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The Permanente Journal

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The Permanente Journal

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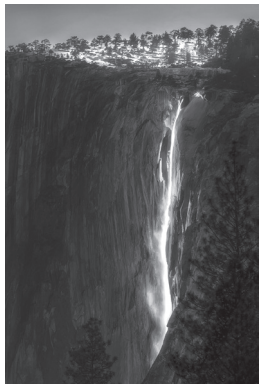

Horsetail Fall
photograph
by Sapna Reddy, MD

Horsetail Fall cascades down the surface of El Capitan, in Yosemite National Park in CA, when there is an adequate snow accumulation combined with warmer temperatures. For only two weeks in February the angle of the setting sun on clear days illuminates the waterfall, transforming its color to that of flaming lava. The phenomenon attracts tens of thousands of visitors every year. Yosemite National Park is a national treasure and must be protected as such for future generations.

Dr Reddy is a Radiologist at the Walnut Creek Medical Center in CA and is pursuing a second career as a landscape/nature photographer. More of her work can be seen at: www.sapnareddy.com.

ORIGINAL RESEARCH & CONTRIBUTIONS

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Diagnostic Prevalence of Ankylosing Spondylitis Using Computerized Health Care Data, 1996 to 2009: Underrecognition in a US Health Care Setting

Jeffrey R Curtis, MD; Leslie R Harrold, MD, MPH; Maryam M Asgari, MD, MPH; Atul Deodhar, MD; Craig Salman; Joel M Gelfand, MD, MSCE; Jashin J Wu, MD; Lisa J Herrinton, PhD

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ABSTRACT

Introduction: Few studies have assessed the prevalence and features of axial spondyloarthritis (axSpA) and ankylosing spondylitis in diverse, population-based, community settings.

Objectives: We used computerized diagnoses to estimate the prevalence of axSpA and ankylosing spondylitis in Kaiser Permanente Northern California (KPNC).

Methods: We identified persons aged 18 years or older with 1 or more International Classification of Diseases, Ninth Revision (ICD-9) diagnosis Code 720.X (ankylosing spondylitis and other inflammatory spondylopathies) in clinical encounter data from 1996 through 2009 to estimate the prevalence of axSpA and ankylosing spondylitis. We reviewed medical records to confirm the diagnosis in a random sample and estimated the positive predictive value of computerized data to identify confirmed cases using various case definitions.

Results: In the computerized data, 5568 adults had diagnostic codes indicating axSpA. On the basis of our case-finding approach using a single physician diagnosis code for ICD-9 720.X, the point prevalence of these conditions, standardized to the 2000 US Census, was 2.26 per 1000 persons for axSpA and 1.07 per 1000 for ankylosing spondylitis. Less than half of suspected cases saw a rheumatologist. The most specific algorithm for confirmed ankylosing spondylitis required 2 or more computerized diagnoses assigned by a rheumatologist, with 67% sensitivity (95% confidence interval, 64%-69%) and 81% positive predictive value (95% confidence interval, 79%-83%).

Conclusions: Observed prevalence in the KPNC population, compared with national estimates for axSpA and ankylosing spondylitis, suggests there is substantial underrecognition of these conditions in routine clinical practice. However, use of computerized data is able to identify true cases of ankylosing spondylitis, facilitating population-based research.

INTRODUCTION

Axial spondyloarthritis (axSpA) is characterized by chronic inflammatory back pain starting before the age of 45 years that involves sacroiliac joints. *AxSpA* is a relatively new umbrella term that includes ankylosing spondylitis and nonradiographic axSpA. Nonradiographic axSpA refers to an inflammatory spinal condition with symptoms that may be quite similar to ankylosing spondylitis, but where definitive x-ray changes in sacroiliac joints are not present. Most patients with nonradiographic axSpA will have visible inflammation in the sacroiliac joints or spine if advanced imaging such as magnetic resonance imaging (MRI) is performed, and some but not all of these patients will progress to ankylosing spondylitis.[1] The clinical features of inflammatory back pain include symptoms that are worse at night and with rest, improve with exercise, and entail prolonged morning stiffness. Physical examination findings and investigations in patients with axSpA include limitation in range of motion of the chest wall and axial joints, association with human leukocyte antigen-B27 (HLA-B27), and inflammation and/or sclerosis/erosions in the spine and sacroiliac joints. Patients with axSpA carry a substantial burden of disease not only because of musculoskeletal features but also because of extra-articular manifestations that include enthesitis, inflammatory bowel disease, uveitis, psoriasis, and fractures. Treatment options include nonsteroidal anti-inflammatory drugs, nonbiologic disease-modifying antirheumatic drugs such as sulfasalazine (for treatment of peripheral arthritis), and tumor necrosis factor blockers.

Classification criteria for spondyloarthritis have evolved over time, making it challenging to assess the incidence and prevalence of axSpA in population-based settings.[2,3] Two recent studies have investigated the prevalence of axSpA in the US using different methods. The National Health and Nutritional Examination Survey (NHANES) of 2009-2010 concluded that the prevalence of axSpA, using either the Amor or the European Spondyloarthritis Study Group classification criteria, was between 0.9% and 1.4% of the US population, or 9 to 14 per 1000.[4] The NHANES surveys, which are nationally representative, are done by selecting noninstitutionalized US adults through a complex, multistage probability design. Strand et al[5] reported the axSpA prevalence as 0.7% (7 per 1000) by retrospective analysis of patients' medical records from 101 randomly selected US rheumatology practices. Both methods have their advantages and shortcomings, but the axSpA prevalence estimates in these 2 studies are similar.

Registries and other population-based resources are useful to assess the prevalence, incidence, risk factors, and outcomes of diseases

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such as axSpA and ankylosing spondylitis. We used computerized clinical databases maintained by Kaiser Permanente to estimate the prevalence of clinically recognized axSpA in a stable, well-characterized, and ethnically diverse population. As a secondary aim, we evaluated the ability of computerized data to validate cases of axSpA and ankylosing spondylitis.

METHODS

The study was conducted under the approval of the Kaiser Foundation Research Institute's institutional review board. Because no participant contact was involved and the study involved only a review of existing electronic health record data and associated information (eg, imaging results), no participant consent was obtained or required.

Study Population

Kaiser Permanente Northern California (KPNC) is a prepaid, comprehensive, integrated care organization that maintains computerized clinical data of all visits, procedures, and prescriptions provided to more than 3 million members in Northern California.

This study included patients with at least 12 months of enrollment in KPNC between 1996 and 2009. Preliminary axSpA cases of patients aged 18 years and older were identified using age on the date of the first diagnosis recorded during the observation period. Because there is no International Classification of Diseases, Ninth Revision (ICD-9) code uniquely appropriate for axSpA, the expectation was that US rheumatologists would use Code 720.X to record such cases. We identified patients with at least 1 assignment of ICD-9 Code 720.X from a physician in the computerized outpatient or inpatient database as preliminary cases. This group of diagnoses included ankylosing spondylitis (Code 720.0), spinal enthesopathy (720.1), sacroiliitis (720.9), and unspecified spondyloarthropathy (720.9). On the basis of the available project resources, an approximate 3% random sample of all preliminary cases was selected for validation using detailed review of the medical record. The sample was stratified on the basis of the type of clinician who recorded the diagnosis (rheumatologist, other clinician), the number of diagnostic codes (1, ≥ 2), the presence of codes for other inflammatory arthritides (rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, or arthritis with inflammatory bowel disease), and prescriptions for disease-modifying antirheumatic drugs.

Data Collection

Data collection occurred during 2010. Observation began on the later of the date of each patient's enrollment with KPNC or January 1, 1996, and ended on disenrollment or December 31, 2009. Computerized medical information was obtained during 1996 through 2009 and included rheumatologist-recorded diagnosis codes recorded into outpatient data, hospital discharge diagnoses, and laboratory results for HLA-B27. All relevant computerized medical information was obtained for possible cases. A manual chart review was performed on a sample of preliminary cases that had at least 1 computerized diagnostic code for axSpA or ankylosing spondylitis. The main purpose of the chart review was to confirm the diagnosis recorded in the computerized data. A secondary purpose was to obtain information on disease manifestations and family history.

A trained medical record abstractor reviewed the medical records to confirm the diagnosis. The abstractor accessed data from the electronic medical record that was established in 2004 and 2005; in addition, she sometimes referred to clinic notes recorded in the paper-based records created before the transition to the electronic medical record. The abstractor reviewed outpatient notes, hospital discharge summaries, laboratory results, and radiology reports to confirm or rule out the diagnoses using a structured case report form developed by the study team.

Study Case Definition

Following case validation, the criteria required to satisfy our study's case definition of axSpA and ankylosing spondylitis was two or more clinical diagnoses recorded by a treating rheumatologist in the medical record and occurring on at least two unique calendar days with no qualifiers such as "rule-out" or "possible." Clinic notes by a primary care clinician, without a rheumatologist consult, and indicating joint inflammation in the spine with or without peripheral involvement and without a more specific diagnosis, were reviewed by a single, now retired rheumatologist. The rheumatologist assessed clinical features, including joint inflammation that lasted at least six weeks; associated laboratory test results; and radiology reports and images and reports for sacroiliitis, erosions of the sacroiliac joints, and other radiographic features consistent with axSpA or ankylosing spondylitis.

Given the retrospective, population-based nature of the study, this case definition was intended to represent a reasonable reference standard to confirm a community-based diagnosis; it was not intended to confirm cases according to formal classification criteria, which would have been infeasible in this setting. The data presented reflected the status of the disease at the time it was assessed and the information available in medical records as part of routine clinical care. The data were not considered to reflect the cumulative prevalence of various manifestations of ankylosing spondylitis based on a systematic, standardized evaluation. During the course of the study and its timeframe in relation to classification criteria for axSpA and the data available to the project (1996-2009), it became apparent that there was not sufficient data available to definitively evaluate the validity of axSpA cases. Therefore, case confirmation was subsequently restricted to ankylosing spondylitis only.

Disease Manifestations of Ankylosing Spondylitis in Confirmed Cases

Disease manifestations were characterized descriptively and included HLA-B27 positivity; comorbid conditions, including those in the spondyloarthritis family; complications or manifestations of axSpA or ankylosing spondylitis (interstitial lung disease/fibrosis, aortic insufficiency, enthesitis, Achilles tendinitis [heel pain], uveitis/iritis, iridocyclitis, kyphosis, costochondritis); radiographic evidence of syndesmophytes, spondylitis, squaring of vertebral bodies, sacroiliitis, and erosions of the sacroiliac joint; and abnormal results of the Schober test. Because of the community-based and retrospective nature of the study, not all possible clinical and radiologic examinations were performed on all patients; thus, absence of these features did not necessarily imply that the ankylosing spondylitis-associated features of interest were not present, only that they were not assessed or recorded.

Statistical Analysis

The positive predictive value (PPV) was determined for each of several a priori case-finding algorithms for ankylosing spondylitis. For each a priori algorithm, sensitivity was defined as the number of confirmed cases of ankylosing spondylitis captured by the a priori algorithm divided by the number of confirmed cases with at least 2 ICD-9 Codes 720.X assigned by any physician or 1 such code from a rheumatologist. The PPV was defined as the number of cases captured by the algorithm that was confirmed with the disease during medical record review divided by the number of confirmed plus unconfirmed cases that were captured by the algorithm. We did not compute specificity or negative predictive value because they generally do not fall below 99% for relatively uncommon diseases.

Variables that were examined for inclusion in case-finding algorithms included 1) inpatient and outpatient visits with relevant codes for axSpA or ankylosing spondylitis (720.X), 2) number of visits to a rheumatologist, 3) use of biologic or nonbiologic disease-modifying antirheumatic drugs, and 4) presence of diagnoses for other inflammatory arthritides such as rheumatoid arthritis or psoriatic arthritis. We evaluated multiple possible case-finding algorithms, with the most inclusive (ie, sensitive) algorithm (≥ 1 physician diagnosis of axSpA) used as the basis for comparison with all other algorithms.

All analyses were conducted using SAS version 9.13 software (SAS Institute, Cary, NC). We used the SAS SURVEYMEANS procedure to estimate the PPV and its 95% confidence interval (CI). The procedure took into account that the sampling design was stratified; thus, the overall PPV was weighted.

Estimation of Point Prevalence

The age- and sex-specific prevalence of axSpA and ankylosing spondylitis was calculated using as the denominator the number of men and women in each age group who were members of KPNC on December 31, 2009. The point prevalence was expressed as the number of adult cases with the disease divided by the number of adults in the Health Plan. The age- and sex-standardized proportion was estimated using the direct method of standardization, with the 2000 US Census population providing weights.[6] The 95% CIs were computed assuming a Poisson distribution.[7]

RESULTS

Application of Case-Finding Algorithm

There were 5568 KPNC members with at least 1 inpatient or outpatient diagnosis code of 720.X for ankylosing spondylitis or another inflammatory spondylopathies; of these, 48% were for ankylosing spondylitis specifically (720.0). However, 2965 (53% overall) of these had only a single code assigned by a primary care clinician. We validated the medical record for a random sample of 44 of these 2965 patients, of which only 1 person (PPV, 2%) was confirmed. Because of the low PPV of this definition and resource constraints of the study, we therefore excluded these patients from further consideration.

Among the 2603 patients remaining who had axSpA or ankylosing spondylitis, 1028 (39%) had 2 or more diagnostic codes by a primary care clinician, 250 (10%) had a single diagnostic code by a rheumatologist (with or without additional codes from a primary care or other type of physician), and 1325 (51%) had 2 or more diagnostic codes by a rheumatologist.

We examined sensitivity and PPV of 4 case-finding algorithms (Table 1). The most inclusive allowed 2 or more diagnoses by a primary care clinician or 1 or more diagnoses by a rheumatologist. By definition (because we excluded possible cases that had only 1 diagnosis code by a primary care clinician), this most inclusive algorithm had 100% sensitivity.

In total, we performed 129 chart reviews to confirm possible ankylosing spondylitis (excluding the 44 chart reviews performed for patients with only a single diagnosis recorded by a primary care clinician). Of these, 80 (62%) were true-positives. The 3 other

Table 1. Sensitivity and positive predictive value of computerized diagnoses for identifying ankylosing spondylitis in 2603 adults at first recorded diagnosis with 1 or more diagnoses[a]

Operational definition	Number in population	Number in stratified sample[b]	Number of true-positives in stratified sample[c]	Number of false-positives in stratified sample[c]	Sensitivity,[d] % (95% CI)	Percentage of diagnoses for AS (ICD-9 code 720.0)	PPV of algorithm to find AS, % (95% CI)[e]
≥ 2 diagnoses in primary care or ≥ 1 diagnosis in rheumatology	2603	129	80	49	100[c]	80	62 (60-64)
≥ 2 diagnoses, any department	2353	102	67	35	96 (95-97)	80	66 (64-68)
≥ 1 diagnosis, rheumatology	1575	83	61	22	72 (70-74)	94	73 (71-76)
≥ 2 diagnoses, rheumatology[f]	**1325**	**56**	**48**	**8**	**67 (64-69)**	96	**81 (79-83)**

[a] Patients aged 18 years or older, from inpatient or outpatient data from Kaiser Permanente Autoimmune Disease Registry, Northern California, 1996 to 2009.
[b] Subjects were sampled for chart review on the basis of the number of visits, the department in which the diagnosis was made, use of disease-modifying antirheumatic drugs, and presence of comorbid autoimmune conditions. The latter 2 variables did not improve the sensitivity or specificity of the algorithm.
[c] Classified on the basis of medical record review.
[d] By definition, given that our search strategy required at least 1 physician diagnosis of ICD-9 code 720.X, and recognizing the likelihood of underascertainment.
[e] Calculated by dividing the number of true-positives by the number in the stratified sample. For example, on the first row, 80 (true-positives)/129 (number in the stratified sample) = 62%.
[f] Boldface indicates most specific algorithm (maximized positive predictive value).
AS = ankylosing spondylitis; CI = confidence interval; ICD-9 = International Classification of Diseases, Ninth Revision; PPV = positive predictive value.

algorithms that we tested were subsets of the most inclusive and considered only the number of diagnostic codes and the department in which they were recorded (Table 1). The sensitivity of the 2 algorithms that required 2 or more physician diagnoses, or 1 or more diagnoses from a rheumatologist, ranged from 72% to 96%, with PPVs ranging from 66% to 73%. The algorithm that maximized PPV required 2 or more diagnoses by a rheumatologist and had a sensitivity of 67% (95% CI, 64%-69%) and PPV of 81% (95% CI, 79%-83%).

Half of the patients with 2 or more rheumatologist diagnoses used biologic or nonbiologic disease-modifying antirheumatic drugs, with the algorithm performing the same in those with and without such drug use. The presence or absence of concomitant diagnoses for other autoimmune diseases did not affect the performance of the algorithm.

Among the 49 false-positives whose charts were reviewed to confirm ankylosing spondylitis, 10 had other autoimmune diseases, including 5 with rheumatoid arthritis, 2 with inflammatory bowel disease, 1 with both rheumatoid arthritis and inflammatory bowel disease, and 2 with psoriatic arthritis. However, only 4 of these 10 patients had 2 or more rheumatologist diagnoses. Although these individuals might have met diagnostic criteria for axSpA, the diagnostic workup and associated clinical data available were inadequate to systematically assess all reviewed cases for axSpA.

Prevalence of Axial Spondyloarthritis and Ankylosing Spondylitis

Using the most sensitive definition for axSpA (any 720.X diagnosis code, n = 5568 cases) among patients enrolled in Kaiser Permanente on December 31, 2009, the point prevalence of axSpA, standardized to the 2000 US Census, was 2.26 (95% CI, 2.20-2.32) per 1000. Using a somewhat more specific definition, 2 or more diagnoses in primary care or 1 or more diagnosis in rheumatology (n = 2603), 80% of which were for ankylosing spondylitis, the corresponding estimate was lower by approximately half (1.07 per 1000, 95% CI, 1.03-1.11).

Characteristics of Ankylosing Spondylitis Cases

Characteristics of the 80 persons confirmed with ankylosing spondylitis were described on the basis of information found in medical records. Most of these specifically mentioned a diagnosis of ankylosing spondylitis. Sixty-one percent of patients were under age 50 years, and 83% were male; 45% were white, 14% Hispanic, and 14% Asian (Table 2). Only 44% had an HLA-B27 test, and only 34% were positive (among those tested). Joint involvement by signs and symptoms was not specifically recorded for 30% of patients. In the remainder, symptoms included the lumbar spine in 55% of patients; x-ray, MRI, or computed tomography evidence for cervical spine involvement in 13%, and sacroiliac and/or hip joint involvement in 26%. About one-fourth of patients had uveitis or iritis.

DISCUSSION

We estimated the prevalence of axSpA using computerized health care data during 1996-2009. A total of 5568 adults had any diagnostic code indicating axSpA in the computerized data. This led to a point prevalence of axSpA, standardized to the 2000 US census, of 2.26 per 1000. We also reviewed the charts of a random sample of 173 of the 5568 patients. The best (most specific) performing algorithm for ankylosing spondylitis required 2 or more computerized diagnoses by a rheumatologist and had a PPV of 81% (95% CI, 79%-83%) compared with our study case definition.

The incidence and prevalence of ankylosing spondylitis have been described in a number of studies. One report was from the Rochester Epidemiology Project[8] in Minnesota, which identified 158 cases with radiographic sacroiliitis recorded on radiology reports from 1935 to 1989. The overall age- and sex-adjusted incidence rate was 7.3 per 100,000 person-years (95% CI, 6.1-8.4), although prevalence was not reported. Kaipiainen-Seppanen and coworkers[9-11] reported the annual incidence and prevalence of ankylosing spondylitis requiring antirheumatic medication among 87,000 inhabitants of Kuopio, Finland. In 2000, the annual incidence was 6.9 per 100,000 adults (95% CI, 6.0-7.8), very similar to the incidence rate in Rochester, MN, and the prevalence was 1.5 per 1000 (95% CI, 0.8-2.7), very similar to the prevalence we estimated for the KPNC population. In Norway, from 1960 through 1993, the annual incidence of ankylosing spondylitis was 8.71 per 100,000 (95% CI, 6.38-11.04), whereas the estimated point prevalence was 2.6 per 1000 on January 1, 1990.[12] Other reports of the occurrence of ankylosing spondylitis have been reviewed.[13] The prevalence of ankylosing spondylitis was much lower, 0.30 per 1000 (95% CI, 0.26-0.33) in Greece from 1983 through 2002,[14] whereas in Japan it was 0.095 per 1000, based on 990 cases.[15] The prevalence of ankylosing spondylitis has been reported to be relatively high in populations indigenous to circumpolar regions.[15-18]

Key differences between this report and earlier reports include the size and diversity of the study populations, with the Rochester, Norway, and Sweden populations being largely white with a more restricted genetic background, and the Northern California population reported here being more racially and ethnically diverse. The KPNC population is more diverse than the US population and is 50% white, 6% African American, 22% Hispanic, and 21% Asian.[19,20] Differing calendar periods, disease duration (which affects prevalence estimates), methods for case ascertainment, and fulfillment of diagnostic vs classification criteria are other potential differences that make these reports somewhat difficult to directly compare with one another.

The 2009-2010 NHANES study is the largest effort to date to assess the prevalence of axSpA in the US.[4] They calculated the prevalence of axSpA to be 14 per 1000 in US adults. This figure is 6 times higher than the prevalence we estimated from the KPNC population. There are several possible explanations for this discrepancy. First, there are major differences in the study designs. Whereas NHANES was designed to actively search for axSpA in a prospective manner in the general US population, the KPNC study was a retrospective analysis of computer records from a community-based patient population. To assess the prevalence of axSpA, NHANES investigators used a specifically designed case ascertainment tool that systematically searched for spondyloarthritis features found during spondyloarthritis-focused physical examinations, as well as systematically assessed for HLA-B27, applying the criteria of Amor and the European Spondyloarthritis Study Group.[1,3] In contrast, clinicians in KPNC were not actively searching for spondyloarthritis, and the study design is a retrospective capture of the computerized data for diagnoses made not just by specialists but also by primary

care physicians, and made without applying these classification criteria. Strand et al[5] estimated the prevalence of axSpA in the US to be 7 per 1000, and 3 per 1000 for ankylosing spondylitis, half that reported by NHANES, despite being conducted in US rheumatologists' practices. Our study showed that many patients suspected of spondyloarthritis were not referred by primary care clinicians to rheumatologists, supported by our data showing that 48% of all 720.X cases were ankylosing spondylitis (720.0) but 94% of 720.X cases seen by rheumatologists were ankylosing spondylitis.

The second major reason for the low prevalence of axSpA in our study may suggest underascertainment of these cases in clinical practice. Indeed, the necessary data to support classifying patients according to our study case definition (much less apply the formal classification criteria for axSpA or ankylosing spondylitis) were frequently absent in the KPNC records. We also call attention to the distinction between population prevalence, the proportion of patients with a diagnosed disease of interest throughout the entire population, vs diagnostic prevalence (which we assessed in this study) Diagnostic prevalence is the proportion of people who have a diagnosis of the disease based on diagnostic codes, physician diagnoses, or other features determined when they seek medical attention. For most conditions, some patients will have the disease of interest, yet it is undiagnosed; diagnostic prevalence would not include these patients and therefore would be expected to underestimate the true disease prevalence. The study by Strand et al[5] noted that the US rheumatologists did not diagnose one-fourth of cases of axSpA even though they fulfilled the Assessment of SpondyloArthritis International Society classification criteria and were subsequently discovered by retrospective chart assessment. It is likely that the underascertainment of these cases in general practice by nonspecialists is even higher, indicating a need for increased awareness.[21-23]

Table 2. Demographic and disease manifestations among 80 confirmed cases of ankylosing spondylitis from Kaiser Permanente Northern California, 1996 to 2009

Characteristic	n (%)
Sex, male	66 (83)
Age, years	
18-29	9 (11)
30-39	18 (23)
40-49	22 (27)
50-59	15 (19)
60-69	11 (14)
70-89	5 (6)
Race/ethnicity	
White	36 (45)
Hispanic	11 (14)
Asian	11 (14)
African American	2 (2)
Other/multiracial/unknown	20 (25)
Disease duration, years	
0-4	12 (15)
5-9	13 (16)
10-19	14 (18)
≥ 20	34 (42)
Not recorded	7(9)
Laboratory and imaging tests	
HLA-B27 test performed	35 (44)
HLA-B27 positive (% of those tested)	12 (34)
X-rays of SI joints and/or spine	61 (76)
CT of SI joints and/or spine	6 (8)
MRI of SI joints and/or spine	16 (20)
Associated immune-mediated disease diagnoses (present at any time)	
None or unmentioned	60 (75)
Psoriasis or psoriatic arthritis	2 (2)
JIA/JRA	1 (1)
Inflammatory bowel disease	2 (2)
Reactive arthritis	4 (5)
Undifferentiated spondyloarthropathy	2 (2)
Other	7 (9)

Characteristic	n (%)
Joint involvement by signs/symptoms	
Lumbar spine	44 (55)
SI joint/hip	21 (26)
Cervical spine/neck	10 (13)
Shoulder	2 (3)
Thoracic spine	4 (5)
Knee	3 (4)
Ankle	3 (4)
Not recorded	24 (30)
Complications	
Uveitis or iritis	19 (24)
Kyphosis	4 (5)
Achilles tendinitis	2 (3)
Enthesitis	1 (1)
None	55 (69)
Positive Schober test	31 (39)
Family history of autoimmune disease[a]	
Mother/father/sibling	19 (24)
Grandparent/distant relative	8 (10)
Medication use[b]	
Oral glucocorticoids	27 (34)
Etanercept	14 (18)
Adalimumab	5 (6)
Infliximab	4 (5)

[a] Family history of any of the following diseases: Addison disease, adult Still disease, alopecia areata, ankylosing spondylitis or axial spondyloarthritis, asthma, autoimmune hepatitis, Behçet syndrome, CREST syndrome, Crohn disease, dermatomyositis/polymyositis, diabetes (type 1), Graves disease, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, inflammatory bowel disease, JIA/JRA, Meniere disease, mixed connective tissue disease, myasthenia gravis, pemphigus vulgaris, pernicious anemia, primary biliary cirrhosis, Sjögren syndrome, psoriasis, psoriatic arthritis, Raynaud disease, Reiter syndrome (reactive arthritis), rheumatoid arthritis, sarcoidosis, spondyloarthropathy excluding ankylosing spondylitis, systemic lupus erythematosus, systemic sclerosis (scleroderma), Hashimoto thyroiditis, ulcerative colitis, uveitis/iritis, and vasculitis.

[b] Used anytime between 1996 and 2009.

CT = computed tomography scan; HLA = human leukocyte antigen; JIA/JRA = juvenile idiopathic arthritis or juvenile rheumatoid arthritis; MRI = magnetic resonance imaging; SI = sacroiliac.

A third reason for the low prevalence of axSpA in our study may be that some patients with chronic low back pain are cared for by chiropractors, not physicians. Such patients will not be found in Health Plan data but will be captured in population-based studies like NHANES.

For all these reasons, and because early identification and treatment of axSpA might prevent patients from progressing to ankylosing spondylitis, it is important to identify these conditions earlier. Early identification might be facilitated by an educational campaign directed at clinicians, or a screening program targeted at patients who have back pain with inflammatory features that began at an early age of onset (eg, age < 40 years).[24]

We required patients to have at least one year of enrollment in KPNC to be included in the study. Differing amounts of data available in future studies could affect the estimated prevalence of ankylosing spondylitis and its manifestations, and should be considered when comparing across populations.

The timeframe of the study prevented us from confirming cases of axSpA,[25,26] and we recognize the possibility that some cases that could not be confirmed as ankylosing spondylitis nevertheless had some features that might suggest this condition (eg, concomitant psoriatic arthritis, 2 or more rheumatologist diagnoses). However, we were able to confirm potential ankylosing spondylitis cases. Only 1610 (29%) of the 5568 patients with at least one 720.X diagnosis in the present study population were inferred to truly have ankylosing spondylitis, suggesting that a single diagnosis code alone is not appropriate. The best performing algorithm (based on maximizing PPV) required 2 or more computerized diagnoses by a rheumatologist and had a sensitivity of 67% and a PPV of 81%. Other investigators have used computerized health care data to ascertain the prevalence of ankylosing spondylitis,[11,27-33] but only 2 studies of which we are aware have validated a case-finding algorithm for ankylosing spondylitis.[31,34] The Veterans Affairs study reviewed medical records for 10 patients with 1 or more rheumatologist-assigned diagnostic code for ankylosing spondylitis as well as for other patients with rheumatic diagnoses.[31] The study investigators reported a single diagnosis in the Rheumatology Department to have a PPV of 83% (CI, 78%-89%) with a sensitivity of 91% (CI, 87%-95%), although they did not include nonrheumatologists' diagnoses of ankylosing spondylitis in the denominator when computing sensitivity. As in the present study, requiring use of disease-modifying antirheumatic drugs greatly reduced the sensitivity of case finding and was not helpful.[31] A separate study conducted in The Health Improvement Network involving 85 patients found that a single diagnostic code for ankylosing spondylitis had a PPV of 72%, and the best performing algorithm for ankylosing spondylitis had a PPV of 89% and required 2 ankylosing spondylitis codes more than 7 days apart.[34] It is possible that rheumatologists assigned ankylosing spondylitis diagnoses to patients who actually had nonradiographic axSpA, which would have lowered the PPV. This circumstance may lessen with transition to use of the ICD-10 system given that the relevant diagnostic codes are somewhat more dissimilar between ankylosing spondylitis (M45) and other specified inflammatory spondylopathies such as nonradiographic axSpA (M46.8). We also acknowledge that the sensitivity computed was predicated on an initial case-finding strategy that used ICD-9 codes. Alternate approaches (eg, presence of HLA-B27 or physician notes mentioning ankylosing spondylitis in the electronic health record) may be useful in the future to maximize sensitivity.

A positive HLA-B27 test has been strongly linked to ankylosing spondylitis. HLA-B27 has a very high prevalence among the native peoples of the circumpolar arctic and the subarctic regions of Eurasia and North America and in some regions of Melanesia, and it is present throughout Eurasia; however, the genotype is virtually absent among native populations of South America, Australia, and many equatorial and Southern African populations.[12] In the sample of our 80 confirmed ankylosing spondylitis cases, only 45% were white, and only 44% were tested for HLA-B27. It is possible that only patients for whom the diagnosis of ankylosing spondylitis was uncertain were tested for the presence of HLA-B27. Restated, patients for whom physicians had greater certainty of ankylosing spondylitis on the basis of clinical and radiographic findings may be less likely to be tested for HLA-B27. Because these patients presumably would have a higher prevalence of HLA-B27, this might account for the lower-than-expected prevalence of HLA-B27 in our sample, and the fact that most (two-thirds) were not tested.

Methods used for case finding in any study will depend on the research question, the setting, and the costs of overascertainment and underascertainment with respect to validity and precision. A case-finding strategy that is insensitive but has a high PPV, such as recruitment through rheumatology clinics, likely will yield fewer and more severe cases. The algorithms we examined provided the typical trade-off between specificity (and PPV) and sensitivity. A case-finding algorithm with high sensitivity is useful for studies requiring complete ascertainment but requires additional resources to confirm cases through a second-stage review of medical records. Case-finding algorithms with higher specificity and PPVs are useful when two-stage case ascertainment is impractical. We found that two or more computerized diagnoses for ankylosing spondylitis from a rheumatologist provided the best combination of sensitivity and PPV.

CONCLUSION

Identification of an algorithm using computerized data enables efficient identification of ankylosing spondylitis and should be useful for advancing understanding of medical service utilization, long-term outcomes, and medication safety. Studying the natural history of the disease and the potential for early intervention to prevent progression from axSpA to ankylosing spondylitis is likely to be fruitful in future investigations. ❖

Disclosure Statement

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ORIGINAL RESEARCH & CONTRIBUTIONS

Safe and Effective Implementation of Telestroke in a US Community Hospital Setting

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ABSTRACT

Context: There is substantial hospital-level variation in use of tissue plasminogen activator (tPA) for treatment of acute ischemic stroke. Telestroke services can bring neurologic expertise to hospitals with fewer resources.

Objective: To determine whether implementation of a telestroke intervention in a large integrated health system would lead to increased tPA utilization and would change rates of hemorrhagic complications.

Design: A stepped-wedge cluster randomized trial of 11 community hospitals connected to 2 tertiary care centers via telestroke, implemented at each hospital incrementally during a 1-year period. We examined pre- and postimplementation data from July 2013 through January 2015. A 2-level mixed-effects logistic regression model accounted for the staggered rollout.

Main Outcome Measures: Receipt of tPA. Secondary outcome was the rate of significant hemorrhagic complications.

Results: Of the 2657 patients, demographic and clinical characteristics were similar in pre- and postintervention cohorts. Utilization of tPA increased from 6.3% before the intervention to 10.9% after the intervention, without a significant change in complication rates. Postintervention patients were more likely to receive tPA than were preintervention patients (odds ratio = 2.0; 95% confidence interval = 1.2-3.4). Before implementation, 8 of the 10 community hospitals were significantly less likely to administer tPA than the highest-volume tertiary care center; however, after implementation, 9 of the 10 were at least as likely to administer tPA as the highest-volume center.

Conclusion: Telestroke implementation in a regional integrated health system was safe and effective. Community hospitals' rates of tPA utilization quickly increased and were similar to the largest-volume tertiary care center.

INTRODUCTION

Tissue plasminogen activator (tPA) is the only treatment approved by the US Food and Drug Administration for acute ischemic stroke, but tPA continues to be underutilized.[1-3] There are many reasons for this underutilization, including patient factors as well as physician and hospital factors. Among the patient factors that exclude patients from receiving tPA are that patients present outside the treatment window or otherwise fail to meet inclusion criteria for the treatment. Physician and hospital-level factors contributing to less-than-ideal tPA utilization include emergency physicians' discomfort with the medication and its risk profile, and varying levels of hospital resources and support. Indeed, in a previous analysis of our 14-hospital regional integrated health care system, we found considerable hospital-level variation in tPA utilization.[4]

Because of this substantial variation between hospitals' tPA utilization in our health care system, a systemwide telestroke project was implemented. Telestroke refers to the use of telecommunication technologies to provide medical information and services for stroke care, and it is a valuable tool to fill gaps in access to acute stroke services.[5,6] In the provision of emergent neurologic expertise, telestroke may enable Medical Centers to overcome major barriers to tPA utilization[6,7] and has a Class I recommendation based on Level A evidence supporting this application.[8]

Kaiser Permanente Southern California (KPSC) is ideally organized for implementation of telestroke. The system includes 2 tertiary Medical Centers with in-house stroke neurology and neurologic intensive care units, as well as 12 community Medical Centers that lack such resources. By connecting the resources of the tertiary centers with the needs at the other hospitals, implementation of telestroke could improve the care of all patients with ischemic stroke in the system.

METHODS

We performed a stepped-wedge cluster randomized trial; this design has advantage over a simple pre-post analysis in that it allows for modeling the effect of time on the effectiveness of the intervention. The telestroke intervention was implemented in 11 Medical Centers and incrementally rolled out over the study period. Each Medical Center's Emergency Department (ED) was connected to an on-call stroke neurologist through telemedicine technology. Emergency physicians were encouraged to consult the on-call stroke neurologist via telestroke on any patient presenting with signs and symptoms

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suggestive of stroke such as sudden difficulty with speech, strength, sensation, balance, or vision, and arriving within 6 hours of onset. Our primary objective was to determine the effectiveness of the intervention as indicated by increased tPA utilization after implementation. Our secondary objective was to assess for safety of the intervention by examining whether there were changes in rates of tPA-related bleeding complications.

Data Source and Populations

Structured data from electronic health and administrative records identified all patients presenting to 1 of 11 participating EDs in our health care system between July 1, 2013, and January 15, 2015, with a primary diagnosis of ischemic stroke using International Classification of Diseases, Ninth Revision (ICD-9) Codes 433.xx, 434.xx, and 436. Because 2 of the community-based sites had previously implemented telestroke through outside vendors, and 1 hospital has 24-hour inhospital neurologist availability because of a neurology residency, we excluded patients from those sites. Instead, we focused our analysis on the 11 community-based sites in which telestroke was a new intervention. These Medical Centers had a staggered implementation of the telestroke intervention. Medical Center 1 began implementation on August 15, 2013, and the other centers began on the following dates in 2014: Medical Center 2 on January 20, Medical Centers 3 and 4 on May 19, Medical Center 5 on June 11, Medical Center 6 on July 2, Medical Centers 7 and 8 on July 28, Medical Center 9 on August 25, Medical Center 10 on September 2, and Medical Center 11 on December 16.

Demographic and clinical details were extracted for each patient, as well as tPA utilization and an indicator of whether telestroke was used for each visit. We excluded patients younger than age 18 years, those with a previous stroke within 90 days, and those with missing or implausible brain imaging or tPA administration times. The data were combined with predefined rollout dates to create indicators of intervention status by Medical Center per rollout month. Each patient was categorized as preintervention or postintervention on the basis of whether telestroke had been implemented at the presenting hospital by the date of patient presentation. Human subjects approval was obtained through the KPSC institutional review board.

Outcome Measures

The primary outcome was tPA receipt, identified by pharmacy code. Our secondary safety outcome was intracranial or gastrointestinal bleeding, identified by ICD-9 codes (432.xx, 430, 431, and 578.xx). One of the authors (AS) reviewed all charts of patients with questions of the outcome variables.

Statistical Analysis

Patient characteristics were described using medians and quartiles or means with standard deviations for all continuous variables, and frequencies and percentages for all categorical variables. All analyses were 2-tailed and were performed at a significance level of 0.05. For continuous variables with missing values, we used mean imputation and constructed indicator variables for missingness. For categorical variables, an "unknown" category was created, along with the same missing indicators. This ensured that study group comparisons could be constructed for all observations.

The outcome of interest was defined as tPA receipt at a given encounter. It was operationalized both at the patient level to assess patient characteristics and at the medical-center level to assess variability in rates between centers and more appropriately account for effects of the study design. For the former, we used logistic regression to assess the intervention effects on tPA utilization at individual encounters. For the latter, we used negative binomial regression to assess whether the telestroke intervention effect varied

Table 1. Patient demographics

Demographic	Preintervention (n = 1613)[a]	Postintervention (n = 1044)[a]	Total (N = 2657)[a]	p value
Age, years, mean (SD)	70.7 (13.6)	71.3 (13.7)	71.0 (13.6)	0.1617
Diagnosis year				
2013	768 (47.6)	46 (4.4)	814 (30.6)	< 0.001
2014	845 (52.4)	915 (87.6)	1760 (66.2)	
2015	0 (0.0)	83 (8.0)	83 (3.1)	
Sex				
Women	779 (48.3)	510 (48.9)	1289 (48.5)	0.7796
Men	834 (51.7)	534 (51.1)	1368 (51.5)	
Race				
White	704 (43.6)	412 (39.5)	1116 (42.0)	0.0003
Black	279 (17.3)	258 (24.7)	537 (20.2)	
Hispanic	464 (28.8)	278 (26.6)	742 (27.9)	
Asian/Pacific Islander	157 (9.7)	88 (8.4)	245 (9.2)	
Other	4 (0.2)	5 (0.5)	9 (0.3)	
Unknown	5 (0.3)	3 (0.3)	8 (0.3)	
Comorbidities				
Previous stroke	98 (6.1)	60 (5.7)	158 (5.9)	0.7266
Diabetes	600 (37.2)	374 (35.8)	974 (36.7)	0.4729
Hypertension	1113 (69.0)	708 (67.8)	1821 (68.5)	0.5203
Atrial fibrillation	280 (17.4)	157 (15.0)	437 (16.4)	0.1150
CHF	212 (13.1)	134 (12.8)	346 (13.0)	0.8178
COPD	100 (6.2)	68 (6.5)	168 (6.3)	0.7455
Valvular heart disease	132 (8.2)	91 (8.7)	223 (8.4)	0.6285
Other characteristics				
Elixhauser index, mean (SD)	3.4 (2.4)	3.4 (2.5)	3.4 (2.4)	0.8471
Use of anticoagulant	306 (19.0)	196 (18.8)	502 (18.9)	0.8992

[a] Data are no. (%) unless indicated otherwise.
CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; SD = standard deviation.

by Medical Center. This approach also allowed us to include an offset term (log stroke volume) to scale each Medical Center's monthly rate relative to its monthly stroke volume.

