.05</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Statistically significant. SD = standard deviation.

Table 8. Correlation between age and scores in different domains of chronic oral mucosal disease questionnaire

<table>
<thead>
<tr>
<th>Karl Pearson correlation coefficient:</th>
<th>r value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age with</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain and functional limitation</td>
<td>0.231</td>
<td>0.054</td>
</tr>
<tr>
<td>Medication and treatment</td>
<td>0.104</td>
<td>0.392</td>
</tr>
<tr>
<td>Social and emotional</td>
<td>0.290</td>
<td>0.015*</td>
</tr>
<tr>
<td>Patient support</td>
<td>0.227</td>
<td>0.058</td>
</tr>
<tr>
<td>Overall</td>
<td>0.275</td>
<td>0.021*</td>
</tr>
</tbody>
</table>

* Statistically significant.