The model included indicators for Medical Centers to account for baseline variability between centers, indicators for exposure and length of exposure to the telestroke intervention, and Medical Center by intervention interactions to assess the heterogeneity in treatment effects. The model adjusted for patient-level demographic and clinical characteristics. We also assessed time-by-intervention interactions but found that the intervention effect did not appear to vary by length of exposure to the telestroke intervention. We also tested for interactions with patient race, ambulance arrival, and patient sex. Where necessary, forest plots were used to assess the interactions between the telestroke intervention and the relevant variables. All analyses were conducted using SAS 9.3 software (SAS Institute Inc, Cary, NC).

RESULTS

Of the 2657 patients included in our analysis, 1613 presented in the preintervention period (before implementation of telestroke), and 1044 presented in the postintervention period. The pre- and postintervention cohorts were similar in demographic characteristics and medical history (Table 1).

As detailed in Table 2, tPA utilization increased from 6.3% to 10.9% from the pre- to postintervention period, with no meaningful change in rates of bleeding complications. Telestroke was engaged in 24% of patient encounters in the postintervention period.

Primary Outcome

Patients treated in the postintervention period were more likely to receive tPA than those treated before the intervention (odds ratio = 2.0, 95% confidence interval = 1.17-3.4).

Before telestroke implementation, 8 of the 10 community Medical Centers were significantly less likely to administer tPA to patients with ischemic stroke compared with the largest-volume stroke center. After the telestroke implementation, however, 9 of the 10 community Medical Centers were at least as likely to administer tPA to ischemic stroke patients as that highest-volume stroke center (Figure 1). The effect of the intervention did not vary significantly by patient race, ambulance arrival, or arrival off-hours (5 pm-8 am Monday to Friday, or anytime Saturday or Sunday).

Secondary Outcomes

There were no meaningful differences in intracranial or gastrointestinal bleeding complications from the pre- to postintervention periods, and overall bleeding complications was slightly lower after the intervention (5.1% vs 4.9%; Table 2).

Table 2. Details of patient encounters

Patient encounter	Preintervention (n = 1613)[a]	Postintervention (n = 1044)[a]	Total (N = 2657)[a]	p value
Transferred from a skilled nursing facility	10 (0.6)	8 (0.8)	18 (0.7)	0.6534
Transported via ambulance	520 (32.2)	307 (29.4)	827 (31.1)	0.1236
Admitted during off-hours[b]	424 (26.3)	283 (27.1)	707 (26.6)	0.6400
Door-to-imaging time, minutes				
Mean (SD)	61.8 (42.3)	55.3 (37.7)	59.2 (40.7)	< 0.001
Median (IQR)	56 (29-89)	44 (25-79)	51 (26-85)	
Door-to-imaging time categories, minutes				
Preregistration[c]	44 (2.7)	6 (0.6)	50 (1.9)	< 0.001
< 30	379 (23.5)	349 (33.4)	728 (27.4)	
31-60	454 (28.1)	307 (29.4)	761 (28.6)	
61-90	356 (22.1)	186 (17.8)	542 (20.4)	
91-120	200 (12.4)	119 (11.4)	319 (12.0)	
> 120	180 (11.2)	77 (7.4)	257 (9.7)	
Door-to-needle time, minutes				
Mean (SD)	75.4 (41.3)	62.6 (28.4)	68.6 (35.5)	0.019
Median (IQR)	66 (46-96)	55 (47-69)	58 (46-82)	
Door-to-needle time categories, minutes				
≤ 30	8 (7.9)	2 (1.8)	10 (0.4)	0.001
31-60	36 (35.6)	73 (64.0)	109 (4.1)	
61-90	28 (27.7)	27 (23.7)	55 (2.1)	
91-120	19 (18.8)	7 (6.1)	26 (1.0)	
121-150	3 (3.0)	2 (1.8)	5 (0.2)	
151-180	3 (3.0)	2 (1.8)	5 (0.2)	
181-210	3 (3.0)	0 (0.0)	3 (0.1)	
211-240	1 (1.0)	1 (0.9)	2 (0.1)	
Bleeding complications				
Any	83 (5.1)	51 (4.9)	134 (5.0)	0.7643
Intracranial	17 (1.1)	15 (1.4)	32 (1.2)	0.3769
Subarachnoid	6 (0.4)	4 (0.4)	10 (0.4)	0.9634
Intracerebral	38 (2.4)	20 (1.9)	58 (2.2)	0.4483
Gastrointestinal	22 (1.4)	12 (1.1)	34 (1.3)	0.6309
Discharge disposition				
Home	1186 (73.5)	775 (74.2)	1961 (73.8)	0.4834
Skilled nursing facility	150 (9.3)	106 (10.2)	256 (9.6)	
Other	277 (17.2)	163 (15.6)	440 (16.6)	
Other clinical factors				
Use of telestroke	—	251 (24.0)	—	< 0.001
Received tPA	101 (6.3)	114 (10.9)	215 (8.1)	< 0.001

[a] Data are no. (%) unless indicated otherwise.
[b] Off-hours defined as encounters between 5 pm and 8 am weekdays and anytime Saturday or Sunday.
[c] Preregistration refers to patients who received brain imaging within 60 minutes before official Emergency Department admission time.
IQR = interquartile range; SD = standard deviation; tPA = tissue plasminogen activator.

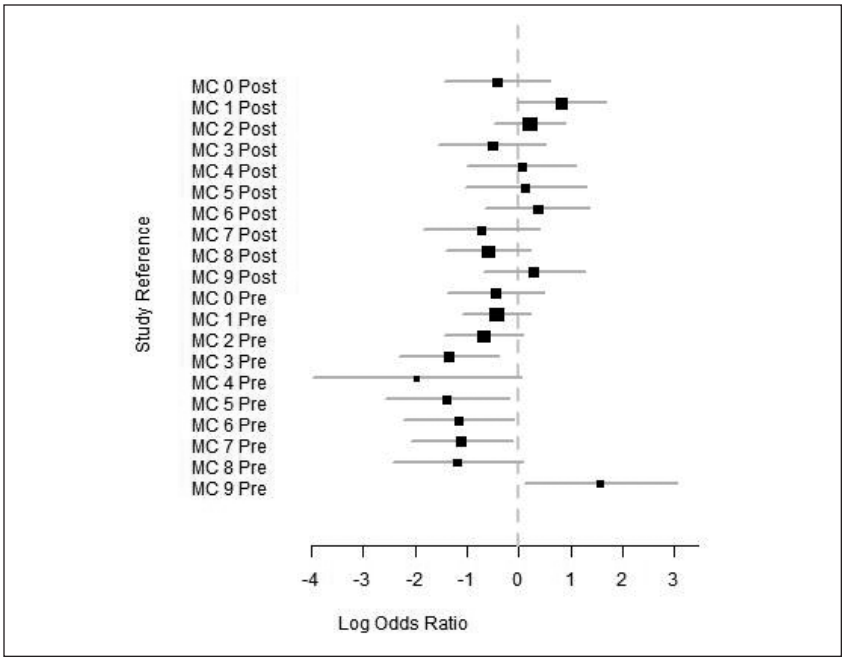

Figure 1. Likelihood of tissue plasminogen activator (tPA) treatment by Medical Center.

Adjusted odds of tPA receipt for each community Medical Center (MC) relative to odds at largest-volume stroke center. Bottom half of forest plot (MC 0 Pre to MC 9 Pre) illustrates relative odds of each MC in preintervention period (Pre). With the exception of MC 0 and MC 9, each MC has lower odds of tPA administration. Top half of forest plot (MC 0 Post to MC 9 Post) illustrates relative odds of each MC in postintervention period (Post). With the exception of MC 8, each MC has similar or higher odds of tPA administration relative to highest-volume academic center.

There were also improvements in median time from door to imaging (preintervention = 56 minutes vs postintervention = 44 minutes) and door to needle (66 minutes vs 55 minutes).

We also assessed the same Medical Center-by-intervention interaction for the patient-level data. This additional analysis revealed a similar pattern as in Figure 1, suggesting that further adjusting for patient characteristics did not change our conclusions. Furthermore, we believe the Medical Center-level analysis provides the added benefit of scaling the monthly rates for each Medical Center by its monthly stroke volumes, and thus provides a clearer interpretation of the findings.

DISCUSSION

In this stepped-wedge cluster randomized trial, we found that implementation of a telestroke intervention in our integrated health system improved rates of tPA administration for patients with ischemic stroke presenting to the community Medical Centers in the postintervention period. Rates of bleeding complications remained acceptably low and did not rise with the increased rate of tPA administration. Our results reinforce the utility of telestroke as previously reported. Many studies have demonstrated the utility of telestroke for assessing stroke severity[9-12] and for increasing the use of tPA among eligible patients.[13-17] Our findings add to this body of literature supporting the value of telestroke for improving tPA administration rates among patients with ischemic stroke presenting to community hospitals. We found that telestroke can be implemented safely and effectively in community hospitals, and that the beneficial effects (increased tPA utilization) occurred quickly after implementation without a significant lag period and without any corresponding change in complications.

These findings have important implications for future delivery of stroke care. Particularly in hospitals with limited local resources and/or limited access to neurologic expertise, telestroke is an important tool to aid in the evaluation and treatment of potential stroke. We specifically found that unwarranted hospital variability in stroke care could be eliminated through a standardized telestroke program. Additionally, telestroke may aid in triage and transfer decisions and in identifying patients potentially eligible for endovascular intervention or patients who might otherwise benefit from transfer to a stroke center. Future work may help to clarify the role for telestroke in such decisions.

Our study does have limitations. Our study design does not allow for a calculation of statistical power. We were unable to define the population of patients eligible for tPA; our finding of increased tPA utilization reflects an increased rate of tPA use among *all* patients with ischemic stroke. However, it is unlikely that our findings reflect a simple increase in the proportion of tPA-eligible patients because the study was conducted over a short period and without any corresponding public health messaging. Secondly, telestroke was utilized in 24% of cases after the intervention, and we do not know what distinguished these cases from those that did not engage telestroke. The seemingly low utilization rate may suggest that most patients with stroke arrived beyond the therapeutic time window. Additional patients may have been excluded if the ED physician noted obvious contraindications to thrombolytic therapy such as recent surgery or anticoagulant use, or if symptoms completely resolved before the telestroke call. Furthermore, we cannot confirm that the 24% of cases in which telestroke was utilized were the same cases in which the improved tPA rate was realized. Yet in the absence of other interventions or quality-improvement initiatives, it is reasonable to attribute the change in tPA utilization to the major systematic change that took place during this intervention period. Finally, we were unable to assess physician satisfaction with telestroke. Future work in our system should examine whether telestroke remains a frequently used tool, clarify the reasons

We specifically found that unwarranted hospital variability in stroke care could be eliminated through a standardized telestroke program.

for physicians' activation or deferral of telestroke, and confirm physician comfort and satisfaction with the use of telestroke for patients with ischemic stroke.

CONCLUSION

In our regional integrated health system, we found that implementation of a telestroke intervention eliminated unwarranted hospital variation in care and led to increased rates of tPA utilization among patients with acute ischemic stroke, with consistently low rates of hemorrhagic complications. Telestroke was implemented safely and effectively in this US community hospital setting. ❖

Disclosure Statement

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

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Health

The aim of the art of medicine is health, but its end is the possession of health. Doctors have to know by which means to bring about health, when it is absent, and by which means to preserve it, when it is present.

— Galen of Pergamon, 129 AD-c200 AD, Roman physician and philosopher of Greek origin

Association of Unplanned Reintubation with Higher Mortality in Old, Frail Patients: A National Surgical Quality-Improvement Program Analysis

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ABSTRACT

Background: Unplanned postoperative reintubation increases the risk of mortality, but associated factors are unclear.

Objective: To elucidate factors associated with increased mortality risk in patients with unplanned postoperative reintubation.

Design: Retrospective study. Patients older than 40 years who underwent unplanned reintubation from 2005 to 2010 were identified using the American College of Surgeons National Surgical Quality Improvement Program database. Multiple regression models were used to examine the impact on mortality of factors that included the modified frailty index (mFI) we developed, American Society of Anesthesiologists (ASA) score, age decile, and days to reintubation.

Main Outcome Measure: Mortality.

Results: A total of 17,051 postoperative reintubations in adults were analyzed. Overall mortality was 29.4% (n = 5009). On postoperative day 1, 4434 patients were reintubated and 878 (19.8%) died. On postoperative day 7 and beyond, 6329 patients were reintubated and 2215 (35.0%) died. Increasing mFI resulted in increasing incidence of mortality (mFl of 0 = 20.5% mortality vs mFl of 0.37-0.45 = 41.7% mortality). As ASA score increased from 1 to 5, reintubation was associated with a mortality of 12.1% to 41.6%, respectively. Similarly, increasing age decile was associated with increasing incidence of mortality (40-49 years, 17.9% vs 80-89 years, 42.1%). After adjustment for confounding factors, mFI, ASA score, age decile, and increasing number of days to reintubation were independently and significantly associated with increased mortality in the study population.

Conclusion: Among patients who underwent unplanned reintubation, older and more frail patients had an increased risk of mortality.

INTRODUCTION

Unplanned reintubation is a measurable complication of surgical care that is associated with significant morbidity and mortality.[1] Postsurgical physiologic deterioration or alterations of normal hormonal and metabolic physiology may contribute to respiratory failure and lead to eventual unplanned reintubation.[2,3] In modern health care, quality is not only expected but is also reportable. Unplanned reintubation is an identifiable event in a patient's postoperative course and serves as an outcome marker for quality improvement.

The population of Americans over the age of 65 years is projected to increase by 53.2% from the year 2003 to 2020.[4] An increasing number of elderly patients will be undergoing surgery, leading to a projected 31% increase in general surgery workload.[5] In recent years, a standardized measure of a patient's physiologic reserve has been developed in an effort to predict postoperative morbidity and mortality.[6,7] Frailty has been utilized to analyze multiple postoperative complications, including mortality.[8,9] However, there is insufficient literature regarding the impact of unplanned reintubation in the elderly population.

We hypothesized that the use of the modified frailty index (mFI) in reintubated patients would be predictive of increased mortality. We further hypothesized that the time to reintubation and American Society of Anesthesiologists (ASA) score would also affect mortality.

METHODS

This study used the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database. The NSQIP is a dataset used by hospitals nationally to help track areas of surgical performance for quality improvement.[10] Trained nurse reviewers at each participating hospital are responsible for collecting the data, which encompasses approximately 136 variables per patient. These variables include patient demographics, preoperative risk factors, and postoperative mortality and complications within 30 days of surgery for patients undergoing major operations, such as unplanned reintubation. The NSQIP database defines unplanned reintubation as placement of an endotracheal tube and mechanical or assisted ventilation because of the onset of respiratory or cardiac failure manifested by severe respiratory distress, hypoxia, hypercarbia, or respiratory acidosis within 30 days of the operation.[11]

Patients age 40 years and older who underwent unplanned reintubation from 2005 to 2010 were included in our study. The following variables were extracted from the NSQIP database for each patient: age, sex, ASA classification, race, wound

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classification at the end of the surgery, whether or not the surgery was emergent, inpatient or outpatient status, surgical subspecialty performing the surgery, diabetes mellitus status, tobacco use and number of packs smoked per year, history of comorbidities, functional status, and preoperative laboratory values (hematocrit and albumin). The total operative time for each patient also was extracted. Additionally, weight and height were used to calculate the body mass index for each patient.

Modified Frailty Index

Frailty has been associated with increased adverse events and prolonged postoperative recovery in several studies.[6,7,12] The Canadian Study of Health and Aging Frailty Index (CSHA-FI) is one index that has been developed to measure frailty. For this study, we calculated mFI by mapping the 70 variables from the CSHA-FI to the existing NSQIP preoperative variables, resulting in 11 matched

Table 1. Univariate comparison of patients' demographics and clinical characteristics of patients who required unplanned reintubation[a]

Characteristic	Overall (N = 17,051)	Alive (n = 12,042)	Dead (n = 5009)	p value
Age at reintubation (years), mean ± SD	69.4 ± 11.8	67.4 ± 11.9	71.4 ± 11.7	< 0.001
Men	9229 (54.2)	6462 (46.3)	2767 (44.6)	0.05
Emergent operation	5344 (31.3)	3583 (29.8)	1761 (35.2)	< 0.001
Inpatient	16,756 (98.3)	11,817 (98.1)	4939 (98.6)	0.032
Tobacco use	4697 (27.5)	3532 (29.3)	1165 (23.3)	< 0.001
Packs per year, mean ± SD	15.6 ± 44.8	17.6 ± 43.1	13.5 ± 46.5	< 0.001
Body mass index (kg/m^2), mean ± SD	28.2 ± 25.1	29.2 ± 42.2	27.2 ± 7.9	0.002
Diabetes				
Type 1	2328 (13.7)	1570 (13.0)	758 (15.1)	< 0.001
Oral medication	1749 (10.3)	1264 (10.5)	485 (9.7)	< 0.001
Comorbidities				
Mechanical ventilation	1233 (7.2)	884 (7.3)	349 (7.0)	0.391
COPD	3263 (19.1)	2272 (18.9)	991 (19.8)	0.166
Pneumonia	705 (4.1)	455 (3.8)	250 (5.0)	0.001
Hypertension requiring medications	12470 (73.1)	8668 (72.0)	3802 (75.9)	< 0.001
Wound classification at end of surgery				
Clean	5582 (32.7)	4034 (33.5)	1548 (30.9)	< 0.001
Clean/contaminated	6391 (37.5)	4559 (37.9)	1832 (36.6)	
Contaminated	1951 (11.4)	1314 (10.9)	637 (12.7)	
Infected	3127 (18.3)	2135 (17.7)	992 (19.8)	
Surgical subspecialty				
Cardiac surgery	324 (1.9)	261 (2.2)	63 (1.3)	< 0.001
Thoracic surgery	316 (1.9)	214 (1.3)	102 (0.6)	
Vascular surgery	3797 (22.3)	2621 (21.8)	1176 (23.5)	
General surgery	11756 (68.9)	8329 (69.2)	3427 (68.4)	
Obstetrics and gynecology	80 (0.5)	57 (0.5)	23 (0.5)	
Neurosurgery	236 (1.4)	170 (1.3)	66 (1.4)	
Orthopedics	285 (1.7)	195 (1.8)	90 (1.7)	
Otolaryngology	78 (0.5)	63 (0.3)	15 (0.5)	
Plastic surgery	36 (0.2)	22 (0.3)	14 (0.2)	
Urology	143 (0.8)	110 (0.6)	33 (0.2)	
Functional status				
Independent	11492 (67.4)	8513 (70.7)	2979 (59.5)	< 0.001
Partially dependent	3314 (19.4)	2079 (17.3)	1235 (24.7)	
Totally dependent	2229 (13.1)	1436 (11.9)	793 (15.8)	
Unknown	16 (0.1)	14 (0.1)	2 (0)	
Other clinical factors				
Total operative time (minutes), mean ± SD	171 ± 127	182 ± 133	159 ± 120	< 0.001
Preoperative hematocrit (%), mean ± SD	35.2 ± 6.6	35.9 ± 6.6	34.5 ± 6.5	< 0.001
Modified frailty index, mean ± SD	0.21 ± 0.14	0.20 ± 0.14	0.23 ± 0.15	< 0.001

[a] Data are no. (%) unless indicated otherwise.
COPD = chronic obstructive pulmonary disease; SD = standard deviation.

variables, and then mapping these variables to the patients' medical history. These 11 variables included nonindependent functional status; history of either chronic obstructive pulmonary disease or pneumonia; history of diabetes mellitus; hypertension requiring the use of medications; history of congestive heart failure; history of myocardial infarction; history of percutaneous coronary intervention, cardiac surgery, or angina; peripheral vascular disease or resting pain; transient ischemic attack or cerebrovascular accident without residual deficit; cerebrovascular accident with deficit; and impaired sensorium. A patient's mFI was calculated as the proportion of variables present ("positive") in a patient's medical history from the total 11 variables. The primary outcome was mortality.

The mFI has been validated in previous studies. Park et al[13] showed that the mFI correlates with postesophagectomy morbidity and mortality using the NSQIP database.

Statistical Analysis

To identify if age predicts mortality in patients undergoing unplanned reintubation, we divided the study population into groups by their age decile (40-49, 50-59, 60-69, 70-79, and 80-89 years). The incidence and odds ratio (OR) for mortality were calculated for each age decile.

To examine the impact of time to reintubation after surgery, we defined 4 different groups: Postoperative Days 0 to 1, 2 to 3, 4 to 6, and 7 and beyond. The postoperative complications were cross-tabulated with mortality and examined for differences using Student's *t*-test or the χ^2 test as appropriate.

The study population was divided in 2 groups: patients who died and patients who survived. A univariate comparison was performed to identify differences between the 2 groups. Categorical variables were compared using the Pearson χ^2 or Fisher exact test as appropriate. Continuous variables were examined for normality of distribution using the Shapiro-Wilk test. Normally distributed variables were compared using the Student *t*-test, and nonnormally distributed variables were compared using the Mann-Whitney *U* test. Variables that were different at $p < 0.05$ were entered in a binary logistic regression to examine the impact on mortality of mFI, ASA, age decile, and days to reintubation. Adjusted ORs with 95% confidence interval (CI) were derived from the regression.

RESULTS

A total of 1,334,886 patients were included in the NSQIP database from 2005 to 2010. Of those, 17,051 (1.3%) met our inclusion criteria and were analyzed. Of these 17,051 reintubated patients, 5009 had a documented death within 30 days of surgery. Therefore, the overall rate of postoperative mortality in patients requiring reintubation was 29.4%. Further analysis was performed to investigate the effect on mortality of patient age, ASA score, days to reintubation, and mFI. Patients who died were significantly more likely to be older compared with patients who survived (mean 71.4 years vs mean 67.4 years, $p < 0.001$), more likely to have undergone an emergent operation (35.2% vs 29.8%, $p < 0.001$), more likely to have type 1 diabetes (15.1% vs 13.0%, $p < 0.001$), and more likely to have an infected wound (19.8% vs 17.7%, $p < 0.001$). The mFI was significantly higher for patients who died (0.23 vs 0.20, $p < 0.001$). Details of patient clinical characteristics and demographics are presented in Table 1.

Table 2 shows the incidence of mortality for different study groups. The mortality rate was higher among patients who were reintubated later after their original surgery, compared with those reintubated sooner after their initial surgery. Patients who required reintubation on postoperative days 0 to 1 had a mortality rate of 19.8%; days 2 to 3, 28.4%; days 4 to 6, 32.9%; and day 7 and beyond, 35.0% ($p < 0.001$). When mortality was calculated for age, an associated increase in mortality with increase in age decile was observed. As patient age increased from the fourth through the eighth decile of age, the mortality rate increased from 17.9% to 42.1%. As seen in Table 1, the mean age of patients requiring reintubation who died was 71.4 years; however, Table 2 illustrates that mortality in patients requiring unplanned reintubation in the younger age deciles was significantly high (40-49 years, 17.9%; 50-59 years, 21.6%; $p < 0.001$). Similarly, Table 2 also illustrates that an increasing ASA score was associated with significantly higher mortality.

The impact of mFI on mortality after reintubation was examined using trend analysis and Mantel-Haenszel testing (Table 3). As mFI increased from 0 to 0.45, mortality rate increased from 20.5% to 41.0% ($p < 0.001$, linear $R^2 = 0.976$).

After adjustment for differences between the 2 groups (dead vs alive), an increasing mFI was significantly associated with

Table 2. Incidence of 30-day mortality by postoperative days to reintubation, age decile, and American Society of Anesthesiologists (ASA) score[a]

Variable	N	Mortality, n (%)	p value
Postoperative days to reintubation			
0-1	4434	878 (19.8)	0.003
2-3	3404	967 (28.4)	
4-6	2884	949 (32.9)	
≥ 7	6329	2215 (35.0)	
Age decile (years)			
40-49	2016	361 (17.9)	< 0.001
50-59	3125	675 (21.6)	
60-69	4678	1212 (25.9)	
70-79	3556	1213 (34.1)	
80-89	3676	1548 (42.1)	
ASA score			
1 - No disturbance	91	11 (12)	< 0.001
2 - Mild disturbance	1651	317 (19.2)	
3 - Severe disturbance	9236	2503 (27.1)	
4 - Life-threatening	5723	2032 (35.5)	
5 - Moribund	350	146 (41.6)	

[a] 5009 total deaths out of 17,051 total reintubations.

Table 3 . Incidence of 30-day mortality by modified frailty index[a]		
Modified frailty index	**N**	**Mortality, n (%)**
0	1990	408 (20.5)
0.01-0.09	4252	1097 (25.8)
0.10-0.18	4486	1301 (29.0)
0.19-0.27	3479	1082 (31.1)
0.28-0.36	1204	437 (36.3)
0.37-0.45	1640	684 (41.7)

[a] Linear $R^2 = 0.976$, $p < 0.001$.

Table 4. Multivariate analysis for 30-day mortality[a]		
Variable	**Adjusted odds ratio (95% CI)**	**Adjusted p value**
Frailty index	2.57 (1.94-3.40)	< 0.001
ASA score	1.27 (1.20-1.35)	< 0.001
Age decile	1.31 (1.27-1.35)	< 0.001
Days to reintubation	1.23 (1.20-1.27)	< 0.001

[a] Adjustment was made for emergent surgery, diabetes, tobacco use, body mass index, history of comorbidities, wound classification at end of surgery, surgical subspecialty performing the operation, functional status of the patient, total operative time, and preoperative hematocrit value.
ASA = American Society of Anesthesiologists; CI = confidence interval.

an increasing probability of dying (adjusted OR = 2.57, 95% CI = 1.94-3.40, p < 0.001; Table 4). Similarly, increased mortality was significantly associated with increasing ASA score (adjusted OR = 1.27, 95% CI = 1.20-1.35, adjusted p < 0.001), age decile (adjusted OR = 1.31, 95% CI = 1.27-1.35, p < 0.001), and days to reintubation (adjusted OR = 1.23, 95% CI = 1.20-1.27, p < 0.001).

DISCUSSION

This retrospective study of mortality in reintubated patients examined well-known risk factors such as age, ASA score, and time to reintubation. However, to the best of our knowledge, this is the first study specifically examining the impact of frailty on mortality in this population.

Unanticipated reintubation in the surgical patient population is a measurable event associated with significant morbidity. The present study suggests that the prognosis of reintubation depends on several factors including frailty, ASA class, age, and time to reintubation. In this study, the overall mortality of patients who required unplanned reintubation was exceedingly high (28.9%), which reflects the physiologic derangement driving respiratory failure.

The incidence and risk factors associated with reintubation have been previously examined.[1,14,15] Snyder et al[15] identified several risk factors for unplanned reintubation including severe chronic obstructive pulmonary disease, previous cardiac surgery, peripheral vascular disease, emergency procedure, dependent functional status, smoking within the past year, alcohol intake greater than 2 drinks per day, prior operation within the past 30 days, and transfer from an acute care hospital. Nafiu et al[14] reported that among all patients requiring emergent reintubation after elective surgery, 3.3% were elderly. However, this classification reflected chronologic age only and not patients' overall fitness and physiologic reserve.

For the present study, a frailty index modified from the CSHA-FI was developed using the 11 variables that are tracked in the NSQIP database. Multiple studies have shown that fewer variables may still yield an adequate assessment of a patient's frailty. Rockwood et al[16] studied the CSHA-FI and showed that using any 10 variables of that index resulted in comparable predictive value in frailty.

Respiratory failure within the first 72 hours after surgery has been related to hypoxemia and analgesic therapy.[17,18] Ramachandran et al[1] examined the incidence of early unplanned reintubation and found that one-half of all reintubations within a 30-day period occurred during the first 3 days, which was associated with a 9-fold increase in mortality. When adjusting for preoperative risk factors, these authors established a mortality rate of 9.7% to 30.6% in the first 3 days.[1] These data, although similar to our findings, represent a patient population much more diverse than ours, because we focused on an older age group.

Several protective measures can be undertaken to potentially avoid the significant morbidity and mortality associated with unplanned reintubation. Early tracheostomy in patients who are anticipated to have a protracted respiratory failure has been advocated, but it remains controversial. The advantages include reduced rates of ventilator-associated pneumonia and decreased hospital length of stay. Several recent studies have tried to compare the outcomes between performing an early vs late tracheostomy, but the data remain controversial. The present study showed an incremental increase in the probability of adverse outcomes as the day to reintubation increased. It is possible that early tracheostomy in people who are anticipated to have a protracted ventilatory need and difficulty weaning off the ventilator would reduce the hypoxia and physiologic stress of an unplanned reintubation and would potentially result in fewer adverse events. It is possible that calculating a patient's mFI will provide clinicians with a risk assessment tool regarding the probability of reintubation-associated mortality and will serve as a guide to patients and family counseling regarding early tracheostomy.

… the prognosis of reintubation depends on several factors including frailty, ASA class, age, and time to reintubation.

There are several limitations to this study. The first is the inability to know the details surrounding the indications for reintubation. This information may extend our knowledge of patients' physiologic deterioration surrounding the event requiring reintubation. Second, NSQIP tracks reintubation as an event in a 30-day postoperative period, but it is not clear on which day a patient was initially extubated. Furthermore, NSQIP data include accidental extubations that require

reintubation, and such events would potentially confound the results. The patient population requiring delayed extubation is likely more acutely ill and has an inherently higher mortality. This may be an area for future research. Another limitation to this study is that although NSQIP variables for preoperative risk assessment are collected prospectively, the mFI was applied retrospectively to these variables.

CONCLUSION

Despite the aforementioned limitations, this study was conducted using the NSQIP database, which is a robust nationwide database comprising data from diverse participating institutions and surgeons. Our overall mortality rate of 29.4% is consistent with prior studies that found 30-day mortality among reintubated patients to be 29.4%.[15] We identified several patient variables that were predictive of mortality in reintubated patients: age, ASA score, time to reintubation, and frailty. Of these variables, frailty had the highest OR of 2.57.

This large, cross-sectional study of reintubated surgical patients found that despite the low overall incidence of postoperative reintubation, it is fraught with significant mortality, especially among older patient populations. ❖

Disclosure Statement

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

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Endure

No skill or art is needed to grow old; the trick is to endure it.

— Johann Wolgang von Goethe, 1749-1832, German author and statesman

Ghosts of the Northern Plains
photograph

Stephen Henry, MD

The farmland of the northern plains is dotted with abandoned farmsteads surrounded by large tracts of corn, soy, beets, or just fallow land. These lonesome structures stand, often containing personal possessions, as a memorial to the families who worked the land. Where are the families now? It's obvious where some of them are, but what of the living? Where do the memories go?

Dr Henry has spent many days during the past few years ranging out from Fargo, ND, photographing these places in order to help remember them after they are gone. Dr Henry is retired from The Permanente Medical Group as Chief of Urology at the San Jose Medical Center. More of his work can be seen at: www.henryimages.net.

Preferential Use of Total Thyroidectomy without Prophylactic Central Lymph Node Dissection for Early-Stage Papillary Thyroid Cancer: Oncologic Outcomes in an Integrated Health Plan

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ABSTRACT

Context: The oncologic benefit of prophylactic central lymph node dissection (pCLND) in node-negative papillary thyroid cancer has been debated.

Objective: To determine the use of pCLND in an integrated health care system and to evaluate recurrence in the cohort.

Design: Retrospective cohort study of patients with clinically node-negative papillary thyroid cancer who underwent total thyroidectomy with or without pCLND in Kaiser Permanente Southern California Region hospitals between January 1996 and December 2008. Chart review of all patients was performed to collect demographic data, tumor features, stage, and recurrences.

Main Outcome Measures: Proportion undergoing pCLND and recurrence rate of papillary thyroid cancer.

Results: There were 864 patients identified (mean age, 46.1 years). Almost all patients had total thyroidectomy alone, and 34 (3.9%) underwent pCLND. The TNM (tumor, node, metastasis) stages for the 2 groups were not significantly different (p = 0.18). Overall recurrence was 24 (2.8%). There were 23 (2.8%) recurrences in the no-pCLND group and 1 (2.9%) recurrence in the pCLND group (p = 0.95). The rate of recurrence in the central neck compartment in those without pCLND was 1.1% and 0% in the pCLND group (p = 0.54). The recurrence rate in the lateral neck compartment in the no-pCLND group was 2.2%, and this rate was 2.9% in the pCLND group (p = 0.76). The no-pCLND group had a recurrence-free survival rate of 96.4% at 10 years vs 96.8% in the pCLND patients (p = 0.80).

Conclusion: Presently, routine pCLND is difficult to advocate in our medical system.

INTRODUCTION

Papillary thyroid cancer has a high propensity for metastases in the central and lateral cervical lymph nodes. However, even with regional lymph node spread, the overall prognosis remains good.[1-3] The presence of nodal disease confers increased risk of recurrence but has traditionally been thought to have no impact on overall survival.[4] More recently, some larger studies have shown differences in prognosis between patients with node-positive cancer and those with node-negative cancer, but these differences have been very small, on the order of 1% to 3% survival differences up to 20 years from treatment.[5,6] Approximately 20% of patients present with clinically palpable nodal disease, and the need for therapeutic lymph node dissection in these patients has been well established.[5] However, controversy remains over the benefit of a prophylactic central lymph node dissection (pCLND) at the time of thyroidectomy when the nodes are clinically negative for metastases, which occurs in about 20% to 40% of patients[6]; the primary reason for the controversy is that until recently, no randomized trial existed that answered the question of the therapeutic benefit of pCLND. Some studies have shown a survival benefit from pCLND, some have shown reduction in locoregional recurrence, and others have shown no benefit.[7-11]

Proponents of pCLND argue that it enhances accurate staging, removes microscopic disease, and reduces recurrence rates.[10,12] Opponents counter that low recurrence rates exist without performing pCLND, the procedure causes increased complications, and that therapeutic central lymph node dissection in the event of central compartment recurrence can be done with low morbidity, no higher than that after an initial pCLND.[11,13-15] A recent randomized controlled trial showed no difference in survival in those patients who had pCLND, but the sample size may have been too small to answer the question without a type II error.[16]

The main objective of this study was to determine the use of pCLND in our integrated medical system at the time of total thyroidectomy for papillary thyroid cancer, and secondarily to attempt to compare overall recurrence rates in patients who underwent pCLND with those who had nodal observation.

METHODS

Subjects

This study was approved by the Kaiser Permanente Southern California (KPSC) institutional review board (Study Identification Number 5830). All patients with papillary thyroid cancer who underwent total thyroidectomy with and without pCLND in KPSC Region hospitals between January 1996 and December 2008

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were identified for the study. They were identified using the International Classification of Diseases, Ninth Revision, code of 193 (malignant neoplasm of thyroid gland) and the Current Procedural Terminology Procedure Codes 60240 (total thyroidectomy) and 60252 (total thyroidectomy with limited neck dissection). An individual chart review on all patients was then conducted. Data on patient demographics, tumor size, number of lymph nodes removed, number of positive lymph nodes, and TNM (tumor, node, metastasis) classification stage were collected. There was no specific protocol or algorithm used for preoperative staging. Operative reports were examined to determine if pCLND was performed; if the surgeon mentioned that lymph nodes were removed from the anatomic boundaries of level VI or anterior compartment in the neck as previously described, the patient was placed in the pCLND group.[17]

Patients were excluded from the study if they had known preoperative or intraoperative regional (either central neck compartment or lateral neck compartment) or distant metastatic disease, if they were age 45 years or older and had T3 (Stage III) tumors, if they underwent less than a total thyroidectomy (hemithyroidectomy, subtotal thyroidectomy, or completion thyroidectomy), had previous thyroid surgery or any cervical lymph node dissection, if they were pregnant, or if they were KPSC members for less than 6 months. Thus, the study cohort included only patients with clinically negative (cN0) papillary thyroid cancer.

Main Outcome Measures

The main outcomes were the proportion undergoing pCLND and recurrence rates. The types of recurrences included the following: central neck recurrence (including central lymph node recurrence and recurrence in the thyroid bed), lateral neck lymph node recurrence, and distant recurrence. Recurrence was determined by clinical suspicion and examination combined with ultrasound and/or radioactive iodine scan, or elevated thyroglobulin level with abnormal results of imaging, with or without cytologic result, or with histopathologic evidence of cancer. There was no specific protocol or algorithm used for surveillance postoperatively. Any evidence of disease after a disease-free interval of one year was categorized as a recurrence.

Statistical Analysis

Chi-squared test or Fisher exact test was used to detect the difference in proportions of categorical variables, which were described using frequencies and percentages between pCLND and no-pCLND groups. Student *t*-test was used for comparing continuous variables between groups. We also described follow-up time, time to recurrence, and percentages of recurrence among treatment groups.

Recurrence-free survival was determined using Kaplan-Meier survival function estimations. P values less than 0.05 indicate statistical significance. All tests were 2-tailed. All statistical analyses were performed using SAS Enterprise Guide 4.3 (SAS Institute Inc, Cary, NC).

Table 1. Demographics and tumor features in patients undergoing total thyroidectomy with or without prophylactic central lymph node dissection

Feature	No prophylactic central lymph node dissection (n = 830)	With prophylactic central lymph node dissection (n = 34)	Total patients (N = 864)	p value
Age at diagnosis, years				
Mean (SD)	46.4 (14.0)	40.0 (11.4)	46.1 (14)	0.005
Median	46.0	38.0	45.0	
Range	14.0-87.0	25.0-67.0	14.0-87.0	
Sex, no. (%)				
Female	709 (85.4)	24 (70.6)	733 (84.8)	0.018
Male	121 (14.6)	10 (29.4)	131 (15.2)	
Tumor size, cm				
Number of tumors	792	33	825	0.014
Mean (SD)	1.9 (1.5)	2.7 (1.9)	2.0 (1.5)	
Median	1.6	2.2	1.6	
Range	0.1-9.0	0.1-8.0	0.1-9.0	
Number of lymph nodes removed, no. (%)				
0	774 (93.3)	1 (2.9)	775 (89.7)	< 0.0001
1	5 (0.6)	0 (0)	5 (0.6)	
2	1 (0.1)	0 (0)	1 (0.1)	
3	23 (2.8)	7 (20.6)	30 (3.5)	
4	14 (1.7)	8 (23.5)	22 (2.5)	
5	5 (0.6)	4 (11.8)	9 (1)	
6	4 (0.5)	7 (20.6)	11 (1.3)	
7	4 (0.5)	7 (20.6)	11 (1.3)	
Number of positive lymph nodes, no. (%)				
0	812 (97.8)	21 (61.8)	833 (96.4)	< 0.0001
1	7 (0.8)	4 (11.8)	11 (1.3)	
2	3 (0.4)	3 (8.8)	6 (0.7)	
3	5 (0.6)	5 (14.7)	10 (1.2)	
4	2 (0.2)	0 (0)	2 (0.2)	
6	1 (0.1)	1 (2.9)	2 (0.2)	
TNM stage, no. (%)				
1	654 (78.8)	30 (88.2)	684 (79.2)	0.184
2	176 (21.2)	4 (11.8)	180 (20.8)	
Radioactive iodine, no. (%)	52 (6.3)	4 (11.8)	56 (6.5)	0.202

SD = standard deviation; TNM = tumor, nodes, metastasis.

RESULTS

There were 864 patients who met the criteria for inclusion into the study. Mean age (± standard deviation) was 46.1 ± 14 years, and 85% were women. Almost all patients had total thyroidectomy without pCLND, and 34 (3.9%) of the patients underwent pCLND (Table 1). The patients in the pCLND group were somewhat younger and men were more represented compared with the no-pCLND patients. Mean tumor size was larger in the pCLND group than in the no-pCLND group (2.7 cm vs 1.93 cm, p = 0.014). The TNM stages for the 2 groups were not statistically significantly different (p = 0.18, Table 1).

Not surprisingly, the pCLND group had more lymph nodes removed. They had more positive lymph nodes compared with the no-pCLND group (p < 0.0001, Table 1). With increasing tumor size, there was a higher proportion of node-positive disease (p = 0.002, Table 2).

The mean follow-up period was 7.9 years. There were no patients lost to follow-up, and there were 36 deaths. The overall number of recurrences in the study period was 24 (2.8%), with the mean time of 4.6 years between the index operation and recurrence. Recurrence in the central neck compartment occurred in 9 patients: 4 patients had recurrence in the central neck compartment only; 4 patients had recurrence synchronously in the central and lateral compartments of the neck; and 1 patient's cancer recurred synchronously in the central neck compartment, the lateral neck compartment, and distant sites. In the remaining 15 patients, 14 had recurrence in the lateral neck compartment as the sole region of disease, and 1 patient had recurrence at distant sites only.

When stratified by pCLND, there were 23 (2.8%) recurrences in the no-pCLND group and 1 (2.9%) recurrence in the pCLND group. No patients in the pCLND group had recurrence in the central compartment of the neck, whereas 9 patients (1.1%) in the no-pCLND group had recurrence in this area (p = 0.54). One patient (2.9%) in the pCLND group had recurrence in the lateral neck compartment, whereas 18 patients (2.2%) in the no-pCLND group had recurrence in this region (p = 0.76). With Kaplan-Meier estimations, the no-pCLND group had a recurrence-free rate of 96.4% at 10 years compared with 96.8% in the pCLND patients (p = 0.80).

Table 2. Tumor size and presence of positive lymph nodes in the 825 tumors

Tumor size (cm)	Positive lymph nodes[a]
< 1	2/248 (0.8)
1 - < 2	6/209 (2.9)
2 - < 3	15/185 (8.1)
3 - < 4	2/92 (2.2)
4 - < 5	0/40 (0)
≥ 5	6/51 (11.8)

[a] Data are no. (%)

DISCUSSION

We found in KPSC that nearly all patients with papillary thyroid cancer were treated with total thyroidectomy without pCLND. Our findings also suggest that performing pCLND in patients with initially clinically node-negative papillary thyroid cancer may not provide additional oncologic benefit. Alternatively, if there was a benefit that was not detectable because of a small number of patients who underwent pCLND, it would appear to be a very low absolute benefit and probably clinically insignificant, with such low recurrence rates found in the study.

The KPSC patient population is ethnically diverse and is representative of the larger community. There are 14 KPSC hospitals, ranging from 154 to 464 beds, all considered general surgical and medical centers. In addition, these operations were performed by more than 100 surgeons in KPSC.

The surgeons in KPSC are predominantly low-volume thyroidectomy surgeons, performing fewer than 10 thyroidectomies per year. In a later period of 2008 to 2013, 83% of total thyroidectomies in KPSC were performed by low-volume KPSC surgeons (Christine Ferioli, personal communication, November 24, 2015[a]). We believe this percentage would be similar in the study period. It has been shown previously that low-volume surgeons make up the majority of surgeons doing thyroidectomies. Sosa et al[18] reported on thyroid surgery in Maryland, and 79% were surgeons who performed fewer than 10 thyroidectomies per year. Similarly, Stavrakis et al[19] found that 65% of surgeons doing thyroid, parathyroid, or adrenal operations in New York and Florida performed only 1 to 3 such operations per year. Thus, our findings of low recurrence rates in our population of patients who are racially mixed and who are operated on by low-volume surgeons who rarely perform pCLND, as in the rest of the country, are probably generalizable to patients undergoing total thyroidectomy with or without pCLND in many other regions or communities in the US.

Our finding that pCLND is rarely performed in KPSC is mirrored outside our medical system in the US. In a population-based study of more than 14,000 patients with papillary thyroid cancer, only 6.6% potentially received a pCLND or a therapeutic central lymph node dissection that retrieved 5 or more lymph nodes.[20] However, it is unclear in that study of the National Cancer Institute's Surveillance, Epidemiology, and End Results database how many patients actually underwent a formal pCLND because data on operative technique are missing; it is probable that nodes were retrieved in the total thyroidectomy specimen inadvertently without formal pCLND. Our study scrutinized each operative report, and so we believe that 4% is accurate regarding who received a formal pCLND. With the limited evidence supporting pCLND, it may be justified that such a low number of pCLND was performed in the KPSC system, and it also may be similar in other hospitals and regions in the US.

Our retrospective study has several limitations. With only a very small minority who underwent pCLND, this group may well have been selected to undergo the procedure, and so a direct comparison with the no-pCLND group could be biased. The low number in the pCLND group and the low event rate also may have contributed to a type II error, with a difference in recurrence rates that was undetectable. Furthermore, it is probable that patients were treated differently by the many physicians involved at the different Medical Centers in the KPSC Region, from initial staging to postoperative adjuvant radioactive iodine therapy to surveillance. Therefore, the outcomes in patients who had pCLND may have been confounded by any number of factors. However, we are quite certain that

those who did and did not have a formal pCLND were assigned correctly, and the absolute recurrence is very low in those who had total thyroidectomy alone, regardless of the ability to discern all other confounders.

Although a randomized clinical trial is necessary to definitively address the oncologic benefit of pCLND, only recently has such a trial been completed, and it showed no benefit; in 181 patients randomly assigned to total thyroidectomy alone or thyroidectomy with pCLND, the outcomes of biochemical and structural recurrence were similar after 5 years of follow-up.[16] It may be argued that the study was not powered appropriately; an impressive sample size of nearly 6000 patients would be required for 80% power.[21] However, the study was powered as a noninferiority trial, and so fewer patients were required, and this is assuming that total thyroidectomy with pCLND would never have higher recurrence rates than total thyroidectomy alone.[16]

Most of the published literature to date has been retrospective studies. In a study of 752 patients with clinically node-negative papillary thyroid cancer, 390 underwent total thyroidectomy alone and 362 underwent total thyroidectomy with pCLND, and similar incidences of locoregional recurrence were found in the 2 groups of patients.[11] Furthermore, those who had bilateral pCLND had greater rates of transient and permanent complications. Our findings of very low recurrence rates in the central compartment in those who did not undergo pCLND were similar to those of Nixon et al.[14] In their review of 275 patients who underwent total thyroidectomy alone, the rate of structural central lymph node recurrence was even lower at 0.4%. On the other hand, Popadich et al[22] reported that the rate of repeated operation in the central neck compartment was higher in those who did not undergo a pCLND compared with the group of patients who did (1.5% vs 6.1%, p = 0.004). They also found lower postoperative stimulated thyroglobulin levels after pCLND. Other studies have also shown decreased thyroglobulin levels with pCLND or transiently decreased levels, but it is unclear if this translates to a survival advantage.[23,24] Finally, systematic reviews have been done on the subject, with no difference in oncologic outcomes with pCLND, yet pCLND may be associated with increased complications, particularly with increased rates of hypoparathyroidism.[25,26]

The American Thyroid Association in 2015 released guidelines on lymph node dissection for well-differentiated thyroid cancer.[27] In Recommendation 36B, the association stated that "pCLND should be considered in patients with papillary thyroid carcinoma with clinically uninvolved central neck lymph nodes (cN0) who have advanced primary tumors (T3 or T4) or clinically involved lateral neck nodes (cN1b), or if the information will be used to plan further steps in therapy."[27] The recommendation was considered weak because of low-quality evidence.[27] Recommendation 36C stated that "thyroidectomy without prophylactic central neck dissection is appropriate for small (T1 or T2), noninvasive, clinically node-negative [papillary thyroid cancer] (cN0) and for most follicular cancers"; this was considered a strong recommendation with moderate-quality evidence.[27] These updated guidelines have slight wording changes compared with the 2009 and the 2006 guidelines, but the general trend has changed to now accept total thyroidectomy alone for early-stage papillary thyroid cancers.[28,29] It appears in our study that surgeons in KPSC had already opted overwhelmingly for total thyroidectomy alone in patients with these early-stage cancers.

CONCLUSION

In our study of patients with early-stage papillary thyroid cancer treated preferentially with total thyroidectomy without pCLND, there was a very low rate of recurrence. Presently, pCLND is difficult to advocate for these patients. If pCLND is ever shown to be beneficial with a large multicenter and appropriately powered randomized trial, it might be difficult to find surgeons at local hospitals who would perform the procedure. ❖

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Disclosure Statement

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

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Feared

Where there are several chronic diseases more
destructive to life than cancer, none is more feared.

— Charles Horace Mayo, MD, 1865-1939, American medical practitioner
and cofounder of the Mayo Clinic

CME credits available for this article — see page 128.

ORIGINAL RESEARCH & CONTRIBUTIONS

Standardizing Management of Adults with Delirium Hospitalized on Medical-Surgical Units

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ABSTRACT

Context: Delirium is common among inpatients aged 65 years and older and is associated with multiple adverse consequences, including increased length of stay (LOS). However, delirium is frequently unrecognized and poorly understood. At one hospital, baseline management of delirium on medical-surgical units varied greatly, and psychiatric consultations focused exclusively on crisis management.

Objective: To implement a multidisciplinary program for rapid identification and proactive management of patients with delirium on medical-surgical units.

Design: A pilot from September 2010 to July 2012 included 920 unique patients, of whom 470 were seen by the delirium management team. A delirium management team included a redesigned role for consulting psychiatrists and a new clinical nurse specialist role; the team provided assistance with diagnosis and recommendations for nonpharmacologic and pharmacologic management of delirium. Multidisciplinary education focused on delirium identification and management and nurses' use of appropriate assessment tools. Electronic health record functions supported accurate problem list coding, referrals to the team, and standardized documentation.

Main Outcome Measure: Length of stay.

Results: During the study period, average LOS in the target population decreased from 8.5 days to 6.5 days ($p = 0.001$); average LOS for the Medical Center remained stable. Compared with patients whose delirium was diagnosed during the baseline period, patients who received a delirium diagnosis during the pilot period had a higher illness burden and were likelier to have a history of delirium and diagnosed dementia.

Conclusion: Program implementation was associated with reduced LOS among older inpatients with delirium. The delirium team is an effective model that can be quickly implemented with few additional resources.

INTRODUCTION

In 2010, a dementia task force at Kaiser Permanente (KP) San Rafael Medical Center (SRMC) recognized a need to improve the management of delirium among adults on medical-surgical units. Scarce inpatient psychiatry resources were directed at crisis intervention, with little proactive management of delirium.

Delirium is an acute confusional state characterized by inattention, abnormal level of consciousness, cognitive impairment, and a fluctuating course.[1] Delirium is frequently unrecognized. Clinicians may miss subtle signs, such as inattention, memory impairment, and difficulty following conversations and may not recognize acute delirium co-occurring with chronic dementia. Delirium and dementia are distinct clinical entities, but delirium superimposed on dementia may account for 50% of cases.[2] Misidentification of delirium is common; it is appropriately coded in just 3% of instances.[3] Accurate diagnosis and coding are essential to providing optimal care, identifying the affected population, understanding incidence and prevalence, and developing population-level interventions.

The prevalence of delirium on hospital admission is 10% to 31%, and the incidence of delirium during hospitalization is 3% to 56%, with variations in the populations being assessed accounting for the broad range.[4,5] In addition to advanced age, many factors influence the development of delirium. In a meta-analysis, 10 factors were consistently associated with incident delirium: dementia, comorbid illness, illness severity, diminished ability to perform activities of daily living, urinary catheterization, polypharmacy, low serum albumin, urea-creatinine ratio abnormalities, hyper- or hyponatremia, and prolonged hospital stay.[6] Other predisposing factors may include male sex, geriatric syndromes (eg, history of falls, pressure ulcers, sensory impairment, and malnutrition), social isolation, and immobility.[7] Precipitating factors may include acute insults, such as dehydration, fracture, hypoxia, infection, ischemia, surgery, uncontrolled pain, and urinary or stool retention, and inpatient experiences, such as sleep deprivation and the use of restraints.[7] Medications are a common iatrogenic cause of delirium.[2]

Adverse outcomes of delirium include longer hospital stays, a need for postdischarge custodial care, and increased morbidity and mortality.[8] In one study, length of stay (LOS) increased by 7.8 days after incident delirium among all inpatients aged 65 years and older.[9] Inpatients with baseline cognitive impairment and incident delirium stayed 3.3 days longer than cognitively impaired seniors without delirium.[10] Total direct annual health care costs in the US attributable to delirium are an estimated $143 to $152 billion, which include the costs of longer stays.[11]

Limited evidence exists about multidisciplinary management of delirium outside intensive care units (ICUs). Comprehensive multidisciplinary and environmental interventions may reduce delirium duration and LOS,[12] but reports assessing the impact of multidisciplinary delirium teams outside the ICU yield conflicting results. Psychiatric or geriatric consultation and liaison nurse follow-up provided minimal benefits.[13,14] Individualized geriatric treatment was associated with improved quality of life but unchanged costs of care.[15] An intervention incorporating dedicated delirium beds was associated with lower mortality and fewer falls but increased LOS.[16] A specialized geriatric unit was associated with shorter LOS,

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improved functional status, less restraint use, lower antipsychotic medication doses, and fewer adverse events.[17]

The purpose of this quality-improvement project was to implement a multidisciplinary program for rapid identification and proactive management of patients with delirium on medical-surgical units.

METHODS

At SRMC, a 116-bed adult medical-surgical and intensive care hospital, 16 full-time equivalent (FTE) hospitalists and 600 FTE registered nurses and ancillary staff care for an annual average of 6320 discharged patients. An integrated electronic health record (EHR), KP HealthConnect, is available in all settings. The Medical Center serves a higher proportion of adults older than age of 65 years (16.7%) than in KP Northern California (KPNC) as a whole (11.4%). The SRMC Medicare case mix index of 1.67 is also higher than for KPNC as a whole (1.56).

Before the project reported here, inpatient psychiatric coverage consisted of one FTE shared by two half-time consulting psychiatrists available four hours each weekday. They provided consultation for all inpatient psychiatric needs, including assessment for mood, anxiety and thought disorders, eating disorders, chemical dependency, delirium, and advanced dementia. Hospitalists identified and managed inpatients with delirium, typically requesting a psychiatric consultation only when patients became

Nonpharmacologic Delirium Management Protocol

Hospital administration

Bed and staff assignments

- Try to maintain continuity of care (nurses, patient care technicians, physicians)
- Avoid room changes
- Try to adhere to a routine as much as possible and communicate the routine frequently to the patient
- Patient should be in a private or semiprivate room. If not possible, the patient should be placed to either of the end beds, not the middle bed

Nursing assessment

- Delirium team referral: Add patient name to the "Delirium Rounds" patient list in the EHR.
- Social worker referral: Assess for home management, coping; perform long-term planning
- Add CAM-ICU flowsheet to shift assessment and perform every shift
- Assess patient for common causes of delirium
  - H: hypoxia or hypercapnia
  - E: electrolyte imbalance or ethanol withdrawal
  - M: medications (see medication list) or acute myocardial infarction
  - I: infection
- Use inpatient nursing notes to chart behavior, sleep, and need for and effect of as-needed behavior medications using SmartPhrase from Epic
- Use a script with patients: "Hi, Mr/Mrs (name). What a shame you wound up in the hospital because you (diagnosis). Your doctor says you're better and you might be going home tomorrow. I am your nurse and my name is (name), and I'll be taking care of you until (time) today."
- Screening questions for confusion
  - What brought you here?
  - How long have you been here?

Patient care technician/nursing activities

Safety

- high-visibility room
- low bed
- bed alarm
- fall risk wristband
- removal of street clothing and shoes from room

Environment

- Provide soothing music or the Care Channel on the TV when appropriate (during day)
- Remove unnecessary equipment and clutter
- Hide IV lines and catheters as much as possible

Orientation

- Call patient by preferred name
- Provide orientation cue using dry-erase board in patient room
- Obtain patient's glasses, dentures, and hearing aids from family if used and have available
- Encourage family to stay with patient during day as much as possible to improve orientation; encourage social interaction and family visits during visiting hours
- Allow patient to have personal items from home (photos, blankets, pillows, etc)
- Reorient the patient frequently using the script above and explain care and activities
- Have a clock visible and provide frequent verbal reminders of time and date

Maintain sleep-wake cycle

- Limit unnecessary awakenings
- If clinically stable, hold temperature and blood pressure checks from 11 pm to 7 am to maintain optimal sleep and rest
- Turn lights off at 10 pm and back on during the day while the patient is awake
- Turn TV off and keep room dark and quiet between 10 pm and 7 am to prevent sleep deprivation
- Pull curtains open to allow sunlight in the room during daylight hours
- Put patient in a private or semiprivate room if possible to avoid excess noise
- Withhold caffeine after noon

Elimination

- Assist with toileting hourly during the day, then every 2 to 4 hours while awake in the evening
- If unable to void after 8 hours, perform bladder scan and notify physician
- On Day 3 of admission, notify morning rounding physician to consider discontinuation of Foley catheter if inserted on admission
- Monitor for constipation. Try prevention measures such as prune juice, stewed prunes, or bran cereal if the patient is taking food by mouth
- For patients who do not have a Foley catheter and are drinking oral liquids, allow no liquids after 8 pm if possible

Ambulation

- Keep a walker and commode at bedside as indicated
- If patient is ambulatory, ambulate three times a day, with assistance if patient is unsteady or mentation is abnormal
- Assist patient out of bed to chair for all meals

CAM-ICU = Confusion Assessment Method for the Intensive Care Unit; EHR = electronic health record; IV = intravenous.

hyperactively delirious. A robust protocol for nonpharmacologic strategies for managing delirium was inconsistently used. On weekends, hospitalists managed patients with psychiatric needs, including delirium. Consulting psychiatrists returning on Monday invested substantial effort into improving pharmacologic management of patients with delirium.

Approach to Improving Delirium Management

The goal was to implement a systematic multidisciplinary process for proactive and timely identification and treatment of delirium among hospitalized adults. Objectives were to 1) raise awareness about delirium by educating clinicians and emphasizing the benefits of a team approach, 2) provide consultation to hospitalists for working up the cause of the delirium and appropriate medical management, and 3) reduce the impact of the hospital environment on delirium.

Measures for Improvement

The target population, which was assessed retrospectively, included all inpatients discharged with an International Classification of Diseases, Ninth Revision (ICD-9) code of 293.0 (delirium due to conditions classified elsewhere) or 780.09 (other alteration of consciousness). Measured outcomes included average LOS, days of restraint use, and fall (assisted and found on floor) rates. Data also were collected on age, sex, previous history of delirium, diagnosed dementia, and discharge disposition. Diagnosis-related group (DRG) cost weights measured disease burden; they reflect the average level of resource use for an average Medicare patient in the DRG, relative to the average resource use for all Medicare patients.[18] More complex conditions have higher DRG weights.[19] Baseline data were collected from January 2009 to August 2010.

Baseline data validated the perceived opportunity to improve management of delirium in inpatients. Among 419 patients meeting inclusion criteria, baseline LOS averaged 8.5 days, more than the reported average LOS for patients with incident delirium.[9] Restraint use occurred on 1.7% of patient days, and falls occurred in 0.2% of hospital admissions. Statistical process control software was used to monitor outcomes. This quality-improvement project was not subject to research oversight.

The Delirium Team

A delirium team was created by redesigning existing staff roles. One of the two half-time psychiatrists began focusing primarily on managing delirium among inpatients. A new half-time clinical nurse specialist (CNS) position was filled by a CNS already on staff. On weekdays, the psychiatrist/CNS team rounded on all referred patients, following them up until delirium resolved. Referrals were based on the clinical judgment of hospitalists and nurses; a positive screening test was not required. From the beginning, the team encouraged hospital staff to promptly refer older adults with fluctuating or sudden onset of confusion and not wait until they became, for example, combative or delusional.

The delirium team recommended interventions including medication management and a nonpharmacologic management protocol (see Sidebar: Nonpharmacologic Delirium Management Protocol). The latter addresses the following: 1) monitoring for common causes (eg, medications, dehydration, constipation, hypoxia, electrolyte imbalance); 2) reducing environmental triggers (eg, bright lights at night, loud noises, intravenous lines); 3) therapeutic strategies for patient care and communication (eg, normalizing sleep-wake cycles, frequent reorientation); and 4) addressing sensory deficits (eg, ensuring the use of eyeglasses, hearing aids, and dentures).

Within one month, SRMC expanded psychiatric consultation on weekends, as part of a larger initiative to provide service seven days per week, as well as to better manage patients with delirium. In addition, hospital social workers screened all referred patients for psychosocial needs, and a dedicated dementia social worker role was created in January 2011. Because of frequent co-occurrence of delirium and dementia, this role provided key support for the program.[2]

Multidisciplinary Education

Evidence-based best practices for identifying and managing delirium were presented at monthly hospitalist meetings and distributed to physicians.[2,20] In April 2011, SRMC grand rounds focused on dementia and delirium. Consulting psychiatrists also provided real-time education for staff hospitalists while collaborating on patient care.

A medication dosing guide was developed and distributed to hospitalists and Emergency Department physicians. It included guidelines for scheduled and as-needed use of olanzapine, quetiapine, risperidone, and haloperidol, restricting lorazepam use to alcohol withdrawal-related delirium (Table 1). In addition, consulting psychiatrists recommended adding or adjusting bowel care and avoiding sedatives and hypnotics for sleep, benzodiazepines in delirium unrelated to alcohol withdrawal, anticholinergics, and other delirogenic medications. Individualized pain management recommendations adjusted and lowered opioid dosages, allowing for as-needed escalation.

Mandatory training for registered nurses addressed identification and management of delirium and use of the Confusion Assessment Method for the ICU (CAM-ICU) tool. Although the tool was developed for ICU use, it was selected for its high sensitivity and specificity and existing availability in the EHR.[21,22] Nurses were expected to complete the CAM-ICU as part of shift assessments for medical-surgical patients referred to the delirium management team. The delirium CNS audited CAM-ICU use, providing feedback, coaching, and targeted education to nursing staff.

Interventions in Delirium Care Quality-Improvement Initiative

- Delirium management team consisting of a psychiatrist and a clinical nurse specialist providing consultation seven days a week
- Social work support
- Pharmacologic and nonpharmacologic management protocols
- Multidisciplinary education to improve delirium diagnosis, ongoing assessment, and documentation in the EHR
- "Drag and drop" referrals in the EHR to the delirium management team
- Standardized documentation templates

EHR = electronic health record.

Health Information Technology Support

Before the quality-improvement project, hospitalists used varying diagnostic codes for patients with delirium; a key objective was increasing the appropriate coding of delirium on the EHR problem list. To facilitate coding, a drop-down menu appeared when hospitalists matched *delirium* in the EHR problem list, listing 11 ICD-9 options that included acute delirium and combinations of delirium and dementias. Hospitalist education emphasized selecting either Code 293.0 or 780.09.

Hospitalists and nurses could refer patients for delirium assessment and management by adding their names to a shared EHR list. The delirium team reviewed the list and provided daily consultation to all referred inpatients. An electronic template standardized assessment, recommendations, and treatment plan documentation. A template for follow-up consultations standardized documentation of changes in clinical condition and recommended medication adjustments. An electronic delirium order set was later created, but an existing paper-based order set for nonpharmacologic management was used during the pilot. The Sidebar: Interventions in the Delirium Care Quality-Improvement Initiative summarizes delirium management strategies.

Implementation

A pilot from September 2010 to July 2012 included 920 patients who were discharged with a qualifying diagnostic code, approximately half of whom were seen by the delirium management team. Some patients were not referred to the delirium management team, and a separate prevention and management protocol was used for delirium in the ICU.

Program enhancements occurred during the pilot. After an initial lack of cross-coverage, SRMC leadership mandated that the Psychiatry Department provide seven-day coverage and allocated trained psychiatric and CNS coverage to the program. The medication dosing guide was updated. Recommendations to prevent pneumonia and falls were added to documentation templates. An EHR SmartPhrase (Epic software from Intergalactic; Verona, WI) was created for nurses to document the effect of medications for hyperactive behaviors (Figure 1).

RESULTS

During the pilot, 920 patients met inclusion criteria, of whom 470 received care from the delirium management team. The pilot data from September 2010 to July 2012 were compared with the baseline data for 419 patients in January 2009 to August 2010. Those in the pilot period were more likely to have a history of delirium and a diagnosis of dementia. Patients in the pilot period had a higher median DRG weight and a different mix of discharge dispositions compared with patients in the baseline period (Table 2).

The average LOS in the target population decreased from 8.5 to 6.5 days ($p = 0.001$); the average LOS for SRMC as a whole remained stable at 3.9 days. The rate of falls and the use of restraints were unchanged.

Assuming an improvement of 2.0 days in average LOS for 480 discharges annually and a variable cost per hospital day of $2700, the delirium management program avoided an estimated annual $2.6 million in costs. The incremental staffing cost of a 0.5 FTE CNS position and inpatient nursing staff training costs offset avoided costs, generating net annual savings of

Table 1. Neuroleptic dosing guide for delirium

Medication	Route of administration	Initial dosing	PRN dosing	Indications	Contraindications	Cautions
Haloperidol (Haldol)	Oral, IV, IM	0.5-1 mg every day to twice daily	0.25-2.0 mg every hour for serious agitation	Delirium, agitation, psychosis	Parkinson disease, QTc > 500 ms	Avoid IV form if QT interval an issue; may cause dystonia/EPS, especially if given IM
Risperidone (Risperdal)	Oral, orally disintegrating tablet (M-tab); available in depot form but not a standard IM	0.5-1 mg every day or twice daily	0.5-1 mg every 4 hours; TD not to exceed 6 mg/d	Delirium, psychosis/ agitation, aggression; less sedating than quetiapine or olanzapine	Parkinson disease, QTc > 500 ms	May cause tachycardia, hypotension
Quetiapine (Seroquel)	Oral	25 mg twice daily or every HS, can increase to 50-100 mg/d	12.5-25 mg every 4-6 hours	Preferred for delirium in patients with Parkinson disease; lower risk of NMS	QTc > 500 ms	Can cause orthostatic hypotension and sedation
Olanzapine (Zyprexa)	Oral, orally disintegrating tablet (Zydis), IM	2.5-5 mg/d	2.5-5 mg every 4 hours; TD not to exceed 20 mg/d	Second choice for delirium in patients with Parkinson disease, psychosis, agitation; lower risk of NMS	QTc > 500 ms	Can cause hypotension, sedation
Lorazepam (Ativan)	Oral, SL, IM, IV	0.5-2 mg	0.5-1.0 mg every 6 hours as needed for signs/ symptoms of withdrawal	Anxiety, ethanol withdrawal	May have paradoxical reaction; monitor for withdrawal syndrome	Will worsen delirium unless delirium from alcohol or benzodiazepine withdrawal

EPS = extrapyramidal symptoms; HS = hora somni (bedtime); IM = intramuscular; IV = intravenous; min = minute; NMS = neuroleptic malignant syndrome; PRN = pro re nata (as needed); QTc = corrected QT interval; SL = sublingual; TD = total dose.

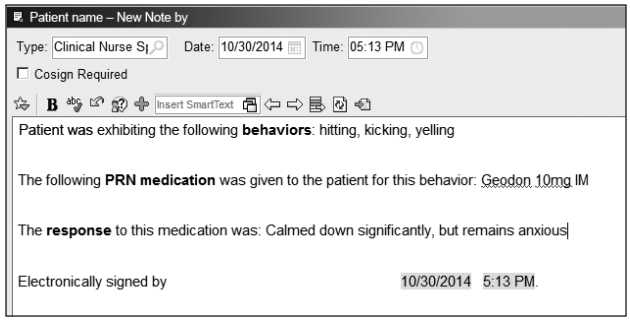

Figure 1. Sample electronic health record showing documentation of effect of medications for hyperactive behaviors.

Geodon = ziprasidone; IM = intramuscular; PRN = as needed.

$2.4 million. The cost of psychiatric coverage on weekends was not included because coverage was expanded to address several needs at SRMC.

DISCUSSION

The delirium management program was a resource-efficient and effective way to improve delirium management among older inpatients, as measured by LOS. The rate of falls and use of restraints did not change. Falls occurred too infrequently to detect statistically significant changes. Measuring changes in the use of restraints was confounded by a 2011 organizational change in staffing and safety-sitter standards that also had an impact on restraint use.

Limitations of the study include the fact that we did not include other measures, such as patient, family, and staff satisfaction, which could have provided additional evidence of benefits. In addition, we were unable to assess the effect of individual program components, such as education, increased emphasis on recognition and management of delirium, and seven-day availability of psychiatric consultations. Improved identification could have reduced LOS if more patients with less severe delirium were included; we did not measure delirium severity. However, a higher prevalence of dementia and a history of delirium and greater illness complexity among patients in the pilot suggest that the project led to accurate identification of delirium among some patients in whom it might otherwise have been overlooked in the context of more complex illness.

Another limitation pertains to including all patients coded as having delirium: those in the ICU, where another delirium management program was in place; those receiving usual care in the baseline period; and those receiving usual care and the intervention in the pilot period. Including all patients with a diagnosis of delirium captured any broader intervention effects. For example, as hospitalists gained experience, they may have managed some patients without referral. However, we did not assess the extent to which this occurred.

Shorter LOS could have resulted from patients with delirium being transferred to other care settings. Compared with the baseline population, fewer patients in the pilot population returned home to routine care and more patients received home health or hospice care after discharge. A robust inpatient palliative care team was implemented during the pilot period, which may have affected discharge dispositions.

A benefit of reduced average LOS among older adults is avoided adverse events. For example, among medical inpatients of all ages in all settings, each additional hospital night increases by 1.6% the baseline risk of infection of 17.6%.[23] Adults aged 65 years and older have a 5-fold higher risk of an inpatient *Clostridium difficile* infection than those aged 45 to 64 years[24]; the benefit is evident of avoiding incremental increases in infection risk among older inpatients.

Delirium team members built collegial relationships that helped change the culture of delirium care at SRMC. The psychiatrist championed the program among physician peers. A psychiatry background is useful—but not essential—for this role. It could

Table 2. Characteristics of older adults with delirium[a]

Characteristic	Baseline (n = 419)[b]	Follow-up (n = 920)[c]	p value
Age, median years (mean, SD)	81 (77, 15)	82 (79, 14)	0.163
Women	215 (51.3)	519 (56.4)	0.086
Previous history of delirium	134 (32.0)	379 (41.2)	0.001
Diagnosed dementia	89 (21.2)	304 (33.0)	0.001
DRG weight,[d] median (mean, SD)	1.16 (1.76, 1.99)	1.49 (1.80, 1.58)	< 0.0001
Discharge disposition			
Died	35 (8.4)	91 (9.9)	< 0.0001
Against medical advice	1 (0.2)	3 (0.3)	
Acute hospital	13 (3.1)	23 (2.5)	
Other inpatient care	10 (2.4)	16 (1.7)	
Long-term care	129 (30.8)	296 (32.1)	
Routine home	187 (44.6)	295 (32.0)	
Home health or hospice care	44 (10.5)	197 (21.4)	

[a] Data are no. (%) unless otherwise indicated.
[b] Collected January 2009 to August 2010.
[c] Collected September 2010 to July 2012.
[d] DRG weights reflect the average level of resources for all patients at baseline and follow-up, compared with the average level of resources for all Medicare patients.
DRG = diagnosis-related group; SD = standard deviation.

be filled by a hospitalist, geriatrician, or neurologist with inpatient experience who is comfortable consulting with peers and knowledgeable about delirium identification and management, particularly effective psychotropic medication use.

The delirium team is generalizable to other settings. The low cost and rapid speed of implementation pose lower economic and logistic barriers than do approaches such as dedicated care settings.[17] The model also can be transferred to Emergency Departments and skilled nursing facilities.

The delirium program continued after the pilot period. The average LOS among patients with a discharge diagnosis code of delirium was 7.2 days between July 2012 and November 2014. Factors affecting sustainability include turnover of delirium team members and competing time demands. The CNS role is pivotal; without feedback and coaching, nursing practice tended to drift from best practices. Sustainability could be enhanced with clinical decision-support tools in the EHR, such as best practice alerts and a simpler CAM-ICU algorithm.

Program enhancements occurred after the pilot. An electronic version of the nonpharmacologic management protocol replaced the paper-based version. The electronic delirium order set expanded to include scheduled and as-needed medication management and laboratory monitoring. These elements in the EHR can contribute to sustainability and enable spread to other settings. Efforts are under way across KPNC to use administrative data to automatically trigger the nonpharmacologic order set for patients at risk of delirium: those older than age 75 years or older than age 65 years and undergoing surgery; those with any history of dementia, cognitive impairment, or delirium; and those taking medications that increase delirium risk.

CONCLUSION

A program to improve delirium management could be quickly implemented with few additional resources and was associated with reduced LOS among older inpatients with delirium. Potential benefits to patient and staff satisfaction and safety as well as the cost savings associated with this program support an investment in implementation. ❖

Disclosure Statement

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

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Hallucinations
acrylic paint on canvas, original size 30” x 40”

Nadia Al Khun

Our perception of our world, our reality, is comprised of colors, dots, lines, and shapes that are integrated in great harmony. Hallucinations represent a state of mind beyond reality. This can be enjoyable; however, unpleasant experiences can distort the beauty of color and sometimes dominate the hallucinatory experience. This painting presents a background of homogeneous colors (representing pleasant hallucinations) that are interrupted by a vexatious network.

Mrs Al Khun is a genetic engineer and biotechnologist who is now mostly dedicated to art. More of her work can be seen at: www.facebook.com/pages/NAdiAalkhun/393134820846880.

The Kaiser Permanente Northern California Adult Member Health Survey

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ABSTRACT

Introduction: The Kaiser Permanente Northern California (KPNC) Member Health Survey (MHS) is used to describe sociodemographic and health-related characteristics of the adult membership of this large, integrated health care delivery system to monitor trends over time, identify health disparities, and conduct research.

Objective: To provide an overview of the KPNC MHS and share findings that illustrate how survey statistics and data have been and can be used for research and programmatic purposes.

Methods: The MHS is a large-scale, institutional review board-approved survey of English-speaking KPNC adult members. The confidential survey has been conducted by mail triennially starting in 1993 with independent age-sex and geographically stratified random samples, with an option for online completion starting in 2005. The full survey sample and survey data are linkable at the individual level to Health Plan and geocoded data. Respondents are assigned weighting factors for their survey year and additional weighting factors for analysis of pooled survey data.

Results: Statistics from the 1999, 2002, 2005, 2008, and 2011 surveys show trends in sociodemographic and health-related characteristics and access to the Internet and e-mail for the adult membership aged 25 to 79 years and for 6 age-sex subgroups. Pooled data from the 2008 and 2011 surveys show many significant differences in these characteristics across the 5 largest race/ethnic groups in KPNC (non-Hispanic whites, blacks, Latinos, Filipinos, and Chinese).

Conclusion: The KPNC MHS has yielded unique insights and provides an opportunity for researchers and public health organizations outside of KPNC to leverage our survey-generated statistics and collaborate on epidemiologic and health services research studies.

INTRODUCTION

Most researchers, public health practitioners, and clinicians are familiar with national and state health surveillance surveys used to monitor trends in health and health-related behaviors over time, such as the National Health Interview Survey (NHIS), the Centers for Disease Control and Prevention's Behavioral Risk Factor Surveillance Survey (BRFSS), the California Health Interview Survey (CHIS), and the Gallup-Healthways Well-Being Index. Many fewer are aware of the Kaiser Permanente (KP) Northern California (KPNC) Adult Member Health Survey (MHS), which has been conducted every 3 years since 1993 to describe the sociodemographic and health-related characteristics of adults within a large, multicenter, integrated health care delivery system and how these characteristics may be changing over time. In 2015, the KPNC adult membership numbered more than 2.9 million, 19.3% of whom were aged at least 65 years. Using CHIS data, we have previously shown that the KPNC adult population is very similar to the insured adult population in Northern California with respect to sociodemographic and health-related characteristics.[1] This longitudinal survey project has yielded unique insights and provides an opportunity for other researchers and public health organizations to leverage our survey-generated statistics and collaborate on epidemiologic and health services research studies.

The MHS aims to provide information to health service planners, program/service managers, and researchers in KPNC and organizations external to KPNC that can be used to

- describe the sociodemographic characteristics, the prevalence of health-related problems, behaviors/lifestyle factors, and the service needs and interests of young, middle-aged, and older KPNC adults for planning and research purposes
- monitor trends over time for the overall adult membership and segments of the membership (eg, age, sex, and race/ethnic groups) in prevalence of health conditions, health risks, use of complementary and alternative medicine and dietary supplements, and Internet access and preferred methods of obtaining health information
- examine important associations between patient-reported predictors and clinical outcomes through linkage to a state-of-the-art electronic medical record
- contribute to an evidence base for service/program development and program evaluation within KPNC and for the community (eg, community health needs assessment and community health initiatives)
- educate health care professionals about factors that affect the total health of adults
- conduct epidemiologic and health services research
- compare the KPNC adult membership to the general and insured populations (using BRFSS, CHIS, and NHIS data) and research populations to the KPNC population.

The KPNC Adult MHS is funded by KPNC's Community Benefit program as part of its portfolio of support for health research. The survey materials are not proprietary, and most of the

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survey results are shared with the public, foundations, government, and research community via conference presentations, publications, and reports posted on our Web site (www.memberhealthsurvey.kaiser.org). With the approval of the Division of Research Director and KPNC's institutional review board, researchers from within and outside the KP Medical Care Program can collaborate on important descriptive and analytic research studies using MHS data.

History of the Member Health Survey

The MHS was created in 1990 to serve a dual purpose: KPNC researchers in the Division of Research required information about characteristics of the adult Health Plan membership in the region and different Medical Center service populations, and KPNC's regional and Medical Center Health Education Departments required data to optimize health education service planning for their service populations. At the time it was first piloted with a regional sample in 1990, there was little information about nonhospitalized members besides age, sex, geographic residence area, and number of outpatient visits. KPNC's pre-electronic health record (EHR) information systems and disease registries had not yet been implemented, so there were no available data to estimate numbers of members with chronic health conditions such as diabetes or hypertension; which patients were getting recommended cancer screening procedures; and numbers of members who smoked and had other behavioral health risks like obesity. Additionally, there was no systematic individual-level or descriptive information about sociodemographic characteristics (eg, race/ethnicity, educational attainment, and household income) for the membership.

Now 25 years later, even with the vast improvement in availability of race/ethnicity, diagnosis, and health risk (body mass index, smoking status, and exercise frequency) data from members' EHRs, the MHS is still used by KPNC researchers and our Health Education Departments to describe the regional and Medical Center adult membership's more detailed sociodemographic characteristics, overall health status, behavioral and psychosocial health risks, access to digital technology, and health education/health information modality preferences—data elements that may not be readily available from EHRs or other sources of Health Plan data. MHS data are used to identify racial/ethnic differences in self-reported health and functional status, health-related behaviors, social determinants of health, and access to/preferences for using digital technologies for health care-related purposes. The survey is also the source of membership statistics over time that is most comparable with results of other population surveys based on self-reported data, such as the BRFSS, CHIS, and NHIS.

Survey Content

The core content categories and examples of items included in these categories are summarized in Table 1. Before 2012, when Stage 1 Meaningful Use requirements were implemented,[2] race/ethnicity was not routinely collected for Health Plan members, and in KPNC, the MHS provides more detailed race/ethnicity

Table 1. Core content of Member Health Surveys

Category	Sample items
Sociodemographic characteristics	Race/ethnicity; educational attainment; income; employment status; marital status; sexual orientation; for ages ≥ 65, transportation situation
Social determinants of health	Educational attainment, income, worry about financial security, chronic stress, satisfaction with life, experience of discrimination/harassment in past year, worry about family safety due to neighborhood violence, intimate partner violence
Health and functional status	Rating of overall, physical, and emotional/mental health; extent to which physical and emotional/mental health problems interfere with daily activities; selected chronic health conditions and health-related problems (eg, back pain, sleep problems, hearing problems, urinary incontinence); and for ages ≥ 65, functional status (ADLs/IADLs), falls, use of hearing aid, oral health problems
Medications used during past year	Prescription medicines for diabetes, hypertension, heart problems, high cholesterol, asthma, depression, anxiety, pain; low-dose aspirin to prevent heart attack/stroke; OTC pain medication; NSAIDs; antacids; stop-smoking aids (eg, nicotine patches and nicotine gum); sleep aids
Health-related behaviors and beliefs	Smoking, height/weight, exercise frequency, daily servings of fruit/vegetables, high-fat food avoidance, high-salt food avoidance (2011), alcohol use, number of sleep hours, actions taken to improve or maintain health, health-related beliefs
CAM modalities used during past year (1996-present)	Modalities vary by year but always include: acupuncture, acupressure, massage, chiropractic treatment, yoga, tai chi, herbal supplements/remedies, homeopathic medicines, deep breathing/mindfulness meditation, guided imagery, special diet, prayer or spiritual practice, religious/spiritual healing by others, psychological counseling, 12-step/self-help program
Dietary supplements used during past year	Supplements vary by year but always include: daily multivitamin, calcium, glucosamine, melatonin, a space to list other supplements
Preventive care and health advice	Flu shot for past flu season; health-related advice received from Health Plan; before 2011, recency of blood pressure and cholesterol checks and breast, cervical, and colorectal cancer screening tests
Access to digital technology	Computer; Internet; e-mail; starting in 2011, mobile phone, text messaging capability, type of device used to go online
Use of and interest in using a variety of modalities to obtain health information and health education	Digital and telephone-based modalities; print modalities; and in-person visits, which change as new modalities become available.

ADLs = activities of daily living; CAM = complementary and alternative medicine; IADLs = instrumental activities of daily living; KPNC = Kaiser Permanente Northern California; NSAIDs = nonsteroidal anti-inflammatory drugs; OTC = over-the-counter

information than is currently captured in the EHR from outpatient visits, especially for Asian and multiracial members. Currently educational attainment, an important social determinant of health,[3] is found in a sparsely populated text field in KPNC members' EHRs, so studies requiring this demographic have generally used census-derived data. Similarly, household income is only estimable from geocoded census block data, and employment status (including number of work hours), marital status, and sexual orientation are not available from any other data source.

Even though information about respondents' diagnosed chronic conditions (eg, diabetes, hypertension, asthma) and prescription medication use is now available from the EHR system, these items are still included in the survey to keep estimates comparable with other surveys based on self-reported data, for quick profiling of segments of the membership; and to study behavioral and social characteristics of members who self-identify with these conditions. Other conditions contained in the health condition checklist, such as severe back, neck, or shoulder pain, urinary incontinence, vision and hearing problems, and frequent sleep problems, are often not reported to physicians and so don't get into EHRs. For seniors, the MHS is currently the best way to profile functional status (mobility issues, difficulties with activities of daily living and instrumental activities of daily living, ability to care for oneself).

Although data about overweight/obesity (body mass index), smoking status, exercise, and measures of alcohol use are now routinely captured in the EHR of KPNC members as "vital signs" at outpatient visits, MHS data are still probably the most reliable way to estimate prevalence of these behavioral risks because the data are collected from members who have and have not recently come in for a medical office visit (during which vital signs are measured) during a six-month period using the same exact question and response wording. Information about other behaviors and psychosocial risk factors that are not currently routinely captured in the EHR, such as usual amount of sleep, number of daily servings of fruits and vegetables, salt/sodium and high-fat food avoidance, satisfaction with life, chronicity of stress and sources of distress (including worry about financial security and neighborhood safety), nutritional supplement and complementary and alternative medicine use, and actions members are taking to improve or maintain their health, are currently available only through the survey. Additionally, since 1999, the MHS has been asking members to evaluate the extent to which they believe their lifestyle/habits (like diet, exercise, and weight) and stress and emotion troubles (like depression) can affect their health.

In all MHS cycles, members have been asked to report whether they had a flu immunization for the last flu season because some members get this immunization outside of KP. From 1999 on, the survey has asked about recency of last dental exam and whether advice or counseling had been received in the past year from a KPNC health care professional about a variety of health risks (eg, increasing exercise, quitting smoking, getting enough sleep, taking steps to reduce falls). In the 1993-2008 surveys, members were asked about recency of their last blood pressure and cholesterol check and cancer screening tests, but screening items were dropped starting in 2011 to enable expansion of questions on other topics.

Finally, because the MHS serves as a health education planning tool, the survey captures information about members' access to digital technology and preferred methods for obtaining health information and health education. In 1996, we began to ask about access to and use of a computer and the Internet. In 1999, we added questions regarding e-mail access and use, and in 2011 we started ascertaining access to mobile phone and text messaging, as well as whether the member could use these digital technologies on their own and the types of device(s) they used to access the Internet and e-mail. Health information modality preferences has been obtained since 1999 using 2 checklist questions. The first question asks members to indicate which of a variety of print, in-person, and online health information sources and health education services they used in the previous 12 months. The second question asks members to indicate which modalities they would prefer to use to learn about taking care of health problems and improving their health, in addition to getting information from their physician.

Survey Methods

For most cycles, the MHS has used different questionnaires for women aged 20-64, men aged 20-64, and women and men aged 65 and older, but all contain the same core set of questions for that survey year. Most of the MHS questionnaires can be downloaded from the MHS Web site. The MHS is a confidential, not anonymous survey, making it possible to link respondent data by medical record number level to other sources of KPNC clinical and administrative data. This makes it possible to obtain objective information on diagnoses, procedures, vital signs, medical care and pharmacy utilization and costs, laboratory testing, registration to use and use of the kp.org patient portal, Health Plan benefits, and other health and health care information. By means of mailing address, respondent data can be linked with geocoded data such as neighborhood sociodemographic and built environment characteristics. Both nonrespondents and respondents can be linked to available Health Plan data and geocoded data to study effects of nonresponse bias.

To ensure that the survey sample reflects geographic differences that may affect health conditions and health-related behaviors, a predetermined number of men and women in 5 age groups (20-44, 45-64, 65-74, 75-79, and ≥ 80 years) are randomly selected from each of the Health Plan's Medical Center service populations, resulting in oversampling of members aged 65 and older. Members are administratively assigned to a Medical Center service population using an algorithm that takes into account the facility where they receive or would be most likely to receive most of their outpatient primary care. Using this approach, we randomly select approximately 2100 current members from 14 of our 19 Medical Center service populations in Northern California, sampling 2400 from our 5 most racially/ethnically diverse service populations. In 1993 and 1996, survey questionnaires were mailed to a stratified random sample of 34,000 adult Health Plan members from 17 Medical Center service populations in the Northern California Region. In 1999 and 2002, the

sample size was increased to 40,000 from 18 Medical Center service populations, and starting in 2005, to approximately 44,000 from 19 Medical Center service populations. In 2014, the decision was made to split data collection for the full sample over 2 years, with independent samples selected each year. Because samples are independently sampled for each survey, there is very little overlap of respondents across multiple survey years.

Questionnaires are mailed out in the spring of a survey year, followed by up to 2 additional mailings in early and late summer. Starting in 2005, members could also complete the survey online at the KPNC Division of Research's secure Web site, and telephone administration has always been available upon request. Before the 2014 to 2015 survey cycle, the survey was conducted only in English owing to cost considerations and our experience of very low response rates to a 2006 pilot mailing of a Spanish-language questionnaire to members whose primary language was Spanish.[4] However, as part of the 2015 survey cycle, in Spring 2016 a separate sample of limited-English proficient Spanish speakers aged 25 to 64 years will be sent up to 2 mailings of a slightly modified bilingual (Spanish/English) version of the 2015 MHS questionnaire.

Each survey respondent is assigned a poststratification weighting factor based on the number of members of his/her sex and age group (five-year intervals) in the Medical Center service population from which s/he was sampled. Weighting factors are also created to use with data combined from two or more survey years. The weighted respondent data are then used to describe the sociodemographic characteristics and health-related characteristics of adults in the KPNC Region, individual Medical Center service populations, and population segments (eg, members with a specific sex, race/ethnicity, chronic condition, risk factor, etc).

Although the overall survey response rate has been declining over time (58.7% in 1993 to 39.5% in 2011), the response rate among those aged 65 and older has consistently been approximately 70%. The overall response rate is comparable with the response rates for recent random-digit dial (RDD) telephone surveys such as the CHIS and California BRFSS (approximately 35% for each in 2011) and significantly higher than the RDD Pew Internet and Society surveys and Gallup-Healthways Well-Being Index surveys (each approximately 11%), all of which are used to support policy-making.[5-8] Table 2 shows the numbers of MHS respondents in each survey year.

Impact of Member Health Survey Results

MHS results have been used by KPNC researchers and Health Education Departments to help identify and estimate number of members with health conditions (such as diabetes, hypertension, urinary incontinence, insomnia, and heartburn) and behavioral/lifestyle risks (such as smoking, obesity, sedentary lifestyle, and stress) known to increase the risk of chronic illness; to examine how sociodemographic and health characteristics vary across Medical Center service populations; and to characterize subgroups of adults who are most likely to have these health problems and risks. Reports profiling the sociodemographic and health-related characteristics of young, middle-aged, and older adults in the KPNC Region and the different Medical Center service populations are produced for each survey cycle. Additional reports show trends in selected characteristics over time or focus on specific health topics, such as race/ethnic differences in education and income, health conditions/risks, and Internet access. Many reports and presentations are shared with the research community and general public

Table 2. Size of Kaiser Permanente Northern California Member Health Survey final respondent samples, 1993-2011, by survey year and age-sex group

	Survey year						
Respondent age-sex groups[a]	1993	1996	1999	2002	2005	2008	2011
All respondents							
≥ 20	19,561	17,735	18,937	18,604	18,733	16,960	16,968
25-79[b]	18,137	16,339	17,243	16,874	16,957	15,352	15,353
≥ 80	689	564	1085	1045	1120	1046	1060
Women							
≥ 20	10,529	9665	10,343	10,087	10,357	9461	9084
25-44	3902	3380	3124	3023	3022	2736	2552
45-64	3446	3130	3229	3161	3171	2940	2820
65-79	2379	2379	3045	2955	3149	2883	2863
≥ 80	375	268	510	507	553	519	513
Men							
≥ 20	9032	8070	8594	8517	8376	7499	7884
25-44	2932	2400	2152	2106	1870	1580	1649
45-64	3030	2628	2669	2730	2640	2308	2661
65-79	2448	2422	3024	2899	3105	2905	2808
≥ 80	314	296	575	538	567	527	547

[a] Age in years.
[b] Trends across survey years and by race/ethnicity are generally restricted to respondents aged 25-79.

via the MHS Web site as well as through presentations and publications.

KPNC researchers have used the survey data alone or combined with supplemental information from KP clinical and administrative data for many purposes, resulting in numerous publications in peer-reviewed professional journals. For example, researchers have used MHS data to estimate the prevalence of health risks; to describe characteristics of adults with specific health conditions or health risks or for population subgroups (eg, by race/ethnicity, age); to create comparison groups for epidemiologic studies; to study accuracy (validity) of member-reported health information; to estimate underrecording of health conditions and behavioral risks in EHRs (based on member-reported health information), and under- or overestimation of these conditions and behaviors for a population based on survey data; and to identify the most promising Medical Center service populations for intervention studies.

The survey has been used to study changes over time in sociodemographic composition of the membership and prevalence of health and lifestyle risks[9]; how prevalence of health conditions and behavioral/lifestyle risks differ by age group, sex, race/ethnicity, and sexual orientation[4,9-14]; trends and differences in complementary and alternative medicine and dietary supplement use[15-18]; senior health[19-21]; health problems, utilization, and cost of care for obesity,[22] alcohol consumption,[23] and smoking[24]; access to digital technology and preferred modalities for receiving health information and advice[25-27]; and methodological issues.[28-30] Presentations and reports can be downloaded from the Special Reports section of the MHS Web site.

KPNC regional and medical facility Health Education Departments have used the survey data to compare and to discern trends in health-related behaviors (eg, prevalence of smoking, fruit/vegetable consumption, exercise frequency) at regional and Medical Center service population levels; to educate health professionals within KPNC and in the community about social determinants of health and health care (eg, stress, financial strain, educational attainment, Internet access) that affect the total health of adults; and to examine differences in health-related behaviors and psychosocial characteristics of women and men with different levels of obesity severity.

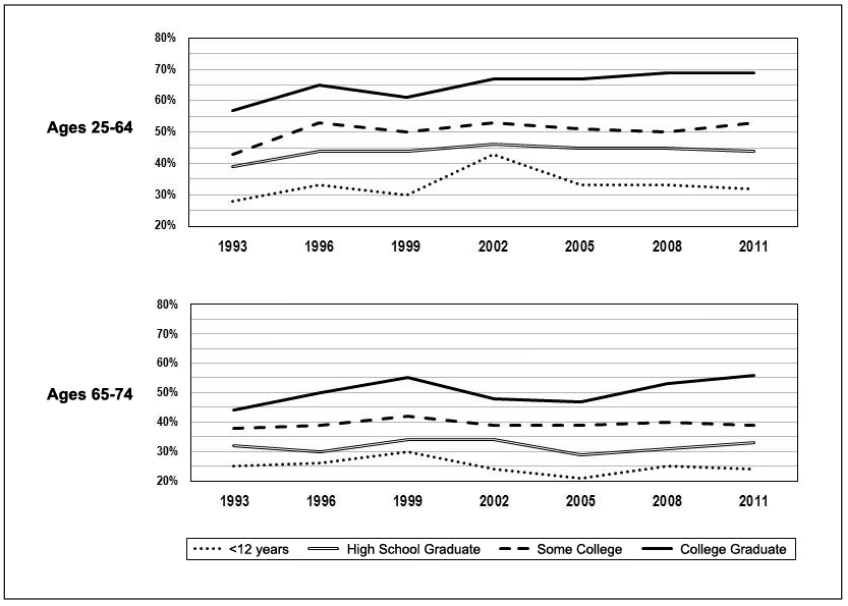

Figure 1. Percentages of adults who considered their health to be very good or excellent, by level of education, 1993-2011.

The estimates of digital technology access and health education modality preferences, and especially how these vary across different demographic segments, have provided valuable information for planning of patient education interventions by Operations and Research Departments. Because members don't always need to register for health education classes or to sign on to the Health Plan Web site to access most online health information and health education materials and programs, the estimates of modalities used in the past year help KPNC's regional Health Education and Digital Services Departments monitor member use of and preferences for different types of health information resources overall and by different subgroups of the membership.

Selected Member Health Survey Trends in Membership Characteristics Over Time

Trends in selected sociodemographic, health, and information technology characteristics 1999 to 2011 are shown for adults aged 25 to 79 years, and for ages 25 to 64 years and 65 to 79 years by sex, in Table 3 (available at: www.thepermanentejournal.org/files/15-225-1.pdf). During that 10-year interval, the adult Health Plan membership became better educated and less non-Hispanic white, with the latter change associated with a significant increase in percentage of Asian members. Compared with 1999, in 2011, the prevalence of self-reported diabetes and hypertension significantly increased in most age-sex groups. There was a small but statistically significant increase in the percentage of those aged 25 to 64 years who considered their health to be very good or excellent, but Figure 1 suggests that increases were primarily among those with higher educational attainment. There was an increase in the percentage of adults who indicated that physical or emotional health problems interfered at least moderately with their daily activities. Prevalence of current smoking, ever smoking, and exercise less than once a week was significantly lower, whereas obesity was significantly higher. The percentage of adults consuming at least 3 servings of fruits/vegetables daily was significantly higher but still less than 50%. Percentages of adults who tried to eat reduced/low fat foods, who experienced chronic stress, and who experienced an episode of depression or anxiety remained relatively flat across the study period. Belief that habits and lifestyle can greatly impact

health significantly increased across all age-sex groups, and as Figures 2 and 3 show, the increase occurred across all levels of education and all race/ethnic groups. A comparison of access to and use of digital technology in 2011 versus 2002 showed large and significant increases across all age groups in percentages with access to a computer, the Internet, e-mail, and health information from Web sites.

Use of the Member Health Survey to Identify Differences Across Race/Ethnic Groups

A comparison of non-Hispanic whites (whiteNHs) with black, Latino, Filipino, and Chinese Health Plan members aged 25-79 years on selected sociodemographic and health characteristics is found in Table 4 (available at: www.thepermanentejournal.org/files/15-225-2.pdf). Prevalence estimates are derived from pooled 2008 and 2011 survey data that were weighted to the 2011 membership and then analyzed using SAS Proc Surveyreg[31,32] (SAS Institute, Cary, NC) to standardize the age-gender composition of the race-ethnic groups. The results show significant race/ethnic differences in education, income, and self-reported health and behavior/psychosocial health risks.

Latinos are significantly less likely than all the other groups to have attended any amount of college, and blacks and Latinos are significantly less likely and Filipinos and Chinese significantly more likely than whiteNHs to have a college degree. Blacks, Latinos, and Filipinos are significantly more likely than whiteNHs to have a household income of $35,000 or less and to worry a great deal about their or their family's financial security. Compared with whiteNHs, blacks, Latinos, and Filipinos are significantly less likely than whiteNHs to report being in very good/excellent health.

With regard to health behavior/lifestyle risks, blacks, Latinos, and Filipinos are significantly more likely than whiteNHs to get exercise less than once a week (age 25-64 years) and to get less than 6 hours sleep per night ("short sleep"), and they are significantly less likely to get exercise at least 5 times a week and to consume at least 3 servings of fruit/vegetables a day. Blacks and Latinos are significantly more likely and Filipinos and Chinese significantly less likely than whiteNHs to be obese, and Latinos, Filipinos, and Chinese are less likely than whiteNHs to have ever smoked. Blacks in all age-sex groups and Latinos aged 25-64 years are significantly more likely than whiteNHs to report at least 1 episode of discrimination/harassment in the prior year, and blacks and Latinos across all age groups are significantly less likely to have had a dental exam in the past 12 months.

Figure 3 shows that whiteNHs are significantly more likely than all the other race/ethnic groups to believe that their health-related behaviors/lifestyle can affect their health quite a bit. Table 5 shows that

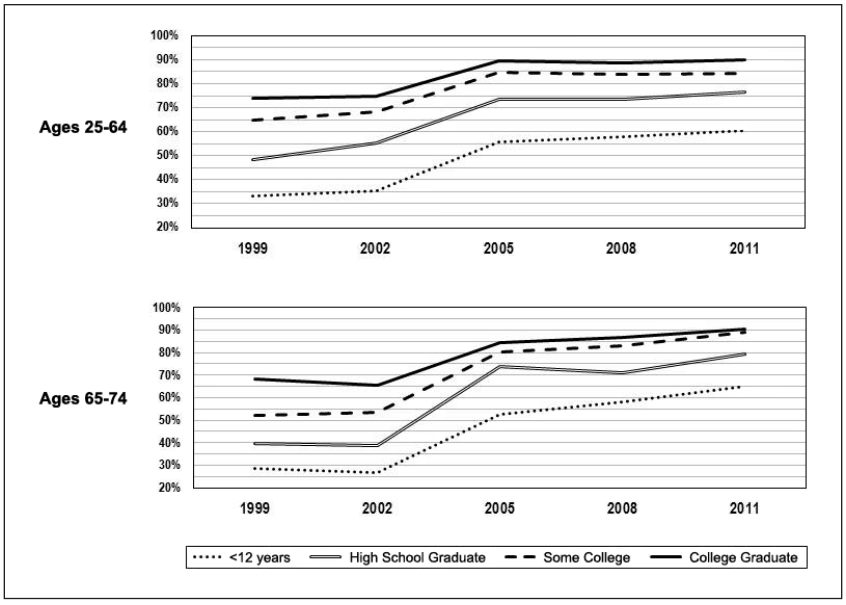

Figure 2. Percentages of adults who believe that their habits/lifestyle (eg, diet, exercise, weight) can affect their health quite a bit, by level of education, 1999-2011.

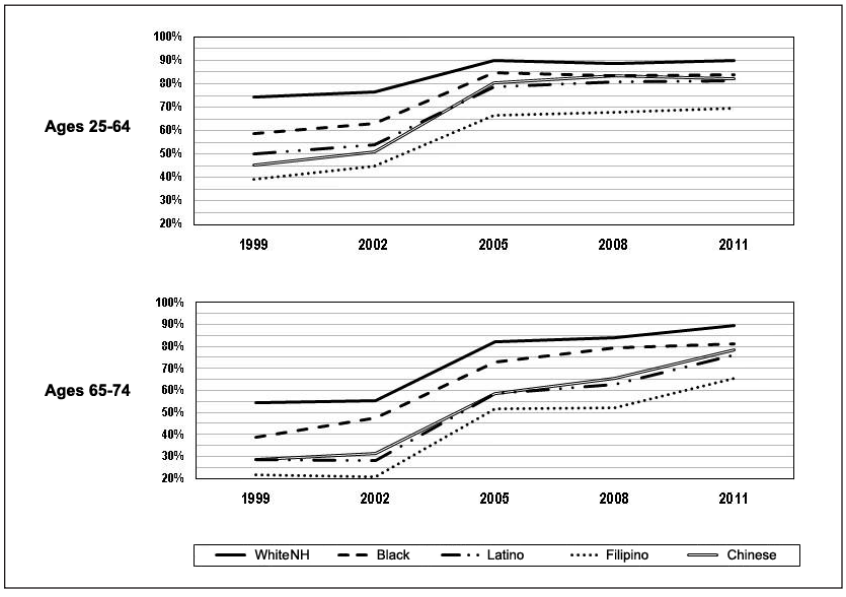

Figure 3. Percentages of adults who believe that their habits/lifestyle (eg, diet, exercise, weight) can affect their health quite a bit, by race/ethnicity, 1999-2011.

WhiteNH = non-Hispanic whites.

Table 5. Internet and e-mail access and preferences for selected health information modalities in 2011 among English-proficient Health Plan members aged 25-79 years, by race/ethnicity[a]

	Race/ethnicity[b]				
Age-sex group	WhiteNH	Black	Latino	Filipino	Chinese
Able to use the Internet to get information from Web sites on own or with help					
All age 25-79	97.4 (0.1)	94.7 (0.5)[c]	94.4 (0.5)[c]	93.1 (0.7)[c]	96.6 (0.6)
Women age 25-64	98.7 (0.2)	97.1 (0.7)	96.4 (0.8)[d]	95.0 (1.1)[d]	98.2 (0.7)
Men age 25-64	> 99.9 (--)	> 99.9 (--)	> 99.9 (--)	> 99.9 (--)	> 99.9 (--)
Women age 65-79	86.5 (0.9)	71.1 (3.9)[d]	75.1 (3.2)[c]	65.2 (4.6)[c]	85.3 (4.3)
Men age 65-79	87.5 (0.8)	73.7 (3.7)[c]	72.8 (3.2)[c]	85.3 (4.3)	81.5 (4.8)
Able to use e-mail on own or with help					
All age 25-79	95.0 (0.2)	88.4 (1.1)[d]	90.5 (0.7)[c]	90.1 (0.9)[c]	94.6 (0.8)
Women age 25-64	97.7 (0.3)	94.4 (1.1)[c]	94.8 (0.9)[d]	94.5 (1.2)[d]	96.3 (1.3)
Men age 25-64	96.3 (0.4)	90.4 (2.2)[d]	95.0 (1.0)	95.0 (1.4)	98.3 (0.6)[d]
Women age 65-79	83.1 (0.9)	64.5 (4.2)[c]	67.1 (3.5)[c]	59.3 (4.8)[c]	79.8 (4.7)
Men age 65-79	84.7 (0.9)	60.8 (4.3)[c]	65.0 (3.6)[c]	70.3 (4.4)[d]	80.0 (4.8)
Got health information from a Web site in the past 12 months					
All age 25-79	49.2 (0.7)	40.7 (1.8)[c]	39.4 (1.4)[c]	39.1 (1.9)[c]	44.8 (2.0)[e]
Women age 25-64	58.0 (10)	48.8 (2.6)[d]	47.7 (2.2)[c]	47.1 (2.8)[c]	49.6 (3.2)[e]
Men age 25-64	45.3 (1.2)	35.4 (3.3)[e]	34.8 (2.4)[d]	34.2 (3.3)[e]	42.6 (3.4)
Women age 65-79	42.2 (1.3)	28.2 (3.6)[d]	27.0 (3.6)[c]	28.2 (4.3)[d]	40.3 (6.2)
Men age 65-79	39.3 (1.3)	34.3 (5.2)	27.7 (3.5)[d]	29.5 (5.0)	32.5 (5.6)
Interested in getting health information/advice from Web sites[f]					
All age 25-79	42.7 (0.7)	40.7 (1.8)[c]	32.0 (1.5)[c]	41.1 (2.1)	47.3 (2.3)
Women age 25-64	58.0 (1.0)	48.8 (2.6)[d]	34.2 (2.2)[c]	46.7 (3.0)	49.7 (3.5)
Men age 25-64	45.0 (1.3)	36.6 (3.8)[e]	34.3 (2.6)[c]	39.8 (3.8)	51.6 (3.7)
Women age 65-79	29.1 (1.3)	17.1 (3.3)[c]	17.4 (3.7)[d]	19.5 (4.3)[e]	33.5 (6.9)
Men age 65-79	33.4 (1.5)	25.8 (5.7)	22.0 (3.6)[d]	38.3 (6.0)	24.0 (6.0)
Interested in getting health information/advice from Web videos[f]					
All age 25-79	19.7 (0.6)	21.1 (1.8)	17.3 (1.2)	21.4 (1.8)	21.7 (.9)
Women age 25-64	20.5 (0.9)	19.2 (2.2)	19.2 (1.8)	19.3 (2.4)	19.8 (2.8)
Men age 25-64	21.4 (1.1)	26.1 (3.5)	18.9 (2.1)	26.2 (3.4)	27.9 (3.4)
Women age 65-79	12.2 (1.0)	11.8 (2.7)	7.1 (2.4)[e]	13.3 (3.6)	16.7 (5.3)
Men age 65-79	13.8 (1.1)	14.8 (4.9)	8.0 (2.3)[e]	16.7 (5.3)	4.2 (2.2)[c]
Interested in getting health information/advice from e-mailed newsletters[f]					
All age 25-79	36.0 (0.7)	30.4 (1.9)[d]	32.8 (1.5)	36.3 (2.0)	39.8 (2.2)
Women age 25-64	39.0 (1.1)	30.9 (2.6)[d]	34.7 (2.3)	42.2 (3.0)	39.7 (3.3)
Men age 25-64	32.8 (1.2)	31.0 (3.6)	34.3 (2.6)	32.8 (3.6)	43.6 (3.8)[d]
Women age 65-79	34.1 (1.8)	24.6 (3.8)[e]	16.7 (3.3)[c]	19.0 (4.1)[c]	29.3 (6.7)
Men age 65-79	37.2 (1.5)	29.9 (5.8)	31.4 (4.0)	39.2 (6.0)	32.0 (6.8)
Interested in telephone-based health coaching[f]					
All age 25-79	32.3 (0.7)	37.8 (2.1)[e]	30.9 (1.5)	23.3 (1.8)[c]	21.4 (1.8)[c]
Women age 25-64	35.6 (1.1)	35.2 (2.8)	30.8 (2.2)[e]	24.1 (2.6)[c]	27.4 (3.1)[e]
Men age 25-64	29.1 (1.2)	42.6 (3.9)[d]	30.5 (2.6)	22.9 (3.2)	15.3 (2.5)[c]
Women age 65-79	33.6 (1.4)	34.2 (4.1)	28.6 (4.3)	25.4 (4.7)	22.4 (5.8)
Men age 65-79	27.7 (1.3)	31.7 (5.6)	37.1 (4.2)	17.6 (4.6)[c]	17.9 (5.5)

[a] Percentages for race/ethnic groups derived from Member Health Survey 2011 data weighted to the 2011 age × sex × service area composition in 2011 and then standardized to the age-sex (for age 25-79) or age distribution of the Kaiser Permanente Northern California membership for that age group in 2011. These should not be used as "official" statistics about the Kaiser Permanente Northern California membership.

[b] Data are weighted % (standard error around estimate).

[c] Significantly ($p < 0.001$) differs (higher or lower) from whiteNH in same age group.

[d] Significantly ($p < 0.01$) differs (higher or lower) from whiteNH in same age group.

[e] Significantly ($p < 0.05$) differs (higher or lower) from whiteNH in same age group.

[f] Statistics based on members who indicated at least 1 health education/information modality preference in a checklist.

WhiteNH = non-Hispanic white.

especially among older women, blacks, Latinas, and Filipinas are significantly less likely than whiteNHs to be able to use the Internet and e-mail, to have obtained health information from a Web site in the past year, and to be interested in getting health information and advice from Web sites or e-mailed newsletters.

Comparisons between Filipinos and Chinese show that these Asian ethnic groups significantly differ on several demographic and health-related measures, with Filipinos often looking more similar to black and Latino than Chinese adults despite having educational attainment comparable with Chinese adults. Significantly higher percentages of Filipinos than Chinese have a household income of $35,000 or less, worry a great deal about their financial security, are obese, and among women and men aged 25-64 years, are smokers and short sleepers (< 6 hours). Significantly lower percentages of Filipinos than Chinese usually consume at least 3 servings of fruits/vegetables per day and believe that their health-related behaviors/lifestyle can have a large impact on their health. Among older women, Filipinas are significantly less likely than Chinese to report being able to use e-mail and the Internet to obtain health information.

DISCUSSION

The information presented in this overview demonstrates that data from KPNC's MHS can be a valuable resource for researchers and service planners inside and outside of KPNC to learn about the prevalence of health-related behaviors and psychosocial risks that are not frequently collected in the clinic setting, such as short sleep, chronic high stress, use of dietary supplements, and recency of dental care, as well as digital access and preference factors that may influence use of Health Plan Web sites. Although the exact prevalence estimates for this Northern California population may not be fully generalizable to adults in other parts of the US or other countries, they represent patterns among a very large and diverse community-based population and suggest health risks that might be considered for inclusion in total health assessments in the clinic setting.

The MHS enables study of trends in health and health-related behaviors and risk factors over time, which can help assess whether secular or Health Plan campaigns appear to have improved specific behaviors, and if so, whether improvements are seen across all patient subgroups. For example, our results suggest that major strides have been made across all race/ethnic groups, age groups, and levels of education in convincing adults that their health-related behaviors and lifestyle can have a major impact on their health. However, this increase in positive health beliefs has not translated into major improvements in fruit and vegetable consumption, exercise frequency, or obesity.

MHS data can also be used to study how health-related characteristics and social determinants of health and health care, including use of digital technology, differ by race-ethnicity, age cohort, education, and income in an insured adult population. Such documented differences can provide the basis for further research, as well as have implications for developing total health assessment questionnaires for adults, population management activities, and translational patient intervention research. Because MHS data are linkable to a state-of-the-art EHR, as well as geocoded data, the survey can also be used to address important methodologic issues, such as sources and effects of nonresponse bias in surveys, how well estimates of health characteristics based on survey data match estimates based on Health Plan clinical data, and whether accuracy of self-report data differs by race/ethnicity, sex, or level of education.

CONCLUSION

In this era of "big data" generated through rapidly expanding EHRs and other clinical and administrative data sources, surveys such as the KPNC MHS provide important complementary data that can inform on patient characteristics over time. The MHS is unique in that it can be readily linked at the individual-patient level to facilitate novel research using combined clinical and self-reported data to address research questions that can have clinical and public health implications. The MHS represents a great resource for new collaborative research, and KPNC encourages pursuing those collaborative opportunities to increase the benefit of this survey to the broader community. ❖

Disclosure Statement

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

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Serious Business

Good health is a serious business.
Like life itself, it has to be worked at and
it takes on added meaning with effort.

— Norman Cousins, 1915-1960, American political journalist, author, professor, and world peace advocate

Reduced Trauma Symptoms and Perceived Stress in Male Prison Inmates through the Transcendental Meditation Program: A Randomized Controlled Trial

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ABSTRACT

Context: Trauma events are four times more prevalent in inmates than in the general public and are associated with increased recidivism and other mental and physical health issues.

Objective: To evaluate the effects of Transcendental Meditation[a] (TM) on trauma symptoms in male inmates.

Design: One hundred eighty-one inmates with a moderate- to high-risk criminal profile were randomly assigned to either the TM program or to a usual care control group.

Main Outcome Measures: The Trauma Symptom Checklist and the Perceived Stress Scale were administered at baseline and four-month posttest.

Results: Significant reductions in total trauma symptoms, anxiety, depression, dissociation, and sleep disturbance subscales, and perceived stress in the TM group were found compared with controls (all p values < 0.001). The high-trauma subgroup analysis further showed a higher magnitude of effects in the TM group compared with controls on all outcomes, with Cohen effect sizes ranging from 0.67 to 0.89.

Conclusion: Results are consistent with those of prior studies of the TM program in other populations and its effects on trauma symptoms and perceived stress.

INTRODUCTION

Trauma events are four times more prevalent in inmates than in the general public.[1] Elevated trauma symptoms are associated with poor lifestyle decision making and higher rates of recidivism.[1] Experience of trauma exposure also is associated with adverse mental and physical health conditions, including cardiovascular disease, metabolic disease, autoimmune disorders, and cancer.[2,3]

Recent research suggests an evolving role for meditation therapies in populations with severe medical and psychiatric symptoms.[4,5] Systematic reviews of clinical trials investigating meditation therapies such as the Transcendental Meditation[a] (TM) technique reported evidence of benefits on outcomes ranging from anxiety and depression to hypertension.[4-7]

Correctional facility residents represent one large-scale population exposed to heightened stress that may benefit from practicing meditation. Prison inmates report high levels of premorbid stress and increased exposure to trauma and violence before incarceration relative to the general population.[8,9] Poor stress management skills may further contribute to behavioral problems among inmates during incarceration that could affect their ability to benefit from rehabilitation opportunities.

In a review of meditation practices in inmate populations, the TM program had the largest body of support, including research showing statistically significant reductions of psychological distress factors among inmates receiving TM instruction.[10] On the basis of these initial findings, a randomized controlled trial of prison inmates was designed to evaluate the impact of this stress reduction program on trauma symptoms and trauma-associated factors.

The current article describes the results of a randomized controlled study investigating the effects of the TM program on total trauma symptoms: anxiety, depression, dissociation, sleep disturbance subscales, and perceived stress in a population of inmates with a moderate- to high-risk criminal profile. Although research has been conducted on this intervention's application to specific types of trauma in other populations,[11,12] this is the first known published study to evaluate the effects of the TM program on trauma symptoms in prison inmates.

METHODS

Subjects

One hundred eighty-one male inmates in the Oregon state correctional system were randomly assigned to either the TM program (n = 90) or a no-treatment control group (n = 91). Two prisons took part in this trial: Oregon State Correctional Institution and Oregon State Penitentiary. Both prisons are run by the Oregon Department of Corrections and are located in Salem, OR. Oregon State Correctional Institution is a medium-security prison housing approximately 900 men. Oregon State Penitentiary is a maximum-security prison housing about 2400 men.

To be eligible for the study, the men had to have at least four months of their prison

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sentence left to serve and have at least a moderate-risk level on the Automated Criminal Risk Score. This score is generated from an algorithm that uses seven risk factors: age, earned time, sentence length, revocation, number of prior incarcerations, prior theft convictions, and type of crime (person, property, or statutory).

Procedures

Transcendental Meditation Program

The treatment group was taught the TM technique in a standard 7-step course (during 5 sessions lasting approximately 1 hour per session). They were then encouraged to practice this stress reduction technique for 20 minutes twice a day, once in the morning and once in the late afternoon. Two certified TM teachers who had more than 10 years of teaching experience were the instructors for this study. The same standardized TM course sequence was used for all study participants; this sequence is described fully in the literature.[13]

The TM technique is a simple, natural, effortless technique that allows the mind to experience finer levels of the thinking process until the mind transcends and experiences the least excited state of human awareness.[13] Overall, TM produces a profound state of "restful alertness."[14] Participants in the TM group also had the option to attend group follow-up training and meditation sessions several times a week during the four-month intervention.

No-Treatment Controls

Subjects in the control group continued with their daily schedule and did not participate in the TM program. All subjects in both groups continued to receive their usual care.

Outcome Measures

The following measures were administered at baseline and four-month posttesting. Written informed consent was received from all subjects before testing.

Trauma Symptom Checklist

The Trauma Symptom Checklist (TSC) assesses trauma-related problems in several categories,[15] with the source of the trauma being psychological and/or physical. A modified TSC inventory was used in this study, which included 30 of the original test items to give a total score and scores on the following subscales: dissociation, depression, anxiety, and sleep problems.[15] Each symptom item was rated according to its frequency of occurrence, using a 4-point scale ranging from "0 = never" to "3 = often." The TSC addresses broad trauma-related symptoms and has strong

Table 1. Background and demographic characteristics by group for entire sample[a]

Variable	Transcendental Meditation (n = 90)	Control (n = 91)	p value
Age, years	28.56 ± 7.18	29.95 ± 8.22	NS
Race/ethnicity, no. (%)			
White	47 (52)	48 (53)	NS
Hispanic	8 (9)	4 (4)	
African American	17 (19)	12 (13)	
Native American	14 (16)	14 (15)	
Other	4 (4)	13 (14)	
ACRS	0.33 ± 0.15	0.31 ± 0.16	
Perceived Stress Scale	29.84 ± 6.81	31.32 ± 6.96	
Trauma Symptom Checklist			
Total trauma	23.68 ± 13.11	30.12 ± 16.10	0.004
Anxiety subscale	2.99 ± 3.30	6.02 ± 4.27	0.001
Dissociation subscale	3.39 ± 2.34	4.31 ± 2.70	0.015
Depression subscale	6.07 ± 3.67	7.68 ± 4.04	0.005
Sleep disturbance subscale	7.72 ± 4.55	8.62 ± 4.62	NS

[a] Data are presented as baseline mean ± standard deviation unless indicated otherwise.
ACRS = automated criminal risk score; NS = not significant.

Table 2. Four-month adjusted posttest scores for trauma-associated symptoms[a]

Variable	Transcendental Meditation (n = 73)	Control (n = 71)	p value	d
Perceived Stress Scale	21.37 ± 0.70	26.41 ± 0.76	< 0.001	0.75
Trauma Symptom Checklist				
Total trauma	12.50 ± 1.03	20.02 ± 1.75	< 0.001	0.57
Anxiety subscale	2.08 ± 0.23	3.61 ± 0.42	< 0.001	0.50
Dissociation subscale	1.80 ± .0.18	3.02 ± .0.29	< 0.001	0.56
Depression subscale	3.25 ± 0.52	5.21 ± .0.32	< 0.001	0.50
Sleep disturbance subscale	3.62 ± 0.39	6.22 ± .51	< 0.001	0.63

[a] Data are presented as adjusted posttest mean ± standard error.
d = effect size based on Cohen's d.

Table 3. Background and demographic characteristics for the high-trauma symptoms subgroup (baseline total trauma score ≥ 26)[a]

Variable	Transcendental Meditation (n = 41)	Control (n = 53)	p value
Age, years	29.90 ± 7.06	30.21 ± 8.29	NS
ACRS	0.36 ± 0.13	0.34 ± 0.16	NS
Perceived Stress Scale	34.59 ± 5.18	34.64 ± 5.74	NS
Trauma Symptom Checklist			
Total trauma	35.27 ± 9.15	41.00 ±11.70	0.011
Anxiety subscale	6.56 ± 2.97	8.47 ± 3.67	0.008
Dissociation subscale	5.00 ± 2.19	5.83 ± 2.40	NS
Depression subscale	8.90 ± 3.02	10.13 ± 3.12	NS
Sleep disturbance subscale	11.02 ± 3.52	11.42 ± 3.70	NS

[a] Data are presented as baseline mean ± standard deviation.
ACRS = automated criminal risk score; NS = not significant.

Table 4. Four-month adjusted posttest scores for trauma-associated symptoms in the high-trauma subgroup (baseline total trauma score ≥ 26)

Variable	Transcendental Meditation (n = 32), mean + SE	Control (n = 41), mean + SE	p value	d
Perceived Stress Scale	21.89 ± 1.21	28.44 ± 1.02	< 0.001	0.89
Trauma Symptom Checklist				
Total trauma	15.63 ± 1.52	26.58 ± 2.47	< 0.001	0.74
Dissociation subscale	2.15 ± 0.28	4.11 ± 0.40	< 0.001	0.79
Depression subscale	3.86 ± 0.46	7.10 ± 0.69	< 0.001	0.78
Anxiety subscale	2.57 ± 0.36	4.96 ± 0.61	< 0.001	0.67
Sleep problems subscale	4.53 ± 0.67	8.00 ± 0.71	< 0.001	0.75

d = effect size based on Cohen's d; SE = standard error.

psychometric properties.[16] The TSC has been found to reliably index trauma sequelae.[17] The modified TSC used in this study produced a Cronbach α = 0.93.

Perceived Stress Scale

The Perceived Stress Scale is a 10-item inventory with a total score designed to assess the self-perception of stress.[18] Responses are based on the previous 4 weeks, using a 5-item response set, ranging from "Never" to "Very often." The level of perceived stress measured by the Perceived Stress Scale has been found to be sensitive to meditation intervention.[19] Cronbach α for the Perceived Stress Scale is reported to be 0.85.[18]

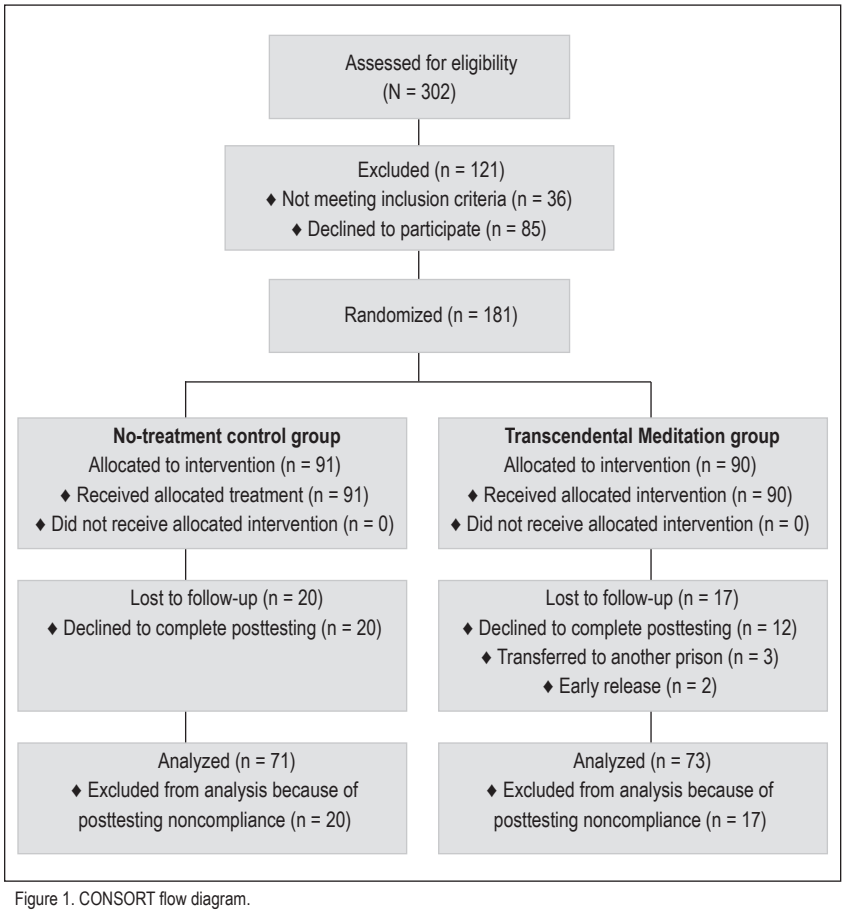

Figure 1. CONSORT flow diagram.
CONSORT = Consolidated Standards of Reporting Trials.

Statistical Analysis

Analysis of covariance, adjusting for baseline dependent scores, was used for all analyses. Effect sizes, based on Cohen's d, were calculated using mean change score group differences/posttest pooled standard deviation. In addition, subgroup analyses were conducted using high-trauma subjects (equal to or greater than the mean baseline total trauma score for the combined groups). Completer analysis was conducted for all subjects who were posttested, regardless of level of treatment compliance. Alpha was set at 0.05, two-tailed.

RESULTS

Table 1 shows the subjects' demographic and background characteristics by group for the entire sample. The mean age of the men participating in the study was 29 years. Approximately 52% were white, 16% were African American, and 15% were Native American.

Figure 1 shows the CONSORT flow diagram for all subjects. A total of 144 subjects (TM: n = 73; Control: n = 71) completed both baseline and 4-month posttesting. Table 2 shows mean changes on the total trauma scale, trauma subscales, and Perceived Stress Scale. Significant reductions in total trauma ($F[1, 141] = 19.73$, $p < 0.001$), as well as the dissociation ($F[1, 141] = 18.21$, $p < 0.001$), depression ($F[1, 141] = 13.32$, $p < 0.001$), anxiety ($F[1, 141] = 14.23$, $p < 0.001$), and sleep disturbance subscales ($F[1, 141] = 21.61$, $p < 0.001$) on the TSC, and perceived stress ($F(1, 140) = 27.09$, $p < 0.001$) were observed in the TM group compared with controls. Effect sizes were mostly in the moderate to large range, with depression and anxiety subscales = 0.50 and the Perceived Stress Scale = 0.75.

Seventy-nine of the 90 men (88%) randomly assigned to the TM group completed the initial TM course. During the course of the study, 80% of the men (72) were compliant with TM practice (defined as at least once a day), with 68% (62) practicing twice a day on average.

Table 3 shows the demographic and baseline data for the high-trauma symptoms subgroup (TM: n = 32; control: n = 41).

Table 4 shows changes on the total trauma scale, trauma subscales, and

the Perceived Stress Scale for the high-trauma symptoms subgroup. Significant reductions in total trauma score ($F[1, 70] = 14.20$, $p < 0.001$); the dissociation ($F[1, 70] = 17.60$, $p < 0.001$), depression ($F[1, 70] = 14.29$, $p < 0.001$), anxiety ($F[1, 70] = 11.97$, $p = 0.003$), and sleep disturbance subscales ($F[1, 70] = 13.09$, $p = 0.001$); and the Perceived Stress Scale ($F[1, 69] = 18.60$, $p < 0.001$) were observed in the TM group compared with controls. Effect sizes were relatively large, ranging from 0.67 to 0.89.

DISCUSSION

In this clinical trial, the TM technique showed significant reductions in TSC total trauma symptoms; anxiety, depression, the dissociation, and sleep disturbance subscales of the TSC; and in the Perceived Stress Scale relative to a usual-care control group. Results for the high-trauma symptoms subgroup indicated that the TM program might be particularly efficacious for those with higher levels of trauma symptoms.

Trauma was the focus of the current intervention effort for three reasons. First, correctional facility residents are known to report high rates of trauma backgrounds compared with noncorrectional facility populations. Second, although previous TM research in correctional settings has shown improvement in other psychosocial stress factors, no known research to date has specifically focused on trauma as a main study outcome. Last, although a growing body of TM research suggests that this technique may be particularly beneficial for reducing trauma symptoms,[11,12] there is a need for larger randomized controlled trials to assess the impact of the TM program on trauma symptoms and associated factors.

To our knowledge, this is the largest randomized controlled trial to date of the effects of the TM program on trauma symptoms, and the first of its kind conducted in a correctional setting. Prior studies have been conducted on veterans and international refugees in community-based settings and have found similar results in reductions in trauma symptoms because of TM practice.[11,12] The current findings therefore build on prior gaps in the literature, extend the range of mental health benefits previously documented on the TM program, and provide further evidence for the clinical value of providing TM in correctional facilities and other institutional settings.

… correctional facility residents are known to report high rates of trauma backgrounds compared with noncorrectional facility populations.

Prior research indicates that regular TM practice decreases hyperarousal of the sympathetic nervous system and hypothalamic-pituitary-adrenal axis,[20,21] providing a possible mechanism for how TM practice may reduce trauma symptoms.[22] This same mechanism has been proposed for the effects of the TM program on cardiovascular disease.[23] Evidence linking trauma exposure and cardiovascular disease has been found across different populations and stressor events.[2]

This trial offered several methodologic strengths, including a randomized controlled design, high treatment-compliance rates, and a high-trauma symptoms subgroup.

Limitations included the use of a no-treatment control condition in the study rather than a more active control condition. There is, therefore, the possibility that at least some of the benefits associated with the TM intervention are not specific to TM. Future research with a more active control group should be used to determine the degree of unique benefits associated with TM. The long-term stability and further improvement in trauma symptoms cannot be determined because of the absence of a follow-up measurement beyond the four-month posttest assessment date. Finally, research on the TM program should be conducted on a female population of inmates to determine the generalizability of effects across genders.

Future studies of trauma symptoms in prison populations should focus specifically on inmates with documented posttraumatic stress disorder and should take into account other psychiatric disorders that may be present, as well as standard psychotherapy and drug treatments being administered. Future research also should assess the relationship of trauma symptoms to functional impairment and other quality of life issues.

CONCLUSION

These findings extend prior research on TM and trauma symptoms. A recent review of posttraumatic stress disorder research indicates a need for novel, evidence-based treatments to supplement first-line therapies.[24] The current study findings, along with those of prior research on TM and posttraumatic stress,[11,12] suggest that the TM program holds promise for the treatment of trauma and stress-related disorders. ❖

[a] Transcendental Meditation and TM are service marks registered in the US Patent and Trademark Office, licensed to Maharishi Foundation, and used under sublicense.

Disclosure Statement

Blaze Compton, MA, is a part-time consultant to Maharishi Foundation USA Inc, Fairfield, IA. The other authors have no conflicts of interest to disclose.

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Authors' Contributions

Sanford Nidich, EdD, and Randi Nidich, EdD, participated in the study design, analysis of data, and drafting and critical review of the final manuscript. Tom O'Connor, PhD, participated in the study design, collection of data, and drafting and critical review of the final manuscript. Angela Seng participated in the statistical analysis and drafting of the manuscript. Blaze Compton, MA, participated in the delivery of Transcendental Meditation treatment. Thomas Rutledge, PhD, participated in drafting of the manuscript and critical review. Jeff Duncan participated in data acquisition and critical review of the manuscript. All authors have given final approval to the manuscript.

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Means

Meditation is not a means to an end. It is both the means and the end.

— Jiddhu Krishnamurti, 1895-1986, Indian theosophist, public speaker, and author

Sunflowers
scanography

Bridget Bourgon, PA-C

This digital image of sunflowers was created on a flatbed scanner—the scanner is the camera, the light source, and the tabletop. The resulting image has significantly enhanced optical resolution and limited depth of field, which produces unique shadows, increased sharpness, and color saturation.

Ms Bourgon is a retired Physician Assistant from Urgent Care at Kaiser Permanente Orange County in Santa Ana, CA. More of Ms Bourgon's images may be seen at: www.bridgetbourgon.com/unscented.

Narrative Medicine

Voices of the "99 Percent": The Role of Online Narrative to Improve Health Care

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ABSTRACT

Context: Communal blogs facilitate online narratives by providing opportunities for individuals to co-construct meaning and to engage in discussion about lived health experiences.

Objective: To examine the role of health as a connective narrative among individuals organizing collectively in an online community. The "We are the 99 percent" Tumblr blog emerged as a spontaneous community platform of the Occupy Wall Street movement in the US.

Design: Researchers conducted a qualitative content analysis of a total of 2003 blog posts.

Main Outcome Measures: Data analysis included a process of data reduction, display, and conclusion drawing and verification.

Results: Bloggers discussed medical crises and the role of injury and illness in maintaining financial solvency. The difficulty of obtaining health care and the lack of accessible quality care emerged as themes. In particular, unemployment and underemployment limited access to health insurance coverage. The bloggers expressed dissatisfaction with the health care system and the impact of financial status on health. These challenges were exacerbated for marginalized populations, such as women and veterans.

Conclusion: Findings offer implications for the value of online narrative to improve health care initiatives and to provide insight to integrated health care systems, including health care practitioners, nonprofit organizations, hospitals, and policy makers. Results suggest opportunities to address the health care gaps of marginalized populations and to develop public health policy.

INTRODUCTION

The Era of Health Reform

On March 23, 2010, US President Barack Obama signed the Patient Protection and Affordable Care Act,[1] passing health insurance reform into law. This legislation followed years of rising premiums, declining health and health care quality, and increasing unemployment, which led the US health care system to the brink of collapse.[2] According to the Organization for Economic Cooperation and Development (OECD), the US spends 250% more on health care per capita (16% of the US gross domestic product in 2007)[2] than the average of all other OECD countries.[2,3] Despite this spending, Americans have some of the worst health indicators in developed countries: the second highest prevalence of chronic diseases, the highest rate of obesity in all OECD countries, and higher infant mortality rates than the OECD average.[3] The US is an outlier in terms of high expenditures and low life expectancy at birth (in the bottom third compared with other OECD countries). These growing health and economic concerns positioned health care as a timely political issue.

Health and health care emerged as key factors in the Occupy Wall Street movement. The goal of the movement was to raise awareness about income inequality and the corporate influence of the wealthiest 1% of Americans on government.[3] The movement captivated national attention in early fall 2011; however, news media had difficulty discerning the goal of participants, especially without the emergence of a clear leader.[4] To address this ambiguity, thousands of bloggers turned to Tumblr, a popular blogging Web site, to share their stories, to demand change, and to raise awareness about the movement. Tumblr encourages users to form online communities on the basis of similar interests as a means to communicate with others and to build support systems. The Tumblr blog "We are the 99 percent" amplified the voices of Occupy Wall Street protesters. The blog is a dynamic artifact, telling the story of the movement's apex, while continuing to serve as a place for individuals to describe their lived experiences. Many posts expressed frustration regarding health care and the difficulty of attaining quality medical care in the US.

Although scholars studied the Occupy Wall Street movement on other social media sites, little research explores the "We are the 99 percent" Tumblr.[4-6] The "We are the 99 percent" Tumblr received more than 100 posts every day during its peak.[7] Although the platform remains anonymous, the creators of the Tumblr blog, Chris and Priscilla Grim, required bloggers to handwrite their story on a piece of paper and to show some portion of their face.[7] In a short period, Occupy Wall Street focused national attention on the issues of health and health care through the use of social media.[8]

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LITERATURE REVIEW

Narrative Storytelling Online

Storytelling is a powerful tool capable of inspiring change within the health care field.[9-13] Online narrative in public health offers a novel opportunity for individuals to communicate about health. The expansion of narrative-based educational and promotional materials to online platforms is based on the success of personal stories in disseminating health information. These personal anecdotes serve as models of behaviors that can impact health.[14] Online narrative provides communities with opportunities to co-create health narratives and allows individuals and experts to bear witness to everyday lived health experiences.[15-18] Engaging with online storytelling platforms such as Twitter, Facebook, and Tumblr allows health care practitioners to monitor and understand the health and health care needs of the public beyond the traditional health care setting, furthering the opportunity to address patient-physician gaps.[19]

Health communication campaigns employ online narratives as a form of persuasive communication to motivate health behavior change.[14,20-22] Experts suggest that readers of personal stories may be able to draw parallels with their lives, eliciting intellectual and emotional engagement.[23] In practice, the use of narrative by health communicators is often less "true story" and more script, in which health care practitioners craft the "right narrative" to increase the chances of behavior change.[14] Scholars argue that narrative-based online storytelling equals that of didactic education in effectiveness of imparting information,[22,24-26] offering real-world examples to supplement concrete data.[27]

The constructed narratives of health campaigns may not be as effective as true personal narratives. Individuals searching for organic experiences may avoid messages from campaigns and experts, in favor of online discussion groups where members create a community of support on the basis of common experiences.[21] Studies show that in medical settings, individuals seek personal experiences from previous patients.[20] As a result, storytelling provides patients with a means to understand their illness through communication with others who faced similar diagnoses.[28] Patients search for narratives from those who have experienced comparable health situations. In a qualitative study of pregnant women, Kraschnewski et al[16] found that women frequently used social media sources (such as Facebook) to share their own experiences and learn about the experience of others—for example, with regard to birth methods. Their findings included key important themes: 1) prenatal care structure is not patient centered, 2) women used technology to fill gaps, and 3) technology has limitations in supporting their pregnancy-related needs. The digital communication platform of the Internet expanded the ability for people to share these experiences and for the personal accounts to disseminate widely.[29]

The possibility of remaining relatively anonymous on the Internet explains the appeal of online narratives. The anonymity of the digital platform creates opportunities for marginalized groups to participate in social activism.[24] In diverse populations, the lack of face-to-face contact may be beneficial and encourage participants to directly communicate their opinions without fear of judgment; as a result, online narrative platforms may provide a safe space for marginalized populations to share and to seek out experiences and opinions that may differ from the mainstream, as the "We are the 99 percent" blog demonstrated.[24,30] Advocates suggest that online groups serve as therapeutic outlets where individuals are freed from impediments.[29] When health centers set up online discussion boards to build support systems within their patient community, the benefits include personal empowerment, reduced depression, better comprehension of medical procedures, and identifying gaps in patient knowledge.[21] Further insight into the perspectives of individuals may shed light on practical, as well as ethical, implications of narrative related to issues of health.[31]

Communal blogs facilitate storytelling online by providing opportunities for individuals to co-construct meaning and to engage in discussion about lived health experiences. In particular, communal blogs aim to create spaces for discussing and sharing experiences and information, thus resulting in communities of individuals interacting online. Few studies describe the role of storytelling online from the perspective of individuals and how these individual experiences can be used to construct public health messages, policies, and health communication campaigns.[29] Therefore, the current study analyzed the use of the multimedia social media platform Tumblr and the role of health as narrative among individuals organizing collectively in an online community. By exploring the perceptions and attitudes toward health and health care of the "We are the 99 percent" bloggers amidst the peak period of social movement, we examined the political views of marginalized community members. Our primary focus was to better understand the role of health and the health care system in the context of the Occupy Wall Street movement. Through qualitative research methods, this study assessed community applications of multimedia blog posts, which also offer implications for the application of new media intervention strategies. Findings offer suggestions for clinicians in understanding the attitudes of their patients in real time through the use of social media.

METHODS

Researchers conducted a content analysis on 15 months of "We are the 99 percent" blog posts beginning September 1, 2011, and concluding November 30, 2012. This period encompassed the height of the Occupy Wall Street movement, comprising 2003 blog posts. Although the Tumblr blog is still active, there have been fewer than 30 posts since December 1, 2012. The "We are the 99 percent" posts provide detailed explanations of the lives of these bloggers, which frequently (approximately 55%; n = 1110) included their personal perceptions of and experiences with health and the health care system. For this reason, the blog represents a unique, experiential account of the role of health in the lives of individuals who identify with the Occupy Wall Street movement. A qualitative content analysis provided the most appropriate approach to study how bloggers made meaning of their lived experience because this method of analysis reveals the perspectives and discourse of individuals situated in a social change dialogue.[32] Because blog posts are publicly available, research using these data does not meet the definition of human participant research. Although an institutional review board application was not required, all researchers completed training in the appropriate

conduct of research and all ethical standards were followed in the completion of the study. Researchers included undergraduate and graduate students studying public health at a liberal arts and sciences university mentored by a faculty member. A class assignment led students to discover the Occupy Wall Street movement and pursue this research project after the completion of the course.

Data Collection

Collection of data was performed in chronologic order to capture all posts written during the designated period, which included the height of the Occupy Wall Street movement. In a database, researchers logged the text from each post, a link to the post, the date of the post, the age of the blogger (if known), and a description of the photograph. In total, 2003 blog posts were collected. Approximately 55% of these blog posts (n = 1110) discussed health topics or health care. Health topics included discussion of disease or illness, medications, medical treatment, and health services, such as preventive care. Health care included health insurance, coverage, medical bills, and paying for services and treatment. Adults posted on behalf of young children and infants younger than age 1 year. Bloggers ranged in age from 12 to 89 years.

Data Analysis

To ensure credible, dependable, and replicable qualitative methods, data analysis included data reduction, data display, and conclusion drawing and verification.[33] Initially, researchers coded each blog post line-by-line to create descriptive codes. When possible, researchers identified "in vivo" codes on the basis of the words and phrases that participants used repeatedly (eg, health insurance, medical bills, preexisting condition, etc). Interpretive codes were used to further reduce the data and provide explanations for participants' experiences (eg, the importance of health insurance, the role of access to care, and quality of health care). Finally, pattern codes allowed researchers to identify emergent themes (eg, patterns among marginalized populations, the cost of injury and illness, and the impact of facing a medical crisis). Researchers were trained to use a book of codes related to health and health care and met frequently throughout the data analysis process to discuss and modify codes. The codebook allowed researchers to maintain consistency and reliability while compiling data from the original source online. Clearly defined codes ensured standardization and categorization of health topics.

Researchers used Miles and Huberman's check-coding formula on 7.5% of the sample. Agreement between coders reached approximately 90%, attaining Miles and Huberman's standard for intercoder consistency, indicating that researchers accurately employed the coding system. Microsoft Excel (Microsoft Corp, Redmond, WA) on Google Drive (Google Inc, Mountain View, CA) provided structure and an interactive data display to code and analyze data. Researchers identified patterns emerging from the data using the codes as a guide through constant comparison of the blog posts.[34] Researchers met to identify concepts, discuss data patterns, and agree upon themes and conclusions emerging from these data.

RESULTS

Data analysis revealed bloggers engaged in narratives about health and health care. The personal narratives of the bloggers provided insight into their perceptions and beliefs with two

Table 1. Themes with illustrative quotes

Topic	Theme	Quote
Health	Facing a medical crisis	"My husband had teeth rotting out of his mouth causing infections … no regular doctor would see him without insurance or medical aide card." (2011 Oct 27; Re: Working hard and Going without)
		"My best friend is pregnant … but her insurance won't pick back up for another 45 days. She's due in 2 weeks." (2011 Sep 27; Re: I have a degree)
	The cost of injury and illness	"I … had to leave my job and put school on hold indefinitely because my 54-year-old mother had a stroke." (2011 Nov 14; Re: I am 21 years)
		"I am a work-at-home mother of 4, 1 of whom was just diagnosed with autism. Insurance in my state will not cover her services because she is less than 6 years old." (2011 Oct 1; Re: I am a work-at-home)
	On the margins	"I worry that even after I give birth I won't be able to work because of the cost of childcare." (2011 Nov 12; Re: I am pregnant, unemployed)
		"My husband has insurance through his job, but he can't cover me because … I'm a man, and we live in Texas." (2011 Oct 20; Re: My grandmother died of)
Health care system	The importance of being insured	"I currently work 2 part-time jobs at a local community college … In the last few weeks I've developed painful lumps in my neck but have no health insurance to see a doctor for it." (2011 Oct 14; Re: I am 24 years old)
		"I am Chinese American and a mother of two. I have been unemployed since 2007. I am disabled from a workplace injury. I don't receive any benefits from the government. Our family relies on my husband's income to live." (2011, Oct 12; Re: I am Chinese American)
	Accessing care	"It is a national security risk not to have 100% of the country having access to healthcare! … We are all protected when ALL people have access to vaccinations and quality health care." (2011 Oct 27; Re: 20 years old)
		"Antidepressants help me through every day … I can't afford them, and so every day is a constant struggle." (2011 Nov 11; Re: I am a junior)
	Quality of health care	"My parents' botched clinical trials … left my dad with cognitive damage and my mom with a heart attack." (2011 Oct 29; Re: This is the sign)
		"I contracted Hep C from a blood transfusion … and am uninsurable." (2011 Nov 11; Re: I'm 49 years old)

overarching themes emerging: 1) the personal and financial toll of health issues and 2) attitudes toward the US health care system. Narratives described facing a medical crisis, being ill or injured, or living on the margins, all of which negatively affected health and financial solvency. The health care system was discussed in relation to the importance of being insured, accessing health care, and the quality of medical services. Themes are presented with illustrative quotes in Table 1. Quotes are a true representation of bloggers' posts. Posts are identified with a link to each individual entry in Table 2.

Health

Facing a Medical Crisis

The financial consequences of medical crises emerged as a critical narrative in the bloggers making meaning around health. Bloggers described how medical bills and debt incurred from health treatments wiped out personal savings and led to credit card debt. Swamped by medical bills and in debt, many bloggers were forced to make difficult decisions, such as compromising quality health care to pay for food or rent. One blogger was "foregoing … annual physicals and any kind of dental work in order to put food on the table" (2011, Oct 27, Re: I live, as my). Many individuals discussed the decision to defer health care to afford more urgent necessities. Children also faced a lack of health care. According to one mother, "rent and food were more important" (2011, Oct 16, Re: I'm 42, disabled after).

The Cost of Injury and Illness

Bloggers described the loss of employment or financial independence caused by injury and illness, including chronic disease. A 34-year-old health care worker wrote a post about losing her job because of a rare medical condition. She was "denied state health insurance because [she made] too much money on unemployment" and was unable to find a job that offered more than the unemployment compensation (2011, Dec 10, Re: I am a 34). The onset of disability owing to living for years without access to health care emerged as a primary concern among bloggers. One woman wrote, "not having insurance ruined my husband's body. He is 47 with the body of a 67 year old. He can barely walk" (2011, Sep 29, Re: All I remember is). Many bloggers discussed the relationship between employment status and health insurance coverage, emphasizing the inability to escape from a cycle of illness. As one blogger stated, "health and

Table 2. "We are the 99 percent" Tumblr blog posts with date, title, and hyperlink

Date[a]	Title	Link
2011, Sep 27	Re: I have a degree	http://wearethe99percent.tumblr.com/post/10765163207
2011, Sep 29	Re: All I remember as far as my parents paying the bills is struggle	http://wearethe99percent.tumblr.com/post/10805800341
2011, Sep 29	Re: No job=no insurance=no help=no job	http://wearethe99percent.tumblr.com/post/10805778915
2011, Oct 1	Re: I am 20 years old and upwards of $275,000 in medical debt	http://wearethe99percent.tumblr.com/post/10890007785
2011, Oct 1	Re: I am a work at home mother	http://wearethe99percent.tumblr.com/post/10890054129
2011, Oct 9	Re: I worked hard and went to school	http://wearethe99percent.tumblr.com/post/11226613846
2011, Oct 12	Re: I am Chinese American	http://wearethe99percent.tumblr.com/post/11353855401
2011, Oct 14	Re: I am 24 years old	http://wearethe99percent.tumblr.com/post/11422007247
2011, Oct 16	Re: I'm 42, disabled after 20 years of nursing, taking care of others	http://wearethe99percent.tumblr.com/post/11512774391
2011, Oct 17	Re: I am a 38 year old married father of three	http://wearethe99percent.tumblr.com/post/11592544446
2011, Oct 17	Re: My dad has his own business and works 70-80 hours a week to take care of me and my mom	http://wearethe99percent.tumblr.com/post/11580641390
2011, Oct 18	Re: Tired and mad as hell	http://wearethe99percent.tumblr.com/post/11612202432
2011, Oct 20	Re: My grandmother died of colon cancer	http://wearethe99percent.tumblr.com/post/11694625078
2011, Oct 23	Re: I am 23 and I borrowed 33k to go to school to be a veterinary technician	http://wearethe99percent.tumblr.com/post/11817603288
2011, Oct 26	Re: I am 31, married with a six month old son	http://wearethe99percent.tumblr.com/post/11948000388
2011, Oct 27	Re: I live, as my mother does, paycheck to paycheck (when I have a job)	http://wearethe99percent.tumblr.com/post/11991560794
2011, Oct 27	Re: Working hard and Going without	http://wearethe99percent.tumblr.com/post/11992296233
2011, Oct 27	Re: 20 years old, college senior	http://wearethe99percent.tumblr.com/post/11991548787
2011, Oct 29	Re: This is the sign I'm taking	http://wearethe99percent.tumblr.com/post/12071717458
2011, Oct 30	Re: My father was fired from the job he held	http://wearethe99percent.tumblr.com/post/12133071034
2011, Oct 31	Re: 33, single mother	http://wearethe99percent.tumblr.com/post/12175341537
2011, Nov 11	Re: I am a junior in college	http://wearethe99percent.tumblr.com/post/12639988282
2011, Nov 11	Re: I'm 49 years old	http://wearethe99percent.tumblr.com/post/12640010064
2011, Nov 12	Re: I am pregnant, unemployed	http://wearethe99percent.tumblr.com/post/12720299887
2011, Nov 14	Re: I am 21 years old, and had to leave my job	http://wearethe99percent.tumblr.com/post/12796610414
2011, Dec 10	Re: I am a 34 year old unemployed health care worker	http://wearethe99percent.tumblr.com/post/14025840885
2012, Apr 17	Re: I'm a 41 year old SAHM of 2	http://wearethe99percent.tumblr.com/post/21268915628

[a] Posts are in chronological order.
SAHM = stay-at-home mother

the ability to work shouldn't be something exclusive to those who can afford it" (2011, Sep 29, Re: No job=no insurance).

On the Margins

Marginalized populations, including women, veterans, homeless, lesbian, gay, bisexual, transgender, and queer or questioning (LGBTQ) men and women, and individuals with mental illness, faced an additional set of obstacles. In particular, women's health care services were perceived as a low priority for health care coverage. One woman noted, "My coverage denied normal, annual GYN visits because being a woman is a preexisting condition" (2011, Oct 30, Re: My father was fired). The high cost of pregnancy and childbirth led many bloggers to describe tremendous financial strain. According to one blogger, "I had a home birth because we do not have health insurance. My son has never seen a doctor" (2011, Oct 26, Re: I am 31, married). A frequent concern included the cost of contraception: "we don't want children so we pay ridiculous $ for birth control" (2011, Oct 18, Re: Tired and mad as). The financial burden of being a woman was perceived as causing debt among these bloggers.

Health Care System

The Importance of Being Insured

Bloggers suggested that the only way to secure affordable health care was through an employer. This led to limited options for a range of individuals, including those who had to work extra hours for health benefits, were unable to work owing to disability, were self-employed, worked part-time with no benefits, or were unemployed. Many blog posts discussed the lack of access to health care because of unemployment or underemployment. One blogger wrote that his father "has his own business and works 70-80 hours a week to take care of me and my mom. He doesn't have health insurance but pays for me and my mom to have coverage" (2011, Oct 17, Re: My dad has his).

The bloggers described a health care system that does not provide adequate coverage for all US citizens. Bloggers described the fear, worry, and frustration of living without insurance and sinking deeper into debt. Even those bloggers with steady employment highlighted the increasing cost of health care. One employee wrote, "My company just cut my pay 20% and increased my health insurance costs 20%, all while doubling my responsibility" (2011, Oct 17, Re: I am a 38). Bloggers discussed an increasingly unstable health care system.

Accessing Care

Bloggers described increasing premiums and deductibles as the primary cause for their inability to afford health insurance and that "pay never kept up with inflation" (2011, Oct 9, Re: I worked hard and). A 41-year-old woman stated that "The insurance premiums are well over 1/3 of each paycheck," exemplifying common worries about the rising cost of health care (2012, Apr 17, Re: I'm a 41 yr). Bloggers described preexisting conditions as a major barrier to accessing adequate health insurance and a cause of financial hardship. A 20-year-old blogger said that she was unable to get health insurance because of a "condition [she] was born with" (2011, Oct 1, Re: I am 20 years). This blogger, like many others, suggested that the health care system allowed those with preexisting conditions to fall through the cracks.

Quality of Health Care

Many bloggers believed that the medical system was taking advantage of patients to earn increasing profits. Posts mentioned the debt and emotional turmoil caused by unnecessary procedures and medications, such as one patient undergoing "800 spinal injections" to treat fractures, which were not helpful and had to be paid for out-of-pocket (2011, Oct 23, Re: I am 23 and). Medical malpractice was another concern of bloggers. One blogger stated that she had to receive a second surgery "to fix the first surgery, which was botched by an inexperienced doctor, whom I still owe [money to]" (2011, Oct 31, Re: 33, single mother). Bloggers perceived that the overuse of medical services and technologies by clinicians drove up the price of medical care and led to unnecessary, costly, and potentially dangerous treatment.

DISCUSSION

The current study explored the role of narrative storytelling by examining how "We are the 99 percent" bloggers co-constructed meaning about health and health care in the context of the Occupy Wall Street social justice movement. The role of health as narrative emerged as bloggers described the impact of facing a medical crisis and the cost of injury and illness on their ability to remain financially solvent. These issues disproportionately impacted individuals living in the margins, including women and veterans. Bloggers discussed the importance of insurance coverage and the limitations of a system dominated by employer-sponsored coverage. Bloggers also identified challenges to accessing health care, including the role of preexisting conditions and denial of quality medical care.

Findings expand existing research on the potential for use of social media as a means to connect to peers and fellow patients. As in previous studies, the "We are the 99 percent" Tumblr demonstrated that social media outlets allow greater connectivity between individuals.[29] In a study by Frost et al,[35] patients with amyotrophic lateral sclerosis ("Lou Gehrig's disease") not only shared their own stories but also commented on others' posts and questions, and used the forum to "foster and solidify relationships based on shared concerns." A Scandinavian study of breast cancer patients[36] who were motivated to use an online support group did so as a means of "breaking the social isolation" that comes along with chronic pain after cancer. Narrative can be a powerful tool in fomenting change when readers are able to identify with the writer. Through this connection, the message offers a greater impact, suggesting that the opportunity exists to influence behavior.[36]

This study provides an understanding of how health care access is intertwined with other current sociopolitical realities faced by society. Typically, individuals turn to specific health-based communication platforms (such as PatientsLikeMe or the Association of Cancer Online Resources) or groups (within Facebook or Twitter) to understand these issues. A wealth of information on how people deal with challenges faced by not only patients with certain conditions, but also by anyone who

interacts with the health care system, can be gleaned through this type of methodology and through defining "health issues" more broadly. In the current study, despite the highly varied backgrounds of the bloggers writing for the "We are the 99 percent" Tumblr, blogging provides the same capacity to unify. The diversity in authorship in the posts is one of the most powerful tools of open source social media because it presents a unified struggle spanning class, geography, and ethnicity. Such varied backgrounds allow a wide range of readers to identify with a given blogger, eliciting empathy for a common struggle. The voices and experiences of the bloggers provided a novel opportunity for health professionals to access audiences using these online platforms for health communication campaigns and public health interventions.[14,20,22,23]

The use of social media activism in the Occupy Wall Street movement constructed a comprehensive narrative illustrating bloggers' dissatisfaction regarding health care in the US and its impact on public health.[14] This grassroots movement demonstrated the widening disparity in health care and health status between low-income and high-income individuals, as evidenced in the "We are the 99 percent" Tumblr. The "We are the 99 percent" Tumblr illustrates that social media allows for the sharing of stories that might ordinarily be suppressed. Localized social stigma surrounding health issues is powerful in silencing affected communities. Online narratives provide the opportunity of anonymity and empower the storyteller to share beyond a local audience.[24] The relatively anonymous arena of the "We are the 99 percent" Tumblr and other online story-sharing platforms provides the opportunity for health communication campaigns to observe and address the stated needs of marginalized individuals who were more difficult to reach before the advent of blogs and other social media tools. Additionally, this type of anonymous blog encourages information sharing. Concerns about privacy have been shown to hamper patients' willingness to fully disclose aspects of their particular condition(s) within health specific sites, such as Association of Cancer Online Resources.[37] By utilizing an anonymous, narrative framework, patients may be more willing to share their experiences, and public health practitioners can gain a better understanding of the real-time health experiences of low-income and marginalized populations as well as use this consciousness-raising platform as a tool in health communication campaigns.[38]

Although the Affordable Care Act[1] was signed into law on March 23, 2010, many of the changes are still in the process of being implemented; and some have been challenged in court.[39,40] Beginning in July 2013, insurance coverage became available to those with preexisting conditions according to Title I of the law. Title I also requires that preventive care be covered, improving opportunities to manage medical conditions early, before they require major intervention.[1] Findings suggest that upholding and strengthening this legislation, including wellness care and contraceptive coverage, may address some of the bloggers' concerns with health care and help to prevent future health crises by requiring a greater number of individuals to maintain health coverage with a greater emphasis on preventive care.[40] Public health practitioners should consider using online narratives to develop and improve future public health policy. In addition, clinicians and community organizations can use online narratives and social media platforms to improve health care for individuals, as well as to garner support for future health care legislation through information sharing and education.

Strengths and Limitations

Qualitative methods provided insight into the narratives of the "We are the 99 percent" bloggers regarding health. However, one limitation may be that those who made use of the Tumblr social media platform may differ in important characteristics from other social media users. According to the Pew Research Center,[41] Tumblr is particularly appealing to young adults, aged 18 to 29 years. Bloggers are evenly divided by gender and tend to represent high and low incomes (including incomes below $30,000).[41] Another limitation is that these bloggers already identified strongly with the ideology of the Occupy Wall Street movement. Therefore, the findings may not be generalizable beyond this population of bloggers; however, the experiences described in the "We are the 99 percent" Tumblr may be suggestive of the experiences with health care of other individuals who may not be as politically inclined as the bloggers in the study. Further research should be conducted to determine whether this population's experiences are reflected in other social media narratives. Future areas of research include facilitating online personal narratives to disseminate health messages and to address health care gaps through health promotion and interventions that reflect the stated needs of these populations. Monitoring of social media by public health practitioners will allow health communicators to gain insight into individuals' needs and attitudes toward health care reform as more aspects of the Affordable Care Act[1] are implemented. This study provides insight into the use of online narrative as a method for understanding these needs and improving public policy. The "We are the 99 percent" Tumblr illustrates the apex of the Occupy Wall Street movement. As such, this study provided the opportunity to explore issues of health and health care during a period of social change in the US. Thus, the study can serve as a basis for future research using online narratives about health to gauge individuals' perceptions of health care.

CONCLUSION

This study offers practical implications for health communicators and health care practitioners related to community applications of multimedia social media platforms. Storytelling is powerful in fostering compassion and self-reflection, challenging listeners to examine their experiences and the experiences of others. The dissemination of a narrative through social media can elicit rapid empathy from a potentially worldwide audience empowering the movement far beyond what was capable in the recent past.[42] This rapid exchange of stories over a broad base, as in the "We are the 99 percent" Tumblr, may provide a model for people to share their personal knowledge of health, further increasing the impact of health communication campaigns as well as providing knowledge about personal health issues and perceptions to health care practitioners. ❖

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Trend of Decreased Length of Stay in the Intensive Care Unit (ICU) and in the Hospital with Palliative Care Integration into the ICU

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ABSTRACT

Context: Is a decrease in length of stay (LOS) in the intensive care unit (ICU) and hospital possible with the implementation of a structured, palliative care, quality-improvement program in the ICU?

Objective: Incorporate palliative care into the routine ICU workflow to increase the numbers of palliative care consultations, improve end-of-life care in the ICU, and demonstrate an impact on ICU and/or hospital LOS.

Design: A program was developed that followed recommendations from the Center to Advance Palliative Care's *Improving Palliative Care in the ICU* project. This program included selecting trigger criteria and a care model, forming guidelines, and developing evaluation criteria. The early identification of multiple measures led to proactive meetings with ICU patients' families and/or palliative care consultations.

Main Outcome Measures: Early identification of advance directives, code status, goals of care, and ICU LOS and hospital LOS.

Results: A comparison between pre- and postintervention data showed positive trends in measured outcomes, including increased early identification of advance directives, code status, and goals of care along with a decrease in ICU LOS and hospital LOS. In addition, the number of ICU family meetings and palliative care consultations increased.

Conclusion: It was concluded that providing palliative care in the ICU is feasible and may decrease both ICU LOS and overall hospital LOS.

INTRODUCTION

Hospital-based palliative care services have been evolving since the late 1980s, and as of 2008, approximately 31% of all US hospitals provided some type of inpatient palliative care.[1,2] Palliative care is medical care that enhances quality of life for patients living with serious advanced illness by helping to align their treatment choices with their values. The World Health Organization defines *palliative care* as an approach that improves the quality of life of patients and their families facing problems associated with life-threatening illness.[3] This is achieved through the prevention and relief of suffering by means of early identification, assessment, and treatment of pain and other physical, psychosocial, and spiritual problems.[3,4]

Numerous reports have examined the effects of palliative care consultations on various outcome measures in the intensive care unit (ICU). Outcomes include the length of stay (LOS) for both the hospital and ICU, but controversy surrounding the potential impact of LOS on a decrease in overall hospital cost remains. A decrease in LOS resulting in an attenuation of hospital costs without compromising quality of care is arguably beneficial because most hospital expenditures occur at the end of life and in the ICU.[5] Evidence also suggests that early identification of goals of care and advanced care planning may reduce the intensity of unwanted care at the end of life, by reducing ICU LOS and numbers of potential ICU admissions.[6]

Our facility has used a palliative care team for the inpatient population since 2010. Like many hospitals, however, our existing palliative care team was not being used to its full potential in our ICU, and there were multiple misconceptions regarding palliative care from both the nursing and medical staff.[7] In addition, there were limited data with regard to the impact of palliative care on the ICU or hospital LOS at the Medical Center. The purpose of this project was to improve the utilization of the palliative care team and to enhance palliative care knowledge and awareness of both the nursing and physician staff in the ICU, thereby improving quality of care for the patients and families. In addition, we studied whether the implementation of palliative care principles and increasing the number of palliative care consultations in the ICU would affect LOS for both the hospital and ICU.

METHODS

Setting

A quality-improvement program was conducted in the 15-bed adult ICU at Kaiser Permanente (KP) Moanalua Medical Center, which is a 318-bed tertiary care hospital in Honolulu, HI. This unit is a closed ICU, run by a team of board-certified intensivists following The Leapfrog Group recommendations.[8] The ICU is a mixed unit that admits patients with medical, surgical, cardiac, and/or neurologic instability, who have the need for close monitoring. The ICU admits approximately 850 patients per year, has an average LOS of 4 to 5 days, and has an average mortality rate of 12%.[9]

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Patient Sample

The target population was all patients admitted to or transferred into the adult ICU. The accessible sample included patients who met daily screening/trigger criteria for a potential palliative care consultation. Although this was an adult ICU, there were times in which pediatric patients (younger than 18 years old) were admitted to the unit. These patients were not included in the sample because of their age.

Most patients were admitted with a variety of general medical ICU conditions, including cardiac and neurologic issues. The surgical patients were represented by all the surgical subspecialties, with the exception of open-heart surgical patients in the immediate postoperative period. Several patients were necessarily readmitted for treatment to the ICU in the same month. When this occurred, for the purposes of this study, they were counted only once, and their resultant ICU days were totaled together.

Procedures

To identify patients who might best benefit from a more timely palliative care consultation, a project team consisting of palliative care physicians, ICU nurses, and ICU physicians developed procedures that followed the suggestions from the *Improving Palliative Care in the ICU* recommendations by the Center to Advance Palliative Care.[10] The center's clinical practice guidelines resulted from standards adopted by the National Quality Forum in its Framework and Preferred Practices for Palliative and Hospice Care, and the National Consensus Project for Quality Palliative Care.[11-17] These recommendations included information on the types of inpatient palliative care models, screening and trigger criteria, guidelines and standards, and methods for the evaluation of a program.

Using a literature review and ICU clinical expertise to identify those with a high risk of dying, we created final trigger criteria that were believed to represent the majority of high-risk patients admitted to the ICU. The trigger criteria were:

1. advanced cancer
2. chronic and severe cognitive dysfunction
3. consistency with or lack of goals of care
4. conflict with goals of care
5. multiorgan system failure
6. LOS in ICU longer than seven days.

The general model was, for the most part, a consultative one, using the existing palliative care team. This team included a board-certified physician, registered nurse, chaplain, and social worker. After patients met at least one of the trigger criteria, the nursing staff was taught to direct patients and families to informational videos on goals of care that exist on the KP Education on Demand Webinar.[18-20] The intent of the videos was to initiate a conversation regarding goals of care and designation of a surrogate, advance directives, and code status. This led to a social worker consultation for finalization of surrogate designation and advance directives, and then to the ICU physician for code status or resuscitation preferences between Days 1 and 3. The range of days was necessary because of the lack of a designated social worker on the weekends and nights. An ICU family meeting was proactively initiated by Day 3 for those patients meeting the trigger criteria, and if further need was identified, a palliative care family meeting with the multidisciplinary palliative care team was proactively initiated by Day 5. This process is demonstrated in Figure 1.

Once the guidelines and flowcharts were formed, an application to the KP institutional review board was submitted for approval, to ensure completeness of

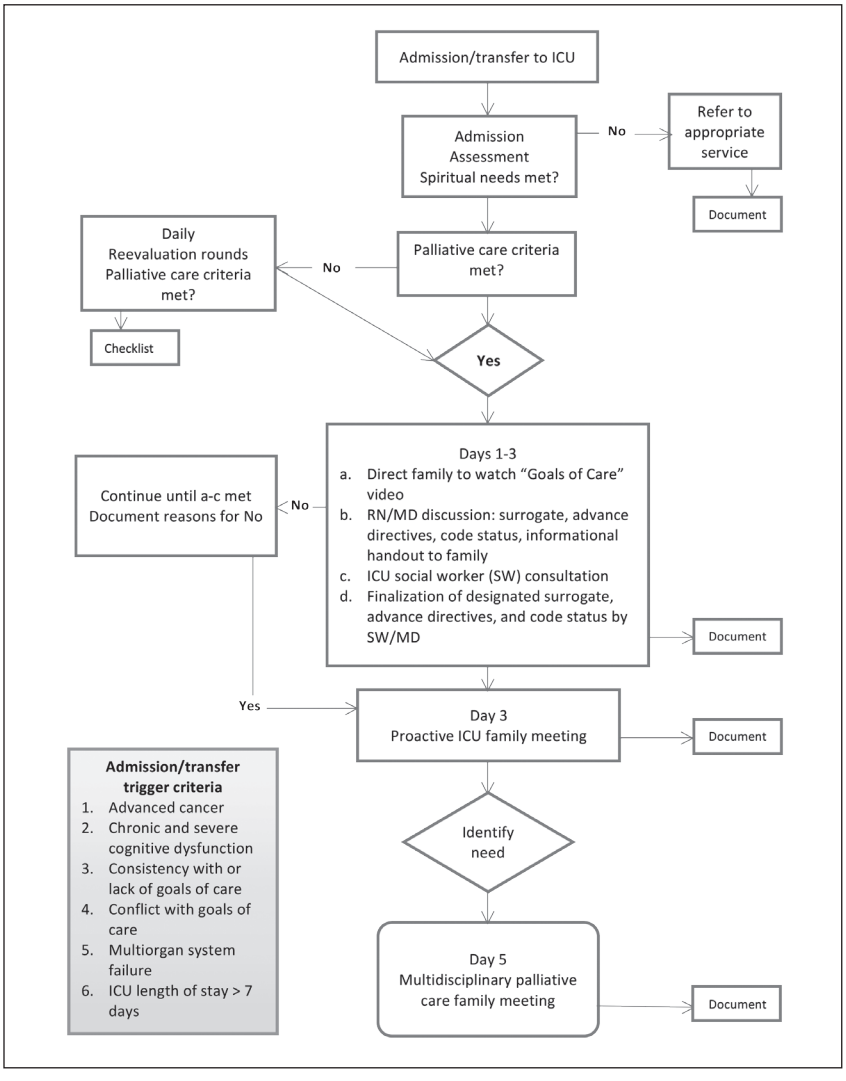

Figure 1. Final workflow, which incorporated guidelines from *Improving Palliative Care in the Intensive Care Unit*[10] recommendations.

ICU = intensive care unit; MD = physician; RN = registered nurse.

the process in implementing this project. Because the implementation of this program would only provide for more timely intervention, without a change of routine practice, and because the study involved only collection of retrospective data without compromising patient confidentiality, the requirement for informed consent was waived by the institutional review board. It was also necessary to notify the KP Quality-Improvement Committee of pending plans, and approval to proceed with implementation was received.

Preintervention patient data were obtained by chart review for a 3-month period from November 1, 2013, through January 30, 2014, for a total of 194 patients. The project commenced on April 1, 2014, and the postintervention data were collected from April 1, 2014, through June 30, 2014. This dataset consisted of 198 patients.

Outcome Measures

The metrics and benchmarks were predetermined and approved by the Quality-Improvement Committee before the implementation of the project. Financial metrics involved the LOS in the ICU and the hospital. Process and outcome measures looked at the early identification of multiple aspects of palliative care practice. These included 1) numbers of patients who met the trigger criteria; 2) goals of care, advance directives, surrogate, code status, and numbers of ICU family meetings by Day 3 of meeting the trigger criteria; 3) use of the "Goals-of-Care" video; 4) numbers of palliative care brochures offered to families; and 5) numbers of palliative care consults.

The pre- and postintervention samples of data were designed to measure the process progression over time. This progression was reported as an aggregate dataset with the intent to show trends before and after intervention.

Data Analysis

This project was an analysis of quality-improvement data. Therefore, experimental design and randomization were not used. Frequencies, means, and standard deviations were used to examine the distribution of measures. An independent *t*-test was used to compare mean scores of the samples that comprised different groups. Terminology, as defined by Field,[21] was used for the reporting of the *t*-test results. The following equation was used[21]:

$t(df) = (t \text{ value}), (p \text{ value}), (r \text{ value})$

where df = degrees of freedom, *t* value = *t*-test result, p value = probability, and *r* value = effect size. A Pearson χ^2 test was used for comparisons of various frequencies. The χ^2 results were reported as the value of the test statistic with its associated degrees of freedom and the significant value. The test statistic is denoted by χ^2.[21] All descriptive statistics were calculated using Microsoft Excel 2013 (Microsoft Corp, Redmond, WA) along with the Statistical Package for the Social Sciences (IBM SPSS, Armonk, NY). The independent *t*-tests and χ^2 tests were calculated using Excel 2013.

RESULTS

The patients' demographics are presented in Table 1. Results of the outcome measures are reported in Table 2. The outcome measures were reported as a total numeric value for the three months, with the exception of the LOS in both the ICU and hospital, which were computed as means.

The numbers of individuals and the numbers of patients who met the trigger criteria in both samples were approximately the same. With use of an independent *t*-test, there was a slight decrease in the mean length of ICU days from the preintervention sample (mean = 5.76, standard error [SE] = 0.97) to the postintervention sample (mean = 4.92, SE = 0.50), both of which included decedents. However, this difference was not significant: $t(289) = 0.78$, $p > 0.05$. There was also a decrease in the mean length of hospital days from the preintervention sample (mean = 17.43, SE = 1.99) to the postintervention sample (mean = 12.88, SE = 1.26). This difference was significant at $t(327) = 1.93$, $p = 0.05$, but it represented a small effect size ($r = 0.11$).

Despite similar numbers of patients between the 2 populations that met the trigger criteria, the numbers of patients in

Table 1. Description of patient sample in Intensive Care Unit palliative care integration study

Measure	Preintervention (n = 194)	Postintervention (n = 198)
Age group, years		
19-30	7	2
31-40	7	7
41-50	17	22
51-60	42	34
61-70	46	57
71-80	39	50
81-90	29	19
> 91	7	7
Sex, no. (%)		
Men	107 (55.2)	120 (60.6)
Women	87 (44.8)	78 (39.4)
Race/ethnicity, no. (%)		
Asian	72 (37.1)	78 (39.4)
White	71 (36.6)	62 (31.3)
Pacific Islander	46 (23.7)	51 (25.8)
Other	5 (2.6)	7 (3.5)
Admitting diagnosis, no. (%)		
Myocardial infarction	19 (9.8)	28 (14.1)
Cerebrovascular accident	16 (8.2)	20 (10.1)
Sepsis	19 (9.8)	20 (10.1)
Respiratory failure	17 (8.8)	14 (7.1)
Surgery	50 (25.8)	53 (26.8)
Other	73 (37.6)	63 (31.8)
Comorbidities, mean no.	4.47	4.0

Table 2. Process and financial measures: Pre- and postintervention results

Measure	Preintervention (n = 194)	Postintervention (n = 198)	p value
Mean length of stay, days			
ICU	5.76	4.92	0.44
Hospital	17.42	12.88	0.05
Mean APACHE III score	56.54	57.08	0.86
No. of patients who met trigger criteria	41	47	
Outcome measure identified by Day 3, no. of patients of meeting trigger criteria[a]			
Goals of care	10	33	0.01
Advance directives	39	43	0.90
Surrogate	23	20	0.46
Code status	16	37	0.05
Video viewed	2	2	0.90
Receipt of palliative care brochure	0	10	0.005
Family meeting	12	37	0.01
Total no. of palliative care consultations	8	14	0.39

[a] The 6 trigger criteria are defined in the text and in Figure 1.
APACHE = Acute Physiology and Chronic Health Evaluation; ICU = intensive care unit.

which the goals of care were identified by Day 3 increased significantly: $\chi^2(1) = 6.62$, $p = 0.01$. Patients in which advance directives were identified by Day 3 of meeting the trigger criteria decreased slightly from 95% to 91%. Those in which a surrogate was identified by Day 3 of meeting the trigger also decreased from 56% to 43%. Neither difference was significant. The numbers of patients who had their code status identified by Day 3 of meeting the trigger criteria increased significantly: $\chi^2(1) = 3.70$, $p = 0.05$. The use of the video remained unchanged, but the use of the palliative care brochure increased from 0% to 21%, reaching significance: $\chi^2(1) = 8.01$, $p < 0.01$. There was a significant increase in the numbers of proactive ICU family meetings by Day 3, from 29% in the preintervention sample, to 79% in the postintervention sample $\chi^2(1) = 6.48$, $p = 0.01$. In addition, there was an increased trend in the numbers of palliative care meetings, which rose slightly, from 20% in the preintervention sample to 30% in the postintervention sample.

DISCUSSION

Limitations

This quality-improvement project had several limitations. The results from this project encompassed a single facility, and it is entirely possible that the resultant trends were an isolated finding. In addition, the data sample size from both the pre- and postintervention periods were limited to 3 months only. As a result, the timing of the data collected, along with the duration of the collection, may have precluded a true representation of the population. The KP Hawaii (KPHI) membership represents less than 20% of the state's population,[22] with approximately 5% of the state inhabitants that remain uninsured.[23] Therefore, it is also feasible that the patient population that makes up the KPHI membership does not accurately represent the total number of inhabitants in the state.

The measures used for this study mostly relied on medical record abstraction from an electronic medical record. Studies have shown that chart abstraction underestimates quality of care by at most 10%, compared with direct observation, and may even overestimate quality in some instances. Because data are lacking on performance of medical record abstraction in palliative care, poor documentation may limit the utility of some of these candidate measures.[24] In an effort to reinforce the charting of pertinent outcome measures, a template devised for easy insertion into the electronic progress notes was designed with key phrases. Despite this, it was noted during chart reviews that documentation was inconsistent. These inconsistencies were apparent, with not only the nursing staff but also the physician staff, and it was sometimes difficult to find specific information. The chart reviews and data collection were performed by the team leader, which resulted in a large time allotment because every progress note was reviewed to search for appropriate documentation. This review did, however, allow for overall consistency in the data collection.

Most of the process and outcome measures were reported as changes in trends. Those measures that were reported as a mean score, however, had an independent *t* test applied. A χ^2 test also was used for the outcomes reported as frequencies, but because this program was a quality-improvement project without experimental design and randomization, the robustness of the inferential statistical results was uncertain.

Potential Cost Savings

The literature shows that most health care expenditures occur at the end of life and in the ICU. Among the nearly 2.5 million annual deaths in the US, one-third occurs in the hospital, and a substantial percentage occurs in the ICU. The ICU can account for up to 80% of the total inpatient costs spent on terminal hospitalizations.[5,25] Approximately 20% of people who die in the US are admitted to an ICU within the last 6 months of life. In addition, patients with life-threatening diseases frequently receive medical care that conflicts with their end-of-life preferences.[26] A reduction in unwanted treatments in the ICU can have an impact on ICU LOS, and interventions that clarify patient's goals of care and whether ICU care is consistent with these goals may reduce the intensity of end-of-life care.[27]

The results from this project saw a decrease in ICU LOS, but the difference between pre- and postintervention samples was not significant. This may, in part, be because of the sample size. There was, however, a significant difference in the hospital LOS between the pre- and postintervention samples, but with a small effect size. Consequently, a larger sample size might have provided greater evidence of effect. It is uncertain how much of an impact this reduction in ICU LOS or hospital LOS would have had on total hospital costs, but the potential for cost savings from the implementation of palliative care in the ICU is a tempting conclusion. In 2006,

a retrospective observational cost analysis by Penrod et al[28] found that palliative care was associated with a significantly lower likelihood of ICU use and lower inpatient costs compared with those of patients who received the usual care. Since then, numerous benefits from the provision of palliative care in the ICU have been demonstrated. Patients who receive advance care planning or palliative care interventions consistently showed trends toward decreased ICU admission and reduced ICU LOS.[6,29] Starks et al[30] suggested that savings could be achieved by earlier involvement of palliative care, and they supported screening efforts to identify patients who could benefit from palliative care services early in admission.

Any number of factors has the potential for affecting not only quality of care but also LOS. There is a general agreement that early identification of the various aspects of goals of care, including code status and the availability of advance directives, influence ultimate care decisions. All these factors have an effect on reducing ICU admission, LOS, and the intensity of treatment of patients who die in the ICU.[6]

This project showed an increase in the percentage of the early identification of goals of care from 24% to 70%, and code status from 39% to 79%, which demonstrated that the effects of the process were positive and significant. The nursing staff also used the palliative care brochure in increased numbers. As demonstrated by Scheunemann et al,[31] printed information can improve family comprehension and emotional outcomes, and there is supporting evidence for the offering of this printed information by the ICU team to improve end-of-life care and family satisfaction.

The use of the videos was, unfortunately, neglected. These informational videos are evidence-based, culturally appropriate communication tools that were designed as an instrument for physicians to use in their discussions of medical conditions and advance care planning.[18-20] These videos exist on the KP Education on Demand Webinar. The intent of this project was to use the videos to initiate a conversation regarding goals of care and designation of a surrogate, advance directives, and code status. Traditionally, it falls to the physician to inform families about a pending palliative consultation. Once the family is aware of the need for a consultation, the registered nurse supplements the information and any questions with printed material. This project was designed so that the nurse, and not the physician, was to offer the video. The lack of results in this area could underscore the continued staff discomfort with the initiation of sensitive discussions regarding advance directives, code status, and end-of-life issues.

Changing a culture in the ICU affords multiple challenges, but this project demonstrated that early identification of key palliative care interventions, which included a proactive ICU and palliative care meeting, were possible once processes were in place to ensure prompt documentation of code status, advance directives, and goals of care. Celso and Meenrajan[32] found that the relationships between days until a family conference, do-not-resuscitate order, number of invasive procedures, and ICU LOS were significant. In addition, the days until the do-not-resuscitate order was found to be a significant predictor variable for total hospital LOS.

CONCLUSION

As the numbers of ICU treatments during the last months of life increase, LOS in both the ICU and in the hospital will continue to be addressed.[33] Inappropriate aggressive treatments in the ICU at the end of life have the potential to result in futile care and an excessive use of hospital resources. In addition, the potential for symptoms from psycho-emotional trauma on family members after an ICU death has proved to be substantial.[27] In an effort to reduce expenditures for end-of-life care in the ICU, it is possible that early clarification of advance directives, code status, and goals of care can ensure that palliative care needs are met, leading to improved quality of care for both patients and families, while reducing cost. ❖

Disclosure Statement

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The Negative Decisions

There are times when compassion should prompt us to forgo prolonged and costly treatment. If a man must die, he has the right to die in peace, as he would prefer to do if asked. … But the negative decisions that ease and shorten suffering have always been ours to make.

— Wilder Penfield, 1891-1976, pioneering Canadian neurosurgeon

Development and Application of a Plant-Based Diet Scoring System for Japanese Patients with Inflammatory Bowel Disease

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ABSTRACT

Context: Plant-based diets (PBDs) are a healthy alternative to westernized diets. A semivegetarian diet, a PBD, has been shown to prevent a relapse in Crohn disease. However, there is no way to measure adherence to PBDs.

Objective: To develop a simple way of evaluating adherence to a PBD for Japanese patients with inflammatory bowel disease (IBD).

Design: PBD scores were assigned according to the frequency of consumption provided on a food-frequency questionnaire, obtained on hospitalization for 159 patients with ulcerative colitis and 70 patients with Crohn disease. Eight items considered to be preventive factors for IBD were scored positively, and 8 items considered to be IBD risk factors were scored negatively. The PBD score was calculated from the sum of plus and minus scores. Higher PBD scores indicated greater adherence to a PBD. The PBD scores were evaluated on hospitalization and 2 years after discharge for 22 patients with Crohn disease whose dietary pattern and prognosis were established.

Main Outcome Measure: Plant-Based Diet score.

Results: The PBD scores differed significantly, in descending order, by dietary type: pro-Japanese diet, mixed type, and pro-westernized diet (Wilcoxon/Kruskal-Wallis test). The PBD scores in the ulcerative colitis and Crohn disease groups were 10.9 ± 9.5 and 8.2 ± 8.2, respectively. For patients with Crohn disease, those with long-term remission and normal C-reactive protein concentration were significantly more likely to have PBD scores of 25 or greater than below 25 (χ^2).

Conclusion: The PBD score is a valid assessment of PBD dietary adherence.

INTRODUCTION

Inflammatory bowel disease (IBD) is a collective term for ulcerative colitis and Crohn disease, which are chronic inflammatory disorders of the gastrointestinal tract marked by episodes of relapse and remission. Originally, IBD comprised diseases predominantly found in Europe and North America. Their incidence and prevalence have been increasing with time and expanding to different regions around the world, indicating that IBD is a global disease.[1] Development of IBD in genetically susceptible subjects is triggered by environmental factors,[2] as with other common chronic diseases.

It is clear now that gut microflora play a role in various chronic diseases, including obesity, diabetes, coronary artery disease, stroke, rheumatoid arthritis, and cancer.[3-7] It is also clear that gut microflora are formed by diet.[7-10] The concept that diet-associated gut dysbiosis (imbalance of gut microflora) is a critical environmental factor for development of chronic diseases has been established. Consequently, diet is a prime critical factor in chronic diseases. Dietary reviews recommend plant-based diets (PBDs) to treat and prevent a variety of common diseases.[11-14]

Crohn disease is worse than ulcerative colitis in respect to relapse rate, surgical rate, and prognosis. The relapse rate per year is 60% to 70% in patients with mild to moderate severity,[15] and lifelong relapse-free status is obtained by only 10% to 15% of patients.[16-18] Clinical remission is gained with total parenteral nutrition or elemental diet. Commencement of omnivorous meals, however, causes gradual elevation of C-reactive protein (CRP) concentration followed by a relapse. Therefore, omnivorous meals are thought to cause gut inflammation.[19] Consequently, an elemental diet, either exclusive or partial, during the active or quiescent phases or both has been developed.[20]

We regard IBD as a lifestyle disease mainly mediated by westernized diets, which tend to cause dysbiosis in gut microflora.[2,19] To provide a healthier alternative to a westernized diet, a semivegetarian diet (SVD) was developed, which is lacto-ovo-vegetarian with fish once a week and meat once every two weeks.[19] This SVD, one of the PBDs, has been shown to prevent a relapse in Crohn disease.[19]

Dietary recommendations and guidelines for the prevention of specific diseases

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and ways of measuring adherence to these guidelines include the following: the Healthy Eating Index,[21] the Alternate Healthy Eating Index-2010,[22] the Alternate Mediterranean Diet score,[23] the Recommended Food Score,[24] and the Dietary Approaches to Stop Hypertension (DASH) Diet score.[25] These indexes or scores are generally the sum of the scores of the indicated food groups. For example, a value of 0 or 1 in the Mediterranean Diet score[23] or a value of 0 to 10 in the Healthy Eating Index[21,22] is assigned to each of the indicated components. Higher scores indicate greater adherence to the corresponding diet. In these dietary guidelines, there are clear common food groups recommended or moderated; namely vegetables, fruits, and legumes are recommended, and meats and sweets are moderated. These dietary recommendations and guidelines are to some extent similar to a PBD.

In IBD, detrimental and beneficial foods have been documented. Because common meals are thought to cause gut inflammation, comprehensive and stricter dietary control is needed. Therefore, detrimental foods are to be scored not as 0 but scored negatively. Assessment of dietary adherence should be simple enough for patients and clinicians to calculate easily. In the future, the term *PBD,*[11-13] which includes diets of various moderating degrees of animal foods, is expected to be used more frequently by the public than is SVD.

The aim of this study was to develop a suitable PBD score for Japanese patients with IBD and to evaluate the validity of the PBD score. We assumed that the PBD score of a Japanese diet was higher than that of a westernized diet and that the PBD score can predict prognosis of Crohn disease more accurately than can dietary type (SVD or omnivorous diet).

METHODS

Development of Plant-Based Diet Score

We developed a simple scoring method to evaluate adherence to a PBD.[26] Components of the PBD,[27] which we consider beneficial to IBD, are scored positively: vegetables,[28] fruits,[28] pulses (beans, soybeans, peas, etc), and potatoes/starches (Table 1). Components of a westernized diet,[29] which we consider as risk factors to IBD, are scored negatively: meat[28,30-36] including minced or processed meat; cheese, butter, and margarine[31,32,35,37]; sweets[28,31,32,37,38]; and soft drinks.[39] Components of the traditional Japanese diet, known as *Washoku,*[40] are scored positively: rice, miso soup, and green tea.[31,32] Green tea increases beneficial bacteria in the gut.[19] Risk factors for IBD in Japanese individuals are scored negatively: fish[34,38] and bread.[37] Plain yogurt, a probiotic, is scored positively. Alcohol is scored negatively.[33]

Scores 5, 3, and 1 are given according to the frequency of consumption: every day, 3 to 5 times/wk, and 1 or 2 times/wk, respectively (Table 1). An exception to the scores is for the consumption of fish. Although fish is a component of *Washoku* and the Mediterranean diet, which are known to be healthy diets, it is also a risk factor in studies in and outside Japan.[34,38] Therefore, its consumption daily, 3 to 5 times/wk, and 1 or 2 times/wk was scored -2, -1, and 0, respectively.

The PBD score is developed from the sum of plus and minus scores (Table 1).

Table 1. Plant-based diet score for Japanese patients with inflammatory bowel disease

	Scoring by frequency of consumption				Measured plant-based diet score for our patient with Crohn disease		
Food group	Daily	3-5 servings/wk	1-2 servings/wk	Rarely	Baseline (before hospitalization)	SVD during hospitalization (7 wks)	2 years after discharge
Positive score							
Vegetables	5	3	1	0	1	5	5
Fruits	5	3	1	0	0	5	5
Pulses (beans, soybeans, peas, etc)	5	3	1	0	0	5	5
Potatoes/starches	5	3	1	0	0	5	1
Rice	5	3	1	0	5	5	5
Miso soup	5	3	1	0	0	5	5
Green tea	5	3	1	0	0	0[a]	5
Yogurt (plain)	5	3	1	0	0	5	5
Negative score							
Meat (beef, pork, chicken)	-5	-3	-1	0	-3	0	0
Minced or processed meat	-5	-3	-1	0	0	0	0
Cheese, butter, margarine	-5	-3	-1	0	0	0	0
Sweets, ice cream, milkshake	-5	-3	-1	0	0	0	0
Soft drinks (cola, carbonated beverages, juice)	-5	-3	-1	0	0	0	0
Alcohol	-5	-3	-1	0	0	0	-5
Bread	-5	-3	-1	0	0	0	0
Fish	-2	-1	0	0	0	0	0
Plant-based diet score					3	35	31

[a] Green tea is recommended to drink at home but is not provided at the hospital.
SVD = semivegetarian diet.

The maximum positive score is 35 for inpatients and 40 for outpatients because green tea is not provided as a drink in the hospital. In hospitals in Japan, inexpensive coarse tea usually is served with meals. The maximum negative score is -37. A higher PBD score indicates a greater adherence to a PBD. An example of how the PBD score is measured is shown for a patient with Crohn disease in Table 1.

Subjects

Patients with IBD who were admitted to Nakadori General Hospital, Akita, Japan, between April 2003 and March 2013 and Akita City Hospital, Akita, Japan, during April 2013 to June 2015 were included in the study. This study (study identification no. UMIN000019061) was approved by the Ethical Committee of each hospital. Informed consent was obtained from all subjects. Three patients with Crohn disease whose food-frequency questionnaire (FFQ)[41] was unavailable were not included in the study. The number of patients with ulcerative colitis and Crohn disease was 159 and 70, respectively (Table 2). The male-to-female ratio was 1.1 (84/75) in ulcerative colitis and 2.7 (51/19) in Crohn disease. Patients age 18 years or younger consisted of 15 patients (9%) with ulcerative colitis and 16 patients (23%) with Crohn disease. The median age of ulcerative colitis and Crohn disease was 36 and 23 years, respectively. Initial onset cases comprised 73 patients (46%) with ulcerative colitis and 48 patients (69%) with Crohn disease.

All patients with IBD were at least initially recommended to be admitted for their treatment. Patients, even those with mild severity, were recommended to experience and familiarize themselves with an SVD through an educational hospitalization for about 2 weeks.[26] Cases of educational hospitalization comprised 48 patients (30%) with ulcerative colitis and 19 patients (27%) with Crohn disease. The subjects' characteristics are presented in Table 2.

Plant-Based Diet during Hospitalization

Our PBD was a lacto-ovo-vegetarian diet with fish allowed once a week and meat allowed once every two weeks, both at about half the Japanese average amount, namely an SVD. Miso (fermented bean paste) soup, vegetables, fruits, legumes, potatoes, pickled vegetables, and plain yogurt were served daily. Details of the SVD were described in a previous article.[19]

Table 2. Study subjects' characteristics

Characteristic	Ulcerative colitis (n = 159)		Crohn disease (n = 70)		p value
Male/female, no.	84/75		51/19		0.0039[a]
Age, years					
Range	11-85		13-78		
Mean	39.7		29.6		< 0.0001[b]
Median	36		23		
≤18 years, no. (%)	15 (9)		16 (23)		0.0083[a]
Type of IBD, no. (%)	Initial attack	73 (46)	Initial case	48 (69)	
	Relapsing-remitting	81 (51)	Relapsed case	22 (31)	
	Chronic continuous	5 (3)	Enteritis	9 (13)	
	Proctitis	61 (38)	Enterocolitis	37 (53)	
	Left-sided colitis	17 (11)	Colitis	24 (34)	
	Entire colitis	78 (49)	Remission	19 (27)	
	Right-sided colitis	3 (2)	Active	51 (73)	
	Mild	86 (54)			
	Moderate	51 (32)			
	Severe	22 (14)			
Educational hospitalization, no. (%)	48 (30)		19 (27)		0.6393[a]

[a] Chi-squared test.
[b] Wilcoxon/Kruskal-Wallis test.
IBD = inflammatory bowel disease.

During hospitalization, foods other than the meal service were discouraged. Consequently, the maximum PBD score during hospitalization was 35 (Table 1). The period of hospitalization differed among patients. Some patients were hospitalized approximately 7 weeks for standard induction therapy with infliximab (3 infusions in 6 weeks),[19] others stayed about 2 weeks for an educational hospitalization,[26] and the other patients stayed from 3 weeks to 5 weeks according to the severity of their disease. At the end of hospitalization, a qualified dietitian gave dietary guidance to the patient and the patient's meal preparer. The responsible physician (MC) advised them to continue this diet after discharge. They were also advised to preferentially drink green tea.[19]

Food-Frequency Questionnaire and Dietary Type

Before providing information about the SVD, patients' dietary habits before onset or relapse of the disease were obtained on the day of admission or immediately thereafter, by means of an FFQ.[41] The questionnaire included 45 questions that covered almost all foods or food groups in Japan.[19] It contained information necessary for calculating the PBD score.

In the questionnaire, there was a question about dietary type that listed 6 types: westernized, pro-westernized, standard mixed diet of *Washoku* and westernized diet, pro-Japanese, Japanese (*Washoku*), and SVD. A definition of dietary types was not mentioned.[19] In ulcerative colitis, the number of patients by dietary type was 3, 19, 92, 25, 17, and 3, respectively (Figure 1A). In Crohn disease, there was no case of SVD. The number of patients by dietary type was 1, 13, 40, 11, and 5, respectively (Figure 1B). The standard mixed diet of *Washoku* and westernized diet was the most popular, making up more than half in both ulcerative colitis (92/159, 58%) and Crohn disease (40/70, 57%) populations (Figure 1).

Evaluation of Plant-Based Diet Score from Food-Frequency Questionnaire

The PBD score was calculated from the patients' dietary type obtained on the FFQ. The FFQ before admission was available for 159 patients with ulcerative colitis and 70 patients with Crohn disease.

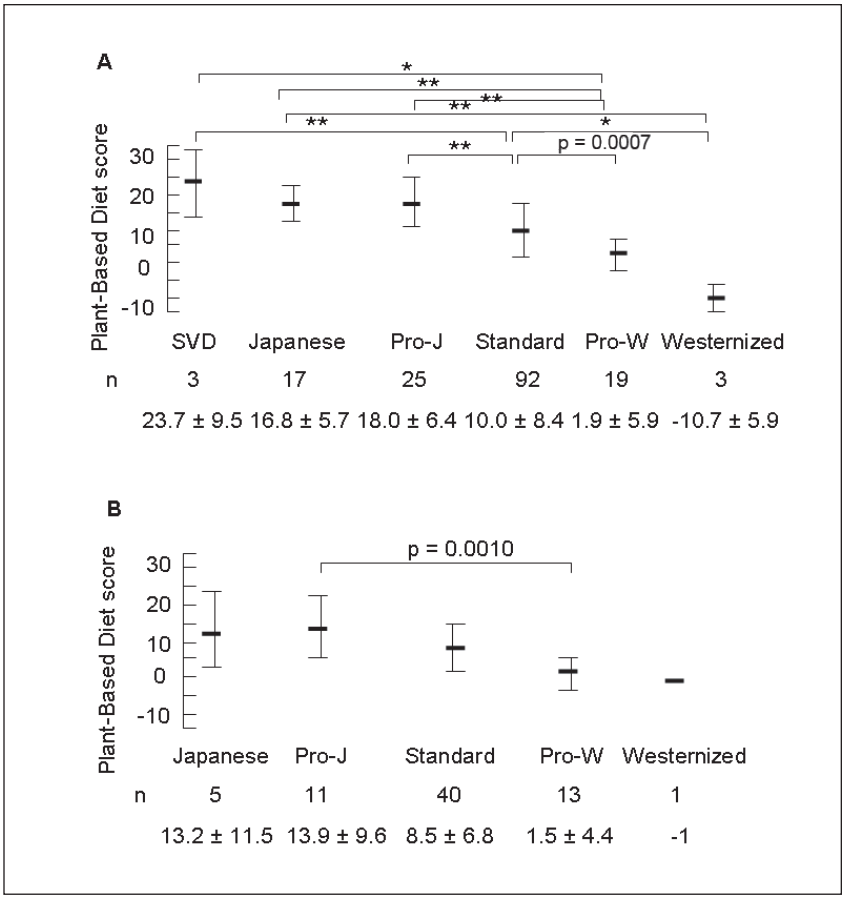

Figure 1. Dietary type and Plant-Based Diet score in patients with ulcerative colitis (n = 159) (A) and Crohn disease (n = 70) (B).

* p = 0.0001, post hoc Tukey honest significant difference test.

** p < 0.0001, post hoc Tukey honest significant difference test.

Bars = mean and standard deviation; Japanese = Japanese diet (*Washoku*); Pro-J = pro-Japanese diet; Pro-W = pro-westernized diet; Standard = standard mixed with Japanese and westernized diet; SVD = semivegetarian diet; Westernized = westernized diet.

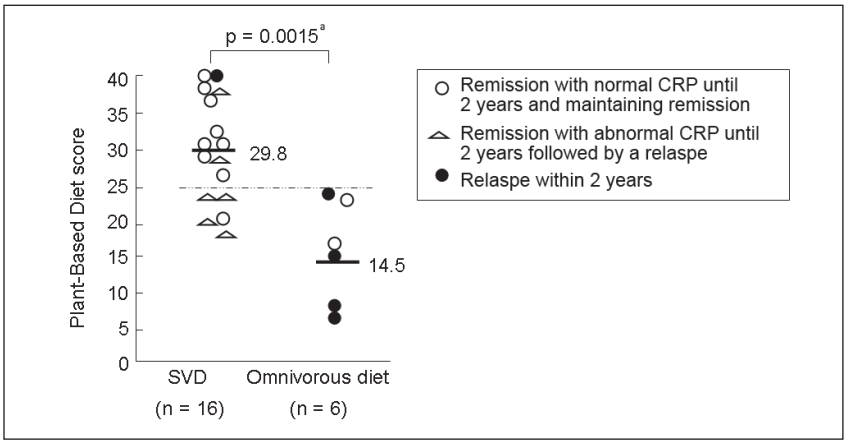

Figure 2. Evaluation of Plant-Based Diet score at 2 years after discharge in 22 patients with Crohn disease, whose prognosis was published.[19]

[a] Analysis of variance.

Bars = mean; CRP = C-reactive protein; SVD = semivegetarian diet.

In a previous study, 22 patients with Crohn disease in remission were followed-up as outpatients.[19] They were provided 5-aminosalicylic acid with no biologics, immunosuppressants, or steroid hormones. The FFQ was obtained at 3 months, 1 year, and 2 years after discharge or at the time of relapse. In that study, the SVD was shown to be preventive in the time to relapse compared with that in the omnivorous diet (p = 0.0003, log rank test).[19] A PBD score was evaluated in the current study for these 22 patients with Crohn disease with a known outcome at 2 years.

An abnormal CRP concentration precedes clinical relapse for various periods from a few months to a few years in Crohn disease.[42] This also happened in our cases. Six patients in remission with abnormal CRP concentrations at 2 years after discharge experienced a relapse, but 11 patients with normal CRP concentrations did not (Figure 2). Therefore, a normal CRP concentration with remission is a prerequisite for a long-lasting remission. We evaluated whether dietary patterns or PBD score is related to remission with a normal CRP concentration.

Statistical Analysis

The frequency of categorical variables was assessed with a χ^2 test. Dietary type and PBD score in ulcerative colitis and Crohn disease was analyzed through the Wilcoxon/Kruskal-Wallis test and analysis of variance (ANOVA), respectively, depending on whether scores showed standard normal distribution. When a significant F-ratio was obtained, differences between the means were isolated with the post hoc Tukey honest significant difference procedure. The χ^2 analysis was used to test the hypothesis that there was no difference in dietary type (SVD and omnivorous diet) or PBD score (high and low) for the prognosis from 2 years after discharge in Crohn disease. All p values are two-tailed. A p value of 0.05 or less was considered to indicate a statistically significant difference. Statistical analysis was performed using JMP 8 (SAS Institute Inc, Cary, NC) software.

RESULTS

Results are expressed as the mean ± standard deviation.

Plant-Based Diet Score in Ulcerative Colitis and Crohn Disease

The positive PBD score (sum of positive scores), negative PBD score (sum of negative scores), and total PBD score were 23.2 ± 8.0, 12.1 ± 6.0, and 10.9 ± 9.5, respectively, in the ulcerative colitis group (n = 159), and 20.0 ± 7.5, 10.8 ± 8.1, and 8.2 ± 8.2, respectively, in the Crohn disease group (n = 70; Table 3). The total PBD score and positive PBD score were significantly elevated in patients with ulcerative colitis vs those with Crohn disease (Wilcoxon/Kruskal-Wallis test; Table 3).

Table 3. Plant-based diet score in ulcerative colitis and Crohn disease[a]

Group	n	PBD score+	PBD score–	PBD score
Ulcerative colitis	159	23.2 ± 8.0	12.1 ± 6.0	10.9 ± 9.5
Crohn disease	70	20.0 ± 7.5	10.8 ± 8.1	8.2 ± 8.2
p value for ulcerative colitis vs Crohn disease[b]		0.0040	0.2692	0.0117

[a] Scores are presented as mean ± standard deviation.
[b] Wilcoxon/Kruskal-Wallis test.
PBD = plant-based diet; PBD score+ = sum of positive scores on Plant-Based Diet; PBD score- = sum of negative scores; PBD score = sum of positive and negative scores.

Relation between Dietary Types and Plant-Based Diet Score

The baseline (preadmission) PBD score by dietary type in the ulcerative colitis group was as follows in a descending order: 23.7 ± 9.5 in SVD (n = 3), 18.0 ± 6.4 in pro-Japanese (n = 25), 16.8 ± 5.7 in Japanese (n = 17), 10.0 ± 8.4 in standard mixed (n = 92), 1.9 ± 5.9 in pro-westernized (n = 19), and -10.7 ± 5.9 in westernized (n = 3, $p < 0.0001$, Wilcoxon/Kruskal-Wallis test, Figure 1A). The PBD score of patients with a pro-westernized diet was significantly lower than for the standard mixed diet, which was significantly lower than for the pro-Japanese diet (see Figure 1A).

The baseline PBD score by dietary type in the Crohn disease group was as follows in a descending order: 13.9 ± 9.6 in pro-Japanese (n = 11), 13.2 ± 11.5 in Japanese (n = 5), 8.5 ± 6.8 in standard mixed (n = 40), 1.5 ± 4.4 in pro-westernized (n = 13), and -1 in westernized (n = 1, p = 0.0008, ANOVA, Figure 1B). The PBD score of patients with the pro-westernized diet was significantly lower than for the pro-Japanese diet (see Figure 1B).

Plant-Based Diet Score and Prognosis in Crohn Disease

The PBD score of patients with an SVD (n = 16) and an omnivorous diet (n = 6) was 29.8 ± 7.2 and 14.5 ± 7.5, respectively (p = 0.0015, ANOVA, Figure 2). Maintenance of remission until 2 years after discharge was higher in patients with an SVD (15/16) than with an omnivorous diet (2/6, p = 0.0036, χ^2). There was no difference in the frequency of maintenance of remission with normal CRP concentration until 2 years after discharge between patients with an SVD (9/16) and with an omnivorous diet (2/6, p = 0.3348, χ^2). The frequency of maintenance of remission with normal CRP concentration until 2 postdischarge years was higher in patients with PBD scores of 25 or greater (8/11) than in those below 25 (3/11, p = 0.0299, χ^2).

DISCUSSION

In Japan, the number of patients with ulcerative colitis is about three times those of Crohn disease.[43] Male predominance over female is an Asian (including Japanese) characteristic for Crohn disease.[44,45] Our subjects in this study are consistent with the epidemiology found in Japan.[43,44] Among dietary types, although their definition was not formal, a mixed type of *Washoku* and Western diet was most popular for both the ulcerative colitis and Crohn disease groups. This means dietary westernization is fully embraced in Japan. The PBD scores by dietary type in both diseases were similar. Although dietary types were distributed across a broad range of PBD score, the PBD score by dietary type on the whole showed significant differences. Namely, the mean PBD scores of patients with a Japanese dietary type and a pro-Japanese type were higher than for patients with pro-westernized and westernized diets, and the standard mixed type was the intermediate of these two groups. This indicates that PBD score reflects dietary type. Our assumption that the PBD score of a Japanese diet was higher than that of a westernized diet was confirmed. Judging from the PBD score, *Washoku* is closer to a PBD than standard mixed, and a westernized diet is far from a PBD.

Altogether, the developed PBD scoring system seems to be successful in reflecting adherence to PBD. The critical factor in our PBD score is the distribution of negative scores to detrimental foods for IBD. Otherwise, scoring would be unable to discriminate dietary patterns or discrimination of the dietary pattern would be less clear than in the present scoring system.

The efficacy of SVD (PBD) in preventing relapse, namely, maintaining remission, in Crohn disease was shown in a previous study.[19] There are two kinds of remission: remission with a normal CRP concentration and remission with an abnormal CRP concentration. The latter lasts for a few months to a few years before a relapse, whereas the former almost guarantees lasting remission.[42] In this study, it was found that a PBD score of more than 25 is required to maintain remission with normal CRP concentration. This is 3 times higher than the baseline PBD score of 8.2.

The sample size in this study is very small (n = 22). Investigation for the sensitivity and specificity of PBD score predicting Crohn disease prognosis on a large scale is awaited. Needless to say, there are factors other than diet linked to relapse, namely, mucosal healing,[46] stress,[47] smoking,[48] acute gastroenteritis,[49] and antibiotics.[50] We experienced a case in which a relapse occurred shortly after discharge even though the patient's PBD score was the maximum of 40. Unpredictability of the prognosis of Crohn disease is well known.[18] Because the concept that IBD is a lifestyle disease mediated mainly by a westernized diet is not widely appreciated, an analysis of diet in the follow-up period in relation to a relapse of IBD has been ignored. Analysis of diet will provide information regarding prediction of relapse and prognosis in patients with IBD.

The variety of diets based on cultural background forms a diversity of gut microflora.[51] In addition, susceptible genes for IBD differ by ethnicity.[52,53] Therefore, some food items of PBDs will differ from

country to country. Since the PBD score was found to be useful in evaluating adherence to a PBD, the PBD score can in practice be applied broadly: Education of PBD, monitoring of PBD, and the relationship between PBD and health.

CONCLUSION

The PBD score was significantly different according to dietary type in a descending order: Pro-Japanese diet, mixed type, and Pro-westernized type. The PBD score of an SVD was significantly higher than that of an omnivorous diet. In patients with Crohn disease, a PBD score of 25 or greater was needed to maintain long-term remission. The PBD score is a valid assessment of dietary adherence to a PBD. The PBD and PBD score can be modified for a variety of diseases and for different national dietary preferences. ❖

Disclosure Statement

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

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Necessity Made Medicine

For the art of Medicine would not have been invented at first, nor would it have been made a subject of investigation (for there would have been no need of it), if when men are indisposed, the same food and other articles of regimen which they eat and drink when in good health were proper for them, and if no others were preferable to these. But now necessity itself made medicine to be sought out and discovered by men.

— Hippocrates of Kos, 460 BC-370 BC, Greek physician of the Age of Pericles

Accreditation Council for Graduate Medical Education Core Competencies at a Community Teaching Hospital: Is There a Gap in Awareness?

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ABSTRACT

Context: Reports evaluating faculty knowledge of the Accreditation Council for Graduate Medical Education (ACGME) core competencies in community hospitals without a dedicated residency program are uncommon.

Objective: Faculty evaluation regarding knowledge of ACGME core competencies before a residency program is started.

Design: Physicians at the Kaiser Permanente Fontana Medical Center (N = 480) were surveyed for their knowledge of ACGME core competencies before starting new residency programs.

Main Outcome Measures: Knowledge of ACGME core competencies.

Results: Fifty percent of physicians responded to the survey, and 172 (71%) of respondents were involved in teaching residents. Of physicians who taught residents and had complete responses (N = 164), 65 (39.7%) were unsure of their knowledge of the core competencies. However, most stated that they provided direct teaching to residents related to the knowledge, skills, and attitudes stated in each of the 6 competencies as follows: medical knowledge (96.3%), patient care (95.7%), professionalism (90.7%), interpersonal and communication skills (86.3%), practice-based learning (85.9%), and system-based practice (79.6%). Physician specialty, years in practice (1-10 vs > 10), and number of rotations taught per year (1-6 vs 7-12) were not associated with knowledge of the competencies ($p > 0.05$); however, full-time faculty (teaching 10-12 rotations per year) were more likely to provide competency-based teaching.

Conclusion: Objective assessment of faculty awareness of ACGME core competencies is essential when starting a residency program. Discrepancy between knowledge of the competencies and acclaimed provision of competency-based teaching emphasizes the need for standardized teaching methods that incorporate the values of these competencies.

INTRODUCTION

It is estimated that the number of graduate medical education residency positions for medical school graduates has grown by 1.7% per year over the past decade.[1] However, this trend is not expected to fulfill the actual projected need of physicians, with an anticipated shortfall of 41,000 to 90,000 physicians by 2025.[2] As the demand for new training positions[3] continues to exist, the Accreditation Council for Graduate Medical Education (ACGME) instituted standard requirements for accrediting new residency programs.[4] These requirements were designed to ensure that each resident will develop the knowledge, skills, and attitudes required to enter unsupervised practice by the end of their training.[4]

The ACGME mandated that all residency programs realign their medical education and residents' evaluation around six core competencies: medical knowledge, patient care, professionalism, interpersonal and communication skills (ICS), practice-based learning and improvement (PBLI), and system-based practice.[5] In 2013, the ACGME went a step further by implementing the Next Accreditation System.[6] In the Next Accreditation System, the evaluation of every residency program is shifted from a process-oriented procedure into an outcome-based procedure that is based on the six ACGME core competencies.[5-7] Because the milestones in the Next Accreditation System are considered the natural progression of the work on the six competencies, faculty awareness of those competencies is considered paramount. In fact, the ACGME expects program faculty to "administer and maintain an educational environment conducive to educating residents in each of the ACGME competency areas."[5] However, faculty evaluation in regard to the knowledge and delivery of competency-based education is left to the discretion of the Program Director[5,6] and, more recently, residents' evaluation of faculty.[6]

This study focuses on the assessment of faculty knowledge of the six ACGME core competencies in a single community teaching hospital. We conducted the survey as part of needs assessment before establishing new residency programs in general surgery, internal medicine, and psychiatry. We hypothesize that at the time of starting a new residency program, objective evaluation of faculty knowledge of the ACGME core competencies is essential. This assessment can help to identify gaps in knowledge that potentially could be addressed before a residency program is started.

METHODS

We surveyed 480 physicians specializing in family medicine, internal medicine, sports medicine, geriatric medicine, psychiatry, pediatrics, general surgery, plastic surgery, obstetrics and gynecology, orthopedics (listed under other specialties), and neurosurgery at the Kaiser Permanente (KP) Fontana Medical Center in CA. The purpose of this survey was to explore faculty knowledge of the

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ACGME core competencies and to assess their implementation of competency-based teaching. At the time of this evaluation, the general surgery, neurosurgery, plastic surgery, and obstetrics and gynecology services were already involved in teaching residents rotating from affiliated residencies; however, the affiliated residency programs were planning to withdraw their residents from our hospital. As such, the KP Fontana Medical Center was planning to start a general surgery residency program integrated with Arrowhead Regional Medical Center, in Colton CA. The Fontana Medical Center also was going to be the sponsoring institution for the internal medicine and psychiatry residency programs. These programs were added to the family medicine residency program, which has been established since 1975.[8]

Pilot testing of the survey was performed among eight students and four faculty members from the University of Southern California Master of Academic Medicine program. The survey questions were revised on the basis of feedback from the participants. The standardized survey was sent electronically. The survey was resent twice, for a total of three times, to improve the participation rate. A copy of the survey can be accessed online at www.thepermanentejournal.org/files/16-067.pdf.

We categorized the participants by their specialty (medical vs surgical), years in practice (1-10 vs > 10 years), and the number of monthly rotations taught per year (1-3, 4-6, 7-9, and 10-12). Full-time faculty was defined as a faculty member who teaches 10 to 12 rotations per year. Surgical specialties included general surgery, plastic surgery, obstetrics and gynecology, orthopedics (listed as "other"), and neurosurgery. Medical specialties included family medicine, internal medicine, sports medicine, psychiatry, pediatrics, and geriatric medicine.

The six competencies as they appeared on the survey included medical knowledge, patient care, professionalism, ICS, PBLI, and system-based practice. We asked faculty members to define the degree of their own level of knowledge of the ACGME core competencies as "not sure," "know the names of the six competencies," or "well versed." The last category included response choices for faculty who "have worked with the subcompetencies/milestones" or "have developed objectives or curricula based on the competencies." Additionally, we asked faculty physicians about their perception of whether they had incorporated each individual core competency in their teaching of residents. Finally, faculty members were asked to assess their residents' performance across the six core competencies. The residents' performance was evaluated as a "strength," "weakness," or "neither a strength nor a weakness."

A χ^2 test was used to test the association of physicians' characteristics with their knowledge of the competencies and whether they provided resident teaching that is pertinent to the objectives stated in each core competency. The study was approved by the institutional review board of KP Southern California. We used STATA/IC Version 11.2 for all statistical analyses (StataCorp, College Station, TX).

RESULTS

Among 480 hospital physicians who were surveyed, 242 (50.4%) responded to the survey. Among the respondents, 172 faculty physicians actively instructed residents, of whom 164 had complete responses. Seventy physicians who responded to the survey did not teach residents. The data of those who taught residents with complete survey responses were analyzed. Fifty-three (32.3%) faculty physicians taught 7 or more rotations per year. Only 33 (20.1%) physicians were full-time teaching faculty (teaching 10-12 rotations per year). One hundred thirty-three (81.1%) of the faculty physicians were teaching medical residents, and 31 (18.9%) were involved in teaching surgical residents (Table 1). Figure 1 demonstrates a comparison of faculty knowledge of ACGME core competencies. Teaching (faculty) physicians were more likely to know the names of (33.5% vs 27.9%) or to be well versed in (26.8% vs 4.4%, $p < 0.01$) the core competencies compared with nonteaching (nonfaculty) physicians.

Most of the faculty physicians surveyed indicated that they teach the knowledge, skills, and attitudes that make up each of the core competencies as follows: medical knowledge (96.3%), patient care (95.7%), professionalism (90.7%), ICS (86.3%), PBLI (85.9%), and system-based practice (79.6%; Figure 2). Faculty characteristics, such as specialty (medical vs surgical), years in practice (1-10 vs >10), and number of rotations taught per year (1-6 vs 7-12) were not associated with the level of knowledge of the core competencies

Table 1. Teaching faculty physician characteristics (N = 164)

Characteristic	n (%)
Faculty specialty	
Teaching surgical residents[a]	31 (18.9)
Teaching medical residents[b]	133 (81.1)
Years in practice	
1-10	76 (46.3)
> 10	88 (53.7)
Formal rotations taught per year	
1-3	81 (49.4)
4-6	30 (18.3)
7-9	20 (12.2)
10-12	33 (20.1)

[a] Includes general surgery, plastic surgery, obstetrics and gynecology, orthopedics (listed under "other"), and neurosurgery.
[b] Includes family medicine, internal medicine, sports medicine, and geriatric medicine.

Table 2. Factors associated with faculty level of knowledge of ACGME core competencies

Factor	Not sure (n = 65), n (%)	Know the names, (n = 55), n (%)	Well versed, (n = 44), n (%)	p value
Faculty specialty				
Surgical	8 (25.8)	15 (48.4)	8 (25.8)	0.11
Medical	57 (42.8)	40 (30.1)	36 (27.1)	
Years in practice				
1-10	24 (31.6)	30 (39.5)	22 (28.9)	0.13
> 10	41 (46.6)	25 (28.4)	22 (25.0)	
Teaching rotations per year				
1-6	49 (44.1)	38 (34.2)	24 (21.6)	0.07
7-12	16 (30.2)	17 (32.1)	20 (37.7)	

ACGME = Accreditation Council for Graduate Medical Education.

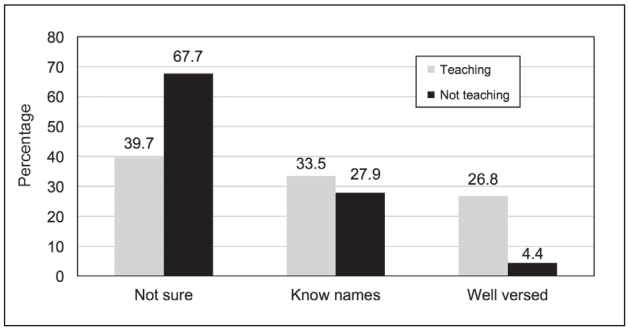

Figure 1. Knowledge of ACGME core competencies by physician's teaching status.

Know names = know names of the ACGME core competencies, well versed = have worked with the ACGME milestones or developed objectives or curricula based on the competencies.
ACGME = Accreditation Council of Graduate Medical Education.

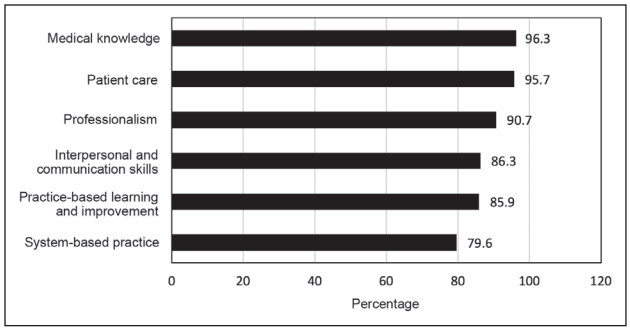

Figure 2. Faculty perception of incorporating ACGME core competencies in resident education enough to achieve mastery of the competency.

ACGME = Accreditation Council of Graduate Medical Education.

($p > 0.05$). Regardless of the faculty characteristics, the percentage of faculty who were "unsure" of their knowledge of the competencies was high (n = 65, 39.6%; Table 2).

Junior (< 10 years in practice) and full-time (teaching 10-12 rotations per year) faculty were more likely than senior faculty and faculty who teach less than 10 rotations per year to endorse competency-based education. These findings were particularly demonstrated for junior faculty who emphasized medical knowledge in residents' education (100% vs 93.2% for senior faculty, $p = 0.021$), and for full-time faculty endorsement of professionalism ($p = 0.003$) and ICS ($p = 0.006$; Table 3).

Faculty perception of residents' performance in relation to the 6 core competencies is demonstrated in Table 4. Most of the faculty thought that residents' performance in relation to the 6 core competencies was not a weakness of the program. When considering residents' performance, 11.6% of faculty thought that medical knowledge was a program weakness. Such weakness was less commonly perceived for system-based practice (6.7%), PBLI (6.1%), patient care (2.4%), ICS (2.4%), and professionalism (2.4%).

DISCUSSION

Competency-Based Teaching

Our study shows that at the time of starting new residency programs (in general surgery, psychiatry, and internal medicine) at a community teaching hospital, only 60% of faculty physicians had some knowledge (well versed or knew the names) of the ACGME core competencies. However, most (80%-96%) of those faculty indicated their dedication and active participation in teaching the principles and goals outlined in the competencies. In addition, the competencies were not equally ingrained in the

Table 3. Factors associated with competency-based teaching regarding each of the six core competencies[a]

Factor	N[b]	Medical knowledge, n (%)	Patient care, n (%)	Professionalism, n (%)	Interpersonal and communication skills, n (%)	Practice-based learning and improvement, n (%)	System-based practice, n (%)
Specialty							
Surgical	31	30 (96.8)	31 (100.0)	28 (90.3)	28 (90.3)	27 (87.1)	23 (74.2)
Medical	132[c]	127 (96.2)	125 (94.7)	118 (90.8)	111 (85.4)	113 (85.6)	106 (80.9)
p value		0.88	0.42	0.93	0.47	0.88	0.53
Years in practice							
1-10	75[c]	75 (100.0)	74 (98.7)	70 (93.3)	64 (87.7)	67 (89.3)	63 (84.0)
> 10	88	82 (93.2)	82 (93.2)	76 (88.4)	75 (85.2)	73 (82.9)	66 (75.9)
p value[d]		**0.02**	0.22	0.28	0.65	0.21	0.41
Teaching rotations per year							
1-3	80[c]	76 (95.0)	76 (95.0)	72 (92.3)	69 (88.5)	68 (85.0)	64 (80.0)
4-6	30	28 (93.3)	29 (96.7)	27 (90.0)	23 (76.7)	25 (83.3)	22 (73.3)
7-9	20	20 (100.0)	18 (90.0)	14 (70.0)	14 (70.0)	17 (85.0)	15 (75.0)
10-12	33	33 (100.0)	33 (100.0)	33 (100.0)	33 (100.0)	30 (90.9)	28 (87.5)
p value[d]		0.37	0.15	**0.003**	**0.006**	0.45	0.18

[a] Percentage is the percentage of the row total; for example, 30/31 = 96.8% of surgical specialists emphasized medical knowledge in their teaching of residents.
[b] Total number of faculty in the cohort.
[c] There was one faculty member who did not answer the questions pertaining to this Table.
[d] Boldface p values indicate statistical significance.

Table 4. Faculty perception of residents' performance across six core competencies

Core competency	Strength, n (%)	Neither strength nor weakness, n (%)	Weakness, n (%)
Medical knowledge	66 (40.2)	79 (48.2)	19 (11.6)
Patient care	93 (56.7)	67 (40.9)	4 (2.4)
Professionalism	90 (54.9)	70 (42.7)	4 (2.4)
Interpersonal and communication skills	82 (50)	78 (47.6)	4 (2.4)
Practice-based learning and improvement	58 (35.4)	94 (57.3)	10 (6.1)
System-based practice	68 (41.5)	85 (51.8)	11 (6.7)

faculty members' teaching methods, with PBLI and system-based practice being the least commonly emphasized. The lack of awareness of the core competencies came in contrast to the acclaimed implementation of competency-based teaching and led our program to establish faculty development educational seminars to improve faculty awareness of the standards of medical education. If the numbers from our study were generalizable to community hospitals without established residency programs, they should alert residency program directors to the importance of conducting needs assessment before starting a residency program. Such assessment should objectively clarify faculty knowledge of the 6 core competencies and competency-based teaching. Such assessment would also be useful for the ACGME in assessing whether the faculty members of a newly proposed residency program have the necessary information regarding educational goals that are set by the ACGME.

… among the six competencies, practice-based learning and improvement and system-based practice were the least likely to be emphasized competencies in residents' education.

Our findings that some physicians from community hospitals without dedicated teaching programs have had gaps in knowledge of the standards of medical education (as set by the ACGME) are important for hospitals that plan to start a new residency program. Faculty members are expected to be well versed in the six core competencies to be able to deliver competency-based education to residents as required by ACGME. A needs assessment survey is potentially an easy and efficient tool to identify such gaps before the start of a residency program. One approach to improve faculty knowledge of the ACGME standards of education is using faculty development seminars to improve competency-based teaching knowledge and skills.[9,10] Our program adopted this strategy to address the gap in knowledge of the six core competencies. Gaps in physicians' knowledge of the educational goals can be far more than expected, and we hypothesize that using educational seminars might become an effective tool to address such deficiency in knowledge.

Our study also shows that individual components of the ACGME core competencies were variably emphasized during residents' education, suggesting the need for systematic and standardized teaching methods to emphasize all six competencies with equal importance. Our data show that among the six competencies, PBLI and system-based practice were the least likely to be emphasized competencies in residents' education. It is not clear whether these findings are related to lack of conceptual understanding of those competencies or to inadequate practical opportunities to apply them. In fact, these competencies were shown to be conceptually difficult for residents and faculty.[11] Therefore, residency programs that instituted resident and faculty teaching that specifically target those competencies seem to have success in improving PBLI and system-based practice for residents and faculty.[11,12]

Certain faculty characteristics seemed to affect their implementation of specific competency-based teaching. Full-time faculty members were more likely to emphasize each of the individual competencies compared with faculty who taught fewer than 6 rotations per year. This was particularly true for teaching professionalism and ICS. Because the understanding and teaching of professionalism and ICS can be challenging,[13] their emphasis by full-time faculty (compared with part-time faculty) might be coming from their more extensive interaction with residents and appreciation of the importance of those competencies. Full-time status might also reflect the faculty interest in resident education with subsequent self-commitment to understanding the educational requirements for residents' education.

Junior faculty members (< 10 years since graduation) were also more likely to emphasize the core competencies. This finding might be explained by ACGME's enforcement of competency-based education, resulting in early and extensive exposure of junior faculty to the values of those competencies during their training. These findings will help identify faculty characteristics that are important for new community-hospital residency programs in meeting the ACGME requirements for residents' education.

Study Limitations

Our study has many limitations. First, the results of this study may not be generalizable because of the limited subject population from a single community hospital. Furthermore, our pool of physicians may not simulate a true faculty distribution at a community teaching hospital, given that only 20% of the surveyed physicians were full-time faculty. Second, we did not objectively assess the effect of the educational seminars on the faculty teaching behaviors and knowledge. Third, the study evaluated faculty perception of implementing competency-based education to achieve residents' mastery of the competencies; however, those answers are subjective and may be biased. Unfortunately, objective assessment of faculty teaching methods can be challenging and difficult to measure.[14] Fourth, the response rate to our survey was 50%, which can affect the validity of our results; however, the response rate in our study is comparable to that of other studies in the literature.[15] One potential explanation of this response rate is the high number of nonteaching physicians in our hospital.

Even in our survey responses, nonteaching physicians formed 28% (n = 70) of the responding physicians.

Fifth, we do not have information about the characteristics of those who did not respond to the survey, which could have biased our results. Sixth, our survey spanned multiple specialties, whereas our intended new residency programs were limited to a few of them. This might limit generalizing the final findings to the faculty from specialties with the newly proposed residency programs. However, our findings were not different between medical and surgical specialties overall. In addition, faculty knowledge of the competencies is not expected to be different by specialty. Seventh, although associations between faculty characteristics and knowledge of the competencies were noticed, these associations do not necessarily imply causality.

Despite these limitations, we presented our experience of conducting a needs assessment before starting new residency programs, which might be helpful for community hospitals planning to begin a new residency program. We highlighted the important findings, lessons learned, and the methods used to address these findings.

CONCLUSION

Awareness of the ACGME core competencies among faculty of new residency programs in community teaching hospitals cannot be assumed without objective assessment; therefore, needs assessment is essential to identify deficits in requirements for starting a new residency program. Although most teaching physicians actively enforce teaching the knowledge surrounding the core competencies, their knowledge of those competencies could be improved. The use of explicit directions during workshops is one of the approaches that has a tangible effect on instilling the virtues of the core competencies. The lack of faculty orientation to the core competencies could be further investigated to include their source of current medical educational guidelines as well as their graduating institutions' degree of raising awareness of the competencies. Further research also is needed to objectively evaluate physicians' teaching methods as they relate to the goals stated for each competency. ❖

Disclosure Statement

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In the Same Class

When a simple, earnest spirit animates a college, there is no appreciable interval between the teacher and the taught—both are in the same class, the one a little more advanced than the other.

— William Osler, MD, 1849-1919, physician, pathologist, teacher, diagnostician, bibliophile, historian, classicist, essayist, conservationalist, organizer, manager, and author

CME credits available for this article — see page 128.

ORIGINAL RESEARCH & CONTRIBUTIONS

Special Report

Anal Health Care Basics

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ABSTRACT

Despite the fact that countless patients suffer from anal problems, there tends to be a lack of understanding of anal health care. Unfortunately, this leads to incorrect diagnoses and treatments. When treating a patient with an anal complaint, the primary goals are to first diagnose the etiology of the symptoms correctly, then to provide an effective and appropriate treatment strategy.

The first step in this process is to take an accurate history and physical examination. Specific questions include details about bowel habits, anal hygiene, and fiber supplementation. Specific components of the physical examination include an external anal examination, a digital rectal examination, and anoscopy if appropriate.

Common diagnoses include pruritus ani, anal fissures, hemorrhoids, anal abscess or fistula, fecal incontinence, and anal skin tags. However, each problem presents differently and requires a different approach for management. It is of paramount importance that the correct diagnosis is reached. Common errors include an inaccurate diagnosis of hemorrhoids when other pathology is present and subsequent treatment with a steroid product, which is harmful to the anal area.

Most of these problems can be avoided by improving bowel habits. Adequate fiber intake with 30 g to 40 g daily is important for many reasons, including improving the quality of stool and preventing colorectal and anal diseases.

In this Special Report, we provide an overview of commonly encountered anal problems, their presentation, initial treatment options, and recommendations for referral to specialists.

INTRODUCTION

Despite the fact that countless patients suffer from anal problems, there tends to be a lack of understanding of anal health care. Unfortunately, this leads to incorrect diagnoses and treatments. This problem is compounded by the stigma associated with suffering from anal problems, which discourages patients from seeking help and getting the appropriate care.

The Basics

When treating a patient with an anal complaint, the primary goals are to

1. diagnose the etiology of the symptoms correctly
2. provide an effective and appropriate treatment strategy
3. confirm with a follow-up appointment that the problem has resolved or is under control. If symptoms have not improved, additional evaluation may be needed.

The chief complaint and history of the present illness are the first pieces of the puzzle to put together to reach the correct diagnosis. Obtaining specific information from the patient is imperative. For example, a chief complaint and history of present illness of "hemorrhoids" is not sufficient and frequently is counterproductive.

History

Discovering the patient's main symptom(s) is key: pain, bleeding, itching, tissue prolapse, excessive tissue, and drainage are some of the most common symptoms of underlying anal disease. Investigating the details of the patient's symptoms is important because "hemorrhoids" comprise less than half of the diseases causing these anal symptoms. For example, although there are many problems that can lead to anal pain, one of the most common is an anal fissure, which is frequently misdiagnosed as hemorrhoidal disease.[1]

Important history questions:

- How often do you have a bowel movement?
- What is the quality and consistency of the bowel movement (ie, hard, soft, watery)?
- How long do you sit on the toilet?
- Do you read or play games on your phone while having a bowel movement?
- Do you have anal pain/bleeding/incontinence to stool or gas?
- How do you clean the area? Do you use any wipes or ointments?
- Do you currently take a fiber supplement? If yes, which type and how much?

ANAL HEALTH PHYSICAL EXAMINATION

The physical examination comprises three components:

1. External Visual Examination

- Thorough visual inspection is important. This requires manual retraction of the surrounding buttocks with both of your gloved hands to expose the perianal skin.
- Look for signs of acute or chronic skin irritation, contact dermatitis, a punctate external fistula opening, erythema and painful raised area (abscess), or thrombosed external hemorrhoid with or without overlying skin ulceration.
- Be knowledgeable about the difference between an anal skin tag, an external hemorrhoid, and a sentinel skin tag adjacent to a fissure that might not be evident.
- Evaluation for anal fissure can be difficult as the patient typically has anal

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Table 1. Anal itching (pruritus ani)	
What is it?	Itching around the anal area, often iatrogenic or because of excessive moisture, cleaning, or harsh chemicals in wipes or ointments. This problem is unrelated to hemorrhoids.
Symptoms	Itching, discomfort, irritation, burning sensation in the perianal area. The itching sensation can be so severe that patients scratch in the middle of the night.
Treatment	1. Properly bulk the stool with adequate fiber to bind any bile irritants or other food or digestive-related irritants to the anal area (Table 8). 2. Clean with water only; excessive cleaning is discouraged. 3. Anal or intimate wipes will induce or exacerbate anal itching. The chemicals found in these products are irritants to the sensitive perianal skin.[2-5] 4. Dry the area without wiping or rubbing. Pat dry, air dry, or use a blow-dryer on low/medium heat if needed. 5. Apply skin-protecting barrier ointments to dry and clean perianal skin (zinc oxide 40%). 6. Avoid petroleum-based topical ointments because patients can develop contact dermatitis with daily use.[6] 7. Anesthetic ointment with dibucaine can decrease the urge to scratch the skin. 8. Stop any scratching. 9. Avoid irritating clothing (avoid G-strings and panty liners; wear underwear made of undyed cotton). 10. **Do NOT prescribe steroid-based hemorrhoid treatments**. They can harm the patients, especially with extended use.[7] 11. There can be visible skin changes, but if those are not resolving over time, the patient may need a biopsy to rule out another pathology (ie, Paget disease).
Key point: Anal itching is most often a dermatologic problem unrelated to hemorrhoids or other anal diseases. Anal itching is typically a secondary symptom of topical remedies for "hemorrhoids" and/or of excessive anal hygiene behaviors.	

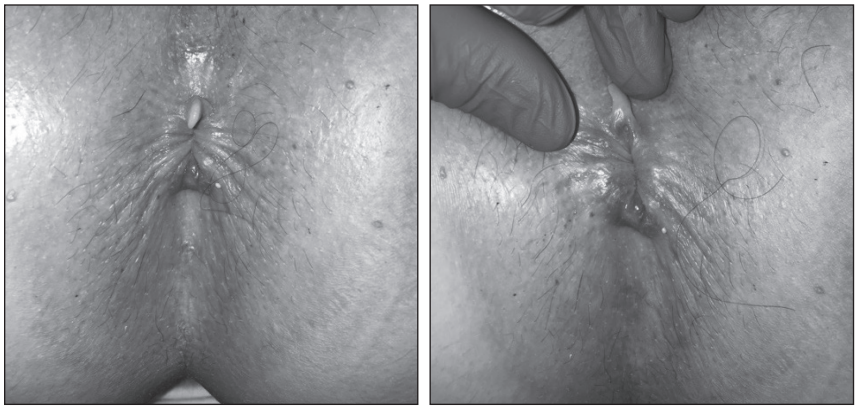

Figure 1. Repeated tearing and healing of an anal fissure can lead to a sentinel tag (1a, left). An anal fissure (1b, right) can be seen in the posterior midline with upward retraction. *Photos courtesy of Daniel Popowich, MD, FACS, FASCRS.*

Table 2. Anal fissure	
What is it?	A cut or tear in the anal canal typically caused by passing a hard stool. Patients often complain of severe anal pain and bleeding with bowel movements. On physical examination, you may see the fissure or just the sentinel tag. If the examination appears normal, you can elicit point tenderness. We recommend against continuing the digital rectal examination or anoscopy if the patient is having pain during the examination. You will need to use both gloved hands or have an assistant help to retract the buttocks and perianal skin to examine the anal canal. Patients frequently have anal hypertonia (spasm) as well, further making the anal canal more difficult to visualize.
Symptoms	Pain and bleeding, often after a hard stool or trauma. Pain can persist for days to years and radiate down to the legs, even when bleeding is no longer present. The patient may also have a burning or tearing sensation.
Treatment	The primary goals are to properly bulk the stool with adequate fiber and relax the anal muscle. Specific steps include the following: 1. Properly bulk the stool with adequate fiber to minimize constipation and diarrhea (Table 8); both frequent bowel movements and hard bowel movements can lead to an anal fissure.[8] 2. Temporary use of laxatives such as daily Miralax or senna. The dose of Miralax can be titrated up or down to achieve desired results. As the patient's fiber supplementation increases, the need for Miralax will diminish. Note: AVOID docusate (Colace) and other stool softeners because these agents are typically ineffective. 3. Chronic use of laxatives should be avoided because it can lead to worsening colonic function and constipation. 4. Diltiazem 2% ointment is to be placed on the anal muscle 3 times daily—continue for a minimum of 8 weeks, even if symptoms improve earlier.[9] 5. If a patient cannot tolerate diltiazem, or is breastfeeding or pregnant, 0.2% nitroglycerin-compounded ointment can be prescribed. However, the proper dose of nitroglycerin is important as too high of a dose can cause severe headaches.[10] 6. Do NOT prescribe hemorrhoid ointments or suppositories, especially steroid-based ones. Steroid ointments **do not** help. They **do** cause perianal skin thinning and dermatitis. At best, they act as a placebo, but they often are used chronically and cause unpleasant perianal skin changes.[11] 7. Use mental anal muscle relaxation: Actively thinking about relaxing sphincter tone. 8. Consider sitz baths: Soaking the anal area in warm water induces relaxation. Warmer water induces more relaxation. No additives are needed.[12] 9. Surgical intervention (such as Botox injections or sphincterotomy) is considered for patients whose symptoms do not improve with the above management strategies. It is imperative that the patient increases fiber and water intake so bowel movements are very soft before surgical intervention to maximize chances of postoperative healing.[13]
Tip: Dibucaine 1% ointment can be added for local pain control. This is for local anesthesia and skin protection and is not a replacement for diltiazem. Tip: Avoid prescribing narcotics because this will make the patient more constipated and prevent the fissure from healing. *Key point: When a chief complaint is anal pain and bleeding, anal fissure should be high on the differential even if the actual fissure is not clearly seen on an examination that is limited because of anal pain.*	

hypertonia (anal spasm) as well. You may need an assistant to help you fully retract the peri-anal skin and efface the anal canal for a complete visual examination. If you find an anal fissure, do NOT proceed with digital rectal examination or anoscopy at this time; digital examination and anoscopy are extremely painful examinations for the patient with an anal fissure. You should perform a digital examination and anoscopy after the patient's symptoms resolve (typically six to eight weeks later with appropriate treatment).

2. Digital Anal Canal and Lower Rectal Examination

- Although it is uncomfortable, most patients without an active fissure, abscess, or thrombosed external hemorrhoid are able to tolerate this examination.
- If a patient reports too much pain to attempt or tolerate the examination and external pathology is not seen (except skin tags), then reexamine the external area and gently press with your finger or a cotton swab to place pressure on all soft tissue circumferentially around the anal area to check for an area of maximum tenderness. If such an area is found, occasionally the more thorough external examination alone reveals the source, such as a fissure or deeper abscess.

3. Anoscopy

Do NOT perform anoscopy if any of the following are present:

- The patient has a midline (anterior or posterior) anal fissure.
- The patient is having anal pain during digital examination or cannot tolerate a digital examination.
- A tender purple marble-like "ball" that is firm is present—it is likely a thrombosed external hemorrhoid.
- A red, fluctuant, tender area is present—it is likely an abscess.

Key point: If a mass is seen on external examination or anoscopy and there is any question of pathology such as malignancy, the area should be evaluated by a physician familiar with diseases of the anus and rectum to further determine whether biopsy is indicated.

COMMON ANAL PROBLEMS

Benign Anal Disease

Many problems may be categorized as hemorrhoids by the general public. However, the etiologies and management can vary, so it is important to differentiate between entities such as anal itching (Table 1), anal fissure (Figure 1, Table 2), hemorrhoids (Table 3), and anal abscess/fistula (Figure 2, Table 4). Another benign anal problem that patients may attribute to hemorrhoids is anal incontinence (Table 5).[2-26]

Table 3. Hemorrhoids

What is it?	Hemorrhoidal venous cushions are normal structures of the anorectum. The term "hemorrhoids" is commonly used to describe the pathologic state when these blood vessels become engorged, become thrombosed, or protrude.
Internal hemorrhoids	
What is it?	Hemorrhoids above the dentate line. These can prolapse below the dentate line and appear as protruding from the anal area. Internal hemorrhoids often bleed, especially during a bowel movement. They typically do not cause severe anal pain. However, internal hemorrhoid prolapse can be associated with discomfort or pressure.
Symptoms	Typically patients will complain of painless bleeding with a bowel movement either in the toilet, on cleaning, or both. Hemorrhoidal tissue may protrude when straining or when having a bowel movement. The tissue may self-reduce or need manual reduction with firm pressure.
External hemorrhoids	
What is it?	Hemorrhoids below the dentate line. These can become thrombosed when blood clots form because of straining or excessive time on the toilet. External hemorrhoids are painful only when thrombosed. This problem tends to be self-limited in duration, with pain decreasing daily after the first 2 or 3 days and the thrombosis resolving over days to weeks.
Symptoms	Anal pain with a firm marble-like area around the anus, typically purplish in color. Bleeding occasionally occurs when there is pressure necrosis and the clot erodes through the overlying ulcerated skin. Pain is usually the worst in the first 48 hours.
Treatment for internal and external hemorrhoids	
1. Properly bulk the stool with adequate fiber and water to minimize constipation and diarrhea (Table 8); both frequent bowel movements and hard bowel movements can lead to hemorrhoidal problems.[14,15]	
2. Temporary use of laxatives such as daily Miralax or senna.[16] The dose of Miralax can be titrated up or down to achieve desired results. As the patient's fiber supplementation increases, the need for Miralax will diminish. Note: AVOID docusate (Colace) and other stool softeners or laxatives because these agents are typically ineffective. Chronic use can lead to worsening colonic function and constipation.	
3. Consider prescribing dibucaine 1% ointment to act as a lubricant helpful for reduction of prolapse or for pain control in the case of thrombosis.	
4. Restrict sitting on the toilet to no longer than 1 to 2 minutes.[17]	
5. When on the toilet, place a stool under the feet to mimic squatting position.[18-21]	
6. Do not recommend donut-shaped pillows, which can worsen the problem because this places more stretch and tension on the anal skin.	
7. Do NOT prescribe hemorrhoid ointments or suppositories, especially steroid-based ones. Steroid ointments *do not* help treat hemorrhoidal problems and do not induce shrinking of hemorrhoidal tissue. They *do* cause perianal skin thinning and dermatitis. At best, they act as a placebo, but they often are used chronically and cause unpleasant perianal skin changes.	
Tip: Thrombosed external hemorrhoids are typically self-limited. Surgical treatment with elliptical excision of the clot and overlying skin has the best results when performed within the first 48 hours of symptom onset or if there is skin ulceration or necrosis. Clot evacuation only relieves symptoms but can eventually result in a skin tag disliked by some patients. Surgical excision of the clot and overlying skin performed after 48 hours of symptoms typically results in worsening pain and bleeding compared with the pain level associated with spontaneous clot absorption.[8,22]	
Key point: Hemorrhoidal disease is a result of inadequate fiber intake that leads to constipation, diarrhea, straining, and spending excess time (more than 2 minutes) on the toilet. A change in lifestyle and bathroom habits is key for relief of symptoms and to prevent recurrence. Even in cases where surgical intervention is needed, implementing these changes first results in better short- and long-term results after surgery.[23-25]	

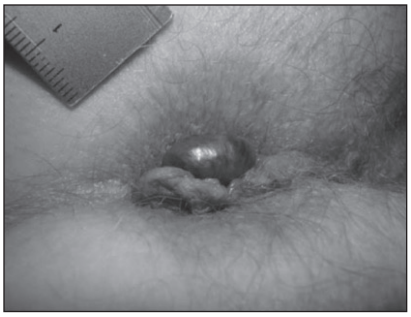

Figure 2. Thrombosed external hemorrhoid.[1]

1. Gebbensleben O, Hilgery Y, Rohde H. Aetiology of thrombosed external haemorrhoids: a questionnaire study. BMC Res Notes 2009 Oct 23;2:216. DOI: http://dx.doi.org/10.1186/1756-0500-2-216. Copyright policy—open access: https://openi.nlm.nih.gov/faq.php#copyright; License: http://creativecommons.org/licenses/by/2.0.

Table 4. Anal abscess/fistula (cryptoglandular disease)

What is it?	Infection of the anal gland. The anal abscess is the acute phase, and the fistula is the chronic phase. A fistula occurs when an anal abscess develops a connection to the perianal skin. This occurs approximately 50% of the time.
Anal abcess	
Symptoms	Acute pain and redness around the anal area. They spontaneously drain or need incision and drainage. Some forms, such as intersphincteric abscesses, can present with a normal external examination but with tenderness and fullness on digital rectal examination.
Treatment	Typically immediate incision and drainage is best; often antibiotics alone are inadequate. Outpatient surgical referral can lead to a delay in treatment. *Key point: Severe new-onset perianal pain without a visible finding could indicate a higher abscess that is not yet visible at the skin. Early surgical evaluation is indicated.*
Anal fistula	
Symptoms	Chronic drainage from the anal area where usually a small opening near the anus with surrounding granulation tissue can be seen. The drainage can include stool, pus, or blood.
Treatment	Referral to surgery department is appropriate.

Common Anal Masses

Similarly, not all masses near the anus represent hemorrhoids, though the difference can be subtle. Anal skin tags (Figure 3, Table 6) are usually the result of excess skin after repeated scarring (such as healing from an anal fissure), and anal warts (Figure 4, Table 7) are commonly outgrowths of tissue caused by viral infection.

DIETARY AND LIFESTYLE CHANGES

Fiber

The Industrial Revolution has resulted in a diet lacking in sufficient fiber. People tend to lack knowledge about how much fiber they are consuming, or how much they should consume.[27] In addition, fiber is typically marketed as a "laxative," and patients with diarrhea or loose stool are frequently nervous about taking a product that is for "constipation." Fiber works by absorbing and retaining fluid,

Table 5. Anal incontinence (accidental bowel leakage)

What is it?	Inability to control stool and/or gas.
Symptoms	Inability to hold in stool and/or gas whenever desired.
Treatment	Primarily consists of increasing fiber intake to bulk stools (Table 8). Kegel exercises and physical therapy referral can be useful.[26] In patients who are taking metformin or other medications that are associated with diarrhea and fecal urgency, alternative medical treatment strategies and therapies can significantly improve the patient's baseline continence level. If the patient has not had a colonoscopy, endoscopic evaluation may be helpful to diagnose inflammation of the colon and rectum that can lead to increased urgency and accidental bowel leakage. For refractory cases in otherwise healthy patients, surgical referral is an option.[8] However, adequate fiber intake and bulking of stool is a necessary prerequisite to all surgical interventions. Therefore, ensure that you have provided this education and management strategy before surgical referral.

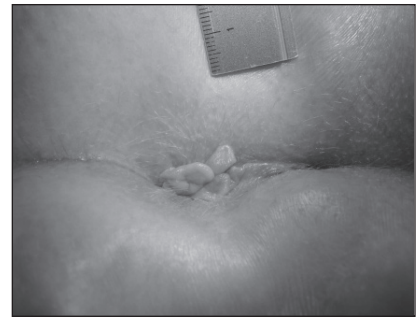

Figure 3a. Anal skin tags.

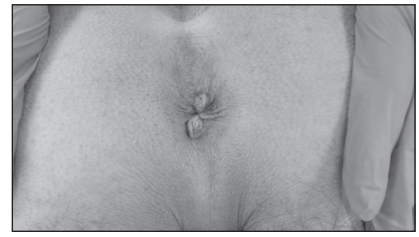

Figure 3b. Anal skin tag.
Photo courtesy of Talar Tejirian, MD, FACS.

Table 6. Anal skin tag

What is it?	A piece of excess skin located around the anal area that often results from healed thrombosed external hemorrhoid or anal fissure and is exacerbated by excess cleaning or rubbing. There should be no pain or bleeding, but patients can be bothered because excess skin is present.
Symptoms	Piece of extra tissue near or in the anal area. It typically starts small but with repeated trauma of excessive cleaning or recurrent thrombosed hemorrhoids or anal fissures, it slowly increases in size.
Treatment	1. Treat the underlying cause, such as recurrent external thrombosed hemorrhoids. 2. Excision can be performed if the patient desires, but it is important for the underlying problem to be addressed first. For example, if the patient gets recurrent anal fissures or thrombosed hemorrhoids, s/he must implement bowel and bathroom habits so these problems do not reoccur after skin tag excision.

thereby softening hard stool and thickening loose stool. Adequately fiber-bulked stool results in more complete evacuation with bowel movements, less sputtering of bowel movements, less straining with bowel movements, and more regularity with bowel movements.

The US Department of Agriculture and US Department of Health and Human Services recommend that you eat 25 g to 40 g of fiber daily,[28] but most people get less than half this recommendation.

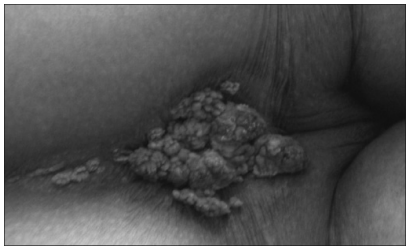

Figure 4. Anal Warts.

Reprinted from Gude D, Chennamsetty S, Jha R. Stalwart approach to stall wart. Indian J Palliat Care 2011 May;17(2):168-9. DOI: http://dx.doi.org/10.4103/0973-1075.84543 with kind permission from IJMS Publishing Team: Ivyspring Inquiry: www.medsci.org.

Table 7. Anal warts (condyloma acuminata)

What is it?	Growths of tissue in the area around and inside the anus that are caused by human papillomavirus. They may first appear as tiny spots or growths but can grow quite large and cover the anal area.
Symptoms	Usually, they do not cause pain or discomfort. Some patients may experience itching, bleeding, mucus discharge, or a feeling of a lump or mass in the area.
Treatment	If warts are small and located only on the skin around the anus, they may be treated with a topical medication such as podophyllin, trichloroacetic acid, and bichloroacetic acid. Topical agents that can be applied at home include imiquimod or 5-fluorouracil. They can also be treated in the office with cryotherapy (freezing with liquid nitrogen). For larger lesions, patients can be referred to a surgeon for fulguration and/or excision.

Table 8. Fiber supplementation instructions

My daily fiber intake goal	25-40 g daily
The US Department of Agriculture and US Department of Health and Human Services recommend that I eat 25 g to 40 g of fiber DAILY	1. Adequate fiber will regulate my bowel movements by a. softening hard stool and reducing the frequency of constipation b. adding bulk to loose stool and reducing the frequency of diarrhea. 2. Adequate fiber will improve my anal problems and bleeding by a. softening hard stool and making bowel movements less traumatic b. thickening loose stool and making bowel movements less traumatic. 3. Adequate fiber will reduce my risk of developing a. colon and rectal cancer b. diverticulosis c. complications of diverticulitis: Perforation, infection, emergency surgery. 4. Adequate fiber will reduce my cholesterol
How much fiber is in the food I eat?	1. The fiber content in foods that you eat can be found on the "Nutrition Facts" label for processed foods. 2. For fresh foods, fruits, and vegetables, there are a variety of Web sites that can give you the amount of fiber per serving. For example: www.NationalFiberCouncil.org; search for "fiber counter."
Go slow and keep it up	*Gradually* work your way up to taking 20 g of fiber daily in the form of a fiber supplement AND increase fiber in your diet so that you are eating at least 10 g to 20 g of dietary fiber daily. **Fiber supplement[a]: 20 g daily** **Dietary fiber: + 10-20 g daily** **Total fiber intake: 25-40 g daily**
Slow and steady fiber supplement ramp-up plan	Week 1: 1. Start counting the amount of fiber you consume in your diet on a daily basis. 2. Purchase a fiber product that you will be able to take every day for the rest of your life. Read the label to check the fiber content. Many fiber products, especially fiber pills, have very small amounts of fiber. Choose a fiber product with 5 g or more of fiber per serving. 3. Start drinking 8 to 10 glasses of water daily.
	Week 2: 1. Supplement your diet with 5 g of additional fiber daily. 2. Drink 8 to 10 eight-oz. glasses of water daily.
	Week 3: 1. Supplement your diet with 10 g of additional fiber daily. 2. Drink 8 to 10 glasses of water daily.
	Week 4 and beyond: Continue to increase the amount of additional fiber daily by 5 g per week until you reach your goal of 25 g to 40 g of fiber daily for life. TIP: If you feel bloated or develop excessive gas, you are increasing your daily fiber too quickly. You may need to increase your daily fiber over a longer period of time.

[a] Common fiber supplements: Metamucil, Konsyl, Citrucel, Fiber One. Choose the fiber supplement that works best for you. Be sure to calculate the fiber amount per serving size. Choose a fiber supplement that you would be willing to take every day as a 20-g dose (goal at the end of the ramp-up period). If you experience diarrhea with a natural fiber supplement or fiber supplement that claims "easy to take/dissolves in water," consider changing to one of the above brand names because some natural fiber supplements contain natural laxatives as well.

Warning: If you take Coumadin (warfarin), please be sure to speak with your primary care physician or cardiologist before starting a fiber supplement because fiber may interfere with your Coumadin international normalized ratio levels.

Adequate fiber intake is important for many reasons:

1. Fiber helps regulate bowel movements by softening hard stool to reduce constipation and adding bulk to loose stool to reduce diarrhea
2. Common anal problems such as fissures and hemorrhoids are caused by inadequate fiber and water intake
3. Adequate fiber will reduce the risk of developing colorectal cancer, diverticulosis, and complications of diverticulitis
4. Adequate fiber will reduce cholesterol.

When advising patients regarding increasing fiber intake (Table 8)

- stress the fact that most people do not consume adequate fiber
- advise patient to keep a log of the daily fiber intake for one week to see exactly how much the intake really is
- ask them to read food labels thoroughly to check fiber content instead of assuming labels such as "whole wheat" mean a high fiber content
- adding fiber supplements is helpful, but caution is needed when choosing the fiber supplement. Commonly used supplements like "fiber pills" and orange-flavored psyllium are inadequate. Reading the labels of these products, including the serving size and fiber content, is important. For example, most fiber pills have half a gram of fiber. Therefore to get 20 g of additional daily fiber, someone would need to take 40 pills a day
- increasing water intake to at least 64 oz daily is needed so fiber can work properly. Daily intake of caffeinated beverages would increase the need for water intake owing to caffeine's diuretic properties.

Proper Bowel Movements

When advising patients on a proper bowel movement, the following key points should be emphasized:

- Spending excessive time on the toilet is harmful. Avoid sitting on the toilet more than two minutes
- The rectum empties better when in a squatting position. When using a Western toilet, place a stool under your feet and lean forward to mimic that position
- Do not clean excessively and avoid cleansing wipes. Use water without chemicals. Using a bidet attachment eases the cleaning process in a quick and simple manner.

CONCLUSION

Most anal health problems are a result of inadequate fiber and water intake along with poor bowel and bathroom habits. With improved awareness and understanding on the physician's part, and guided changes in dietary intake and bathroom behavior modifications on the patient's part, most patients will have complete resolution of their symptoms. Accurate evaluation and diagnosis are the key. This can be achieved with a thorough history and physical examination. The assumption by patients and physicians that most anal problems are caused by "hemorrhoids" leads to an error in diagnosis, incorrect management strategies, worsening of disease-related symptoms, development of new symptoms such as contact dermatitis, and delay in accurate diagnosis and resolution of symptoms. Avoiding harmful products such as anal wipes and steroid ointments or suppositories is important because contact dermatitis is associated with worsening of the anal symptoms and delayed symptom improvement, once an accurate diagnosis has been made. If there is a question as to the correct diagnosis or treatment, referral to a specialist in diseases of the anal and rectal area can be helpful. Online resources may be found in the Sidebar: Useful Online Resources. ❖

Useful Online Resources

The American Society of Colon and Rectal Surgery Web site is an excellent resource for both patients and physicians. There are a variety of online learning tools for physicians. In addition, each and every anal disease that we covered in this article is thoroughly presented in a patient-friendly format that can be printed for additional patient education. The Web addresses are as follows:

www.fascrs.org
www.fascrs.org/patients/disease-condition/pruritis-ani
www.fascrs.org/patients/disease-condition/anal-fissure
www.fascrs.org/patients/disease-condition/anal-fissure-expanded-information
www.fascrs.org/patients/disease-condition/hemorrhoids
www.fascrs.org/patients/disease-condition/hemorrhoids-expanded-version
www.fascrs.org/patients/disease-condition/abscess-and-fistula-expanded-information
www.fascrs.org/patients/disease-condition/bowel-incontinence
www.fascrs.org/patients/disease-condition/anal-warts-and-anal-dysplasia-expanded-information

Patient friendly educational material is available from: www.bootymd.org

Disclosure Statement

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

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Bubo

Bubo is an apostem breeding within the anus in the rectum with great hardness but little aching. This I say, before it ulcerates, is nothing else than a hidden cancer … . Out of the bubo [cancer] goes hard excretions and sometime they may not pass, because of the constriction caused by the bubo, and they are retained firmly within the rectum … . I never saw nor heard of any man that was cured … but I have known many that died of the foresaid sickness.

— John of Arderne, 1307-1392, English surgeon: Father of English Surgery

Bamberg
photograph

Samuel H Glassner, MD

This photograph was taken in the city of Bamberg, in southern Germany. The historic Town of Bamberg is a designated UNESCO World Heritage Site—some of its well-preserved medieval architecture and layout dates back to the 11th century. The sculpture pictured here, *Centurione I,* represents a modern (2002) interpretation of classical themes.

Dr Glassner is a retired Emergency Physician from the Walnut Creek Medical Center in CA.

Special Report

Implementation of the YMCA Diabetes Prevention Program throughout an Integrated Health System: A Translational Study

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Perm J 2016 Fall;20(4):15-241

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ABSTRACT

Context: HealthSpan Physicians (HSP), an integrated medical system in Northeast Ohio, partnered with the Young Men's Christian Association (YMCA) of Greater Cleveland to implement a referral system for the evidence-based Diabetes Prevention Program (DPP) throughout HSP. The YMCA of USA employs a cost-effective, customized version of the original DPP in which coaches take the place of in-house clinical staff. Efficacy of the YMCA DPP was shown earlier in the DEPLOY Study.

Objective: To improve outcomes of metrics used in the DEPLOY Study.

Design: Observational study focusing on engagement, persistence, recruitment, and adherence to the DPP. In August 2014, HSP mailed an invitation to 2200 patients identified as both Medicare eligible and at risk of prediabetes to attend no-obligation information sessions about the DPP. After these sessions, YMCA staff called interested participants and asked them to enroll in and to commit to the program. Motivation and reinforcement were provided to patients through YMCA-provided signs, brochures, and posters; the HSP Web site; and in-person conversations with primary care physicians.

Main Outcome Measures: Average weight loss at the end of 16 weeks in the program and average retention through Session 9.

Results: Of the 2200 patients contacted, 351 (16.0%) responded by attending the information session, and 228 enrolled in the YMCA DPP (11.3%) and persisted through at least Week 9. This result is an improvement over the 1.7% of eligible enrollees who responded to the DEPLOY Study's mailing.

Conclusions: A marketing approach to implementing the YMCA DPP in an integrated medical system results in excellent outcomes.

INTRODUCTION

As reported by the Centers for Disease Control and Prevention (CDC), more than 86 million patients have prediabetes, defined as impaired glucose tolerance (2-hour plasma glucose level between 140 and 199 mg/dL) or impaired fasting glucose level between 100 and 125 mg/dL.[1] People with prediabetes are at increased risk for development of Type 2 diabetes.[2] Obesity and/or overweight conditions (body mass index [BMI] > 25 kg/m^2) are major contributing factors to prediabetes and Type 2 diabetes.

However, the progression from prediabetes to Type 2 diabetes can be significantly slowed and/or reduced by patients' adhering to the protocol of an evidence-based Diabetes Prevention Program (DPP), developed in the mid-1990s with funding from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). In the first 3 years of the randomized, NIDDK-sponsored DPP Outcomes Study, the DPP lifestyle intervention group reduced the number of new cases of Type 2 diabetes by 58% compared with a placebo group.[3] In more than 10 years of randomized trials, the diabetes incidence in high-risk adults was reduced by 34% with intensive lifestyle intervention through the DPP.[4]

The DPP as originally constructed[5] was hard to implement and sustain in busy health care settings, where cost was also a major issue.[6] This problem has called for real-world adaptation, as with the Young Men's Christian Association (YMCA) of the USA's customized 52-week version of the program (16 weekly sessions followed by 9 more sessions during the following 8 months), wherein specially trained lifestyle coaches provide mentoring and support to the participants in group settings.[7] Even with referrals from primary care physicians (PCPs), enrollment and program attendance/adherence has been challenging in YMCA implementation efforts. For instance, in the well-known DEPLOY Study (Translating the Diabetes Prevention Program into the Community)—involving the Indiana School of Medicine and the YMCA of Indianapolis—there was a 1.7% client enrollment resulting from the initial mailing to 7500 Indianapolis households (Figure 1).[6p357]

Although the long-term effects of untreated prediabetes are well-known, education and information-only approaches to clients with prediabetes and to health providers have not resulted in adherence to the three pillars of prediabetes treatment: diet and nutrition change, change in exercise habits, and lifestyle change.[8] Unchecked obesity is a prime predictor of prediabetes, leading to the onset of Type 2 diabetes.

Despite this knowledge in patients and providers alike, the YMCA has experienced difficulty in attracting new clients to the preventive intervention of the YMCA DPP and in securing client adherence to the program protocol.

Here, we report unusually high outcomes in initial attendance, persistence, and weight loss resulting from a marketing approach to implementation of the DPP. This accomplishment was made possible through a partnership between the YMCA of Greater Cleveland and HealthSpan Physicians (HSP), a division of Mercy Health in Northeast Ohio.

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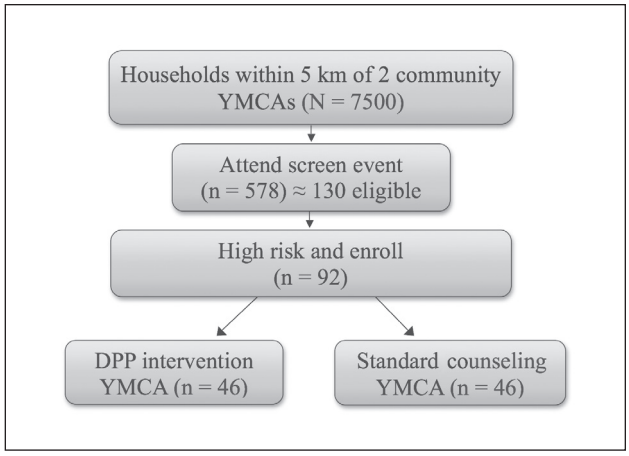

Figure 1. Implementation of the YMCA's Diabetes Prevention Program in the DEPLOY Study.[1]

[1] Ackermann RT, Finch EA, Brizendine E, Zhou H, Marrero DG. Translating the Diabetes Prevention Program into the community. The DEPLOY pilot study. Am J Prev Med 2008 Oct;35(4):357-63. DOI: http://dx.doi.org/10.1016/j.amepre.2008.06.035.

YMCA = Young Men's Christian Association; DPP = Diabetes Prevention Program.

METHODS

The initial thrust of the present partnership and translational study between the YMCA of Greater Cleveland and HSP, an integrated medical system, has been to motivate attendance at information sessions. The next goal was to encourage enrollment in the YMCA's DPP and adherence to the program protocol through at least the first nine weeks of the program. Nine weeks' attendance is the CDC-approved standard for persistence in the program, leading presumably to lasting behavior change.[9]

Because of demographic factors (location, income, and employment patterns), the present study was able to attract primarily (95%) African American women with prediabetes in the research cohort. The women were predominately older than age 50 years. Most were Medicare patients.

Obesity, as stated, is a leading indicator of risk for the onset of Type 2 diabetes. As Hamman et al[10] found in a large field study of DPP participants after 3 years of follow-up: "Weight loss was the dominant predictor of reduced diabetes incidence ... For every kilogram of weight loss there was a 16% reduction in risk."

Race is another major contributing variable in efforts to maintain weight loss. Largely because of obesity or overweight conditions, some racial and ethnic groups have a much higher risk for development of Type 2 diabetes. In 2003 to 2004, approximately 30% of non-Hispanic white adults were obese, as were 45% of non-Hispanic black adults and 36.8% of Mexican Americans. In that same period, black women exhibited the highest rates of overweight and obesity, at 58% of the population aged 40 to 59 years compared with about 38% of non-Hispanic white women of the same age.[11] Study after study has shown that both achievement and maintenance of weight loss has been particularly problematic for African American women, and the DPP protocol has been no exception.[12,13] In one controlled study using the DPP among different groups, West et al[14] found that African American women achieved and sustained roughly half the weight loss experienced by other ethnic groups.

Pilot Study (Phase 1)

In October 2013, HSP of Northeast Ohio and the YMCA of Greater Cleveland entered into a collaboration in which HSP would refer its eligible clients with prediabetes and the YMCA would conduct its customized version of the program (up to 25 sessions during the course of a year using trained lifestyle coaches). The first 9 weeks of the program focused on engagement, persistence, and recruitment.

In Phase 1 of this project, the pilot phase, the partners relied primarily on the following tactics to attract clients. First, the PCP recommended that his/her client investigate the YMCA DPP, because the client was suspected of having prediabetes. Second, if interested, the patient picked up an engagement brochure in the examination office—which was noted in the patient's record—giving a description of the program's content, plus the time and location of the next informational session. Also provided was a YMCA telephone number to call with questions. We then relied on the patient's own motivation (Stage 2 in the DiClemente and Prochaska "Stages of Change" hierarchy, "Contemplation" of lifestyle change) as to whether the patient would show up for the information session.[15] At this point, HSP engaged in a minimum of 2 telephone calls to repeat the invitation to attend the information session to those who had picked up the informational brochure in either the outer office or the examination room.

Initial efforts were focused on 2 HSP locations, each of which featured a predominately African American population. From October 2013 to July 2014, there were approximately 100 referrals to the information sessions, which resulted in 33 enrollees in the yearlong program. The enrollees provided consent to the tracking measures that were to be used. After 5 months of Phase 1 participation in the YMCA DPP, the following outcomes were reported: 1) 17 patients, or slightly more than 50%, persisted in the program through Week 16, the final weekly session; 2) of these 17 patients, the average weight loss was approximately 4.7% of body weight, which conforms closely to the national average at this stage. The goal for the 16-week period was 7% of body weight lost.

Phase 2

Because of the perceived success of the pilot effort, the project entered into Phase 2 (August 2014 through November 2015), extended to the entirety of the HSP network of patients in Northeast Ohio.

Thanks to a grant for Medicare-eligible older adults, Phase 2 of the project began in August 2014 with an HSP mailer to 2200 clients who had been identified in the electronic health record as both Medicare eligible and at risk of diabetes. The mailer invited them to information sessions to be held throughout the region. A follow-up mailer was sent to 1200 clients largely duplicative of these same people.

In addition, HSP and the YMCA decided to employ more of a marketing approach, featuring many touchpoints, or "touches" (methods or modes of contact between the organization and the consumer), and direct contact from the Population Management

Department staff. Via a referral form at our Cleveland locations, we captured the names of the clients who were referred to the YMCA DPP, which set into motion the following mechanism. Anyone who showed interest in the program—and was perceived as eligible—was exposed to additional motivators provided through signage, brochures, and telephone follow-up for scheduled sessions, in which the name of the PCP was invoked. A sample phone script follows:

Hi! I'm calling on behalf of Dr ___, from HealthSpan. In a recent visit, [s/]he noted that you were very possibly prediabetic and were in danger of developing Type 2 diabetes if this condition were not brought under control. Your doctor also mentioned the YMCA's Diabetes Prevention Program, in which trained coaches help you to bring about necessary changes in ____.

The next no-obligation information session on the YMCA's Diabetes Prevention Program is scheduled for ___ at either 1 pm or 6 pm. Which session would be most convenient for you to attend?

[If needed] We have other sessions … .

As described by Jay Conrad Levinson,[16] lead author of the best-selling book, *Guerilla Marketing for Non-Profits,* the idea here is (once a name is captured): "Follow-up, Follow-up, Follow-up!" At HSP, all were involved: the PCP, the clinical staff, and (using the electronic health records) the Population Management Department.

RESULTS

The summary impact of Phase 2, in terms of engagement and subsequent enrollment in the YMCA's DPP, was much greater than usually experienced with a direct-mail campaign and resulted in a greater turnout than in previous YMCA joint projects. Outcomes were

1. Of the 2200 Medicare patients identified as having or likely to have prediabetes and encouraged to attend a YMCA information session in their community, 185 attended various information sessions.
2. Of the attendees, 168 evidenced interest in enrolling in the program.
3. After screening, 160 remained eligible and provided informed consent, and 152 formally enrolled in the program.
4. Remarkably, 137 of these persisted in the program through the 9th class or longer. As mentioned previously, the 9th class is the CDC-approved standard for persistence in the program.

With this success, we amplified our efforts, involving supportive follow-up telephone calls from our Population Management Department. We sent a second mailer to 1200 persons from a duplicative group of Medicare clients identified—with the help of our electronic health record—as likely to have prediabetes. These results are displayed in Table 1, with an overall enrollment of 248 persons and a persistence rate through Week 9 of 228 enrollees, or 11.3% of those perceived as eligible for the program. This represents a far greater persistence rate than similar efforts heretofore reported in the DPP literature.[17,18]

Finally, in terms of weight loss, program outcomes exceeded national averages for the YMCA DPP, which are average weight loss at the end of the weekly sessions (week 16) of 4.6% and average retention (persistence) through Session 9 of 83.6%. As can be seen in Table 2, our corresponding figures were an average weight loss of 5.37% and a persistence rate through Week 9 of 91%.

There were only 20 dropouts in the program after Phase 1 and even fewer (N = 5) after the conclusion of Phase 2. This lower dropout rate in Phase 2 was counterintuitive because of the initially high participation rate. This phenomenon will be the subject of further analysis in forthcoming publications.

Tentatively, we have identified the salient factors in the success of the program as 1) PCP referral, 2) intervention from Population Management with personalized telephone calls, and 3) personalized follow-up from YMCA staff. The follow-up process, designed to maximize marketing touches with the patient, can best be summarized as

- PCP provides the patient referral and fills out referral form
- Population Management employee makes a telephone call to remind the patient of the upcoming information session and encourages attendance
- Patient attends the information session and provides a release of information to obtain BMI and blood test results
- Release documents are sent to Population Management to verify the BMI and qualifying blood test
- Information is sent to the YMCA
- YMCA makes up to three calls to patients who met the enrollment criteria to invite them to enroll in the program; those who did not meet the criteria are not invited to enroll.

Table 1. HealthSpan Physicians' and the YMCA's Diabetes Prevention Program enrollment data (October 13, 2013 to September 4, 2015)

Participant category	Group 1 (October 13, 2013)	Group 2 (April 15, 2014)	Total
Patients perceived as eligible and sent a letter	2200[a]	1220	3420
Attended an information session	186	165	351
Registered initial interest	168	158	326
Remained eligible after screening	160	118	278
Enrolled and attended the first class	152	96	248
Attended the ninth class[b]	137	91	228
Dropped out before the ninth class	15	5	20

[a] Of this total, 1220 patients received an additional duplicate mailing in March 2015 for classes commencing April 15, 2015.
[b] The ninth class is taken as the client's measure of efficacy/changed behavior, according to the Centers for Disease Control and Prevention.
YMCA = Young Men's Christian Association.

Table 2. Weight loss outcome measures in 228 participants who completed the program (Phase 2)[a]

Measure	Percentage
Persistence (attended ninth class)	91.0
Percentage of body weight loss	
Mean	5.37
Median	5.57

[a] Program completion was defined as completing a minimum of 9 classes, with some groups still in progress at the time of this writing.

DISCUSSION

Cost-Effectiveness

In conceiving cost-effectiveness metrics for the YMCA's DPP, there are at least 3 perspectives to be considered: 1) the cost of "doing nothing"—the cost to the patient and the medical provider/insurer incurred in treating diabetes itself, 2) the cost of the "next best (medicinal)" alternative, and 3) the added years of life expectancy.

With respect to the cost of doing nothing, the American Diabetes Association provides these statistics: "People with diabetes have health care expenditures that are 2.3 times higher ($13,741 vs $5853) than expenditures that would be expected for this same population in the absence of diabetes … [suggesting that] diabetes is responsible for $7888 in excess expenditures per year for the person with diabetes."[19] This latter figure is exclusive of indirect costs (unemployment, absenteeism, etc), which are considerable.

There is a significant difference in cost of the YMCA's DPP vs the cost of some recently approved weight loss drug treatments, which also result in an average 5% sustained weight loss over time (which is the Food and Drug Administration standard as of October 10, 2015).[20] As of this writing, the Food and Drug Administration has approved 5 weight loss drugs, ranging in cost from orlistat at $173/month to injectable liraglutide (Victoza) at $658/month.[21] The latter is approved for weight loss only in patients with Type 2 diabetes, but higher-dose liraglutide marketed as Saxenda was approved for weight management in December 2014 for use in obese adults (BMI of 30 kg/m^2 or greater) or in overweight adults (BMI of 27 kg/m^2 or greater) who have at least 1 weight-related condition such as hypertension, Type 2 diabetes, or dyslipidemia.[22] Alternatively, the full cost of the YMCA of the USA's DPP is $429/year ($36 per month), which carries with it a proven 5% average weight loss and is therefore less costly, with fewer risks, than any of the above-mentioned drugs.

Although there are various formulations of added life expectancy, the calculation is pretty much in the eyes of the beholder. At minimum, 29% of all adults with prediabetes progress to a diagnosis of Type 2 diabetes at the rate of 5% to 15% per year.[3,19] According to some experts, Type 2 diabetes reduces life expectancy by 6 to 10 years.[23] Previously cited studies have shown that the DPP, particularly with older adult populations, has been able to reduce the incidence of new cases of diabetes by 71%.

Phase 3

Because of the perceived efficacy of this project in the Northeast Ohio region, the HSP-YMCA partnership in the YMCA's DPP has been extended statewide, throughout the Mercy\HealthSpan Integrated Medical system and wherever YMCAs are located (approximately 11 regional YMCAs and upward of 200,000 potential prediabetic referrals). On the basis of the Greater Cleveland experience and the learnings that resulted therefrom, we expect even greater rates of enrollment and engagement than those reported above.

In terms of scalability to other integrated health systems, Matt Longjohn, MD, of the YMCA offered the following observation (personal communication, July 14, 2015)[a]: "The rapid transformation of our health care system towards accountability and value indicates that the collaboration between HSP and the YMCA in Ohio will be an attractive model for clinicians, health care systems and policy makers to explore and replicate."

Limitations

A key limitation of this current study is that it was an observational study and not a randomized clinical trial. The analytic results were not intended to reflect an experimental design. In future and ongoing work as the program expands, we will have the opportunity to conduct a more rigorous stepped-wedge or cluster randomized trial, incorporating controls and taking into account critical factors unobserved in the current analysis (eg, selection, dropout, and intent-to-treat analysis).

CONCLUSIONS

The earlier DEPLOY study demonstrated that the YMCA possesses both a promising vehicle for the dissemination of the DPP lifestyle intervention and one that is cost-effective. The present study indicates what is possible in an integrated health care system with a concentrated systemwide effort in reaching and engaging those at risk of developing diabetes. Both HSP and the YMCA embraced principles of marketing in which a maximum number of "touches" and follow-up with potential clients was the key ingredient.

Now that the client has been engaged, it remains to be seen how long on average patients will persist in the lifestyle change that has been found to be effective. In our next effort together, HSP and the YMCA are engaging in a pilot study focusing on maintenance of lifestyle change in the YMCA DPP participants. We have designed a project, termed SISTERS,[24] which makes use of avatars in a home setting to encourage exercise and thus weight loss maintenance. We propose to enhance our current capital-intense, facility-based care delivery system with an in-home digital health-enabled obesity-care delivery system, working in concert with the YMCA DPP. ❖

[a] National Health Officer, YMCA of the USA, Chicago, IL.

Disclosure Statement

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

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Carbon in Fat

Every carbon in fat is derived from sugar that man ate or that the cow ate.
Oil or fat is nothing more than congealed candy.

— Rachmiel Levine, MD, 1910-1998, physician and researcher
in how insulin increases the body's use of blood sugars

Special Report

Assessing the Value of High-Quality Care for Work-Associated Carpal Tunnel Syndrome in a Large Integrated Health Care System: Study Design

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ABSTRACT

Context: Little is known about quality of care for occupational health disorders, although it may affect worker health and workers' compensation costs. Carpal tunnel syndrome (CTS) is a common work-associated condition that causes substantial disability.

Objective: To describe the design of a study that is assessing quality of care for work-associated CTS and associations with clinical outcomes and costs.

Design: Prospective observational study of 477 individuals with new workers' compensation claims for CTS without acute trauma who were treated at 30 occupational health clinics from 2011 to 2013 and followed for 18 months.

Main Outcome Measures: Timing of key clinical events, adherence to 45 quality measures, changes in scores on the Boston Carpal Tunnel Questionnaire and 12-item Short Form Health Survey Version 2 (SF-12v2), and costs associated with medical care and disability.

Results: Two hundred sixty-seven subjects (56%) received a diagnosis of CTS and had claims filed around the first visit to occupational health, 104 (22%) received a diagnosis before that visit and claim, and 98 (21%) received a diagnosis or had claims filed after that visit. One hundred seventy-eight (37%) subjects had time off work, which started around the time of surgery in 147 (83%) cases and lasted a median of 41 days (interquartile range = 42 days).

Conclusions: The timing of diagnosis varied, but time off work was generally short and related to surgery. If associations of quality of care with key medical, economic, and quality-of-life outcomes are identified for work-associated CTS, systematic efforts to evaluate and improve quality of medical care for this condition are warranted.

INTRODUCTION

Efforts to ensure that patients receive high-quality medical care have intensified in recent years, as the public has come to appreciate the pervasiveness of quality problems and their effects on clinical outcomes and costs.[1-3] Because the entities paying for improvements in quality seldom reap the benefits,[4] national programs designed to drive improvement now exist in most health care sectors.[5-7] Workers' compensation accounts for a relatively small percentage of US health care expenditures,[8] but it has a unique characteristic[9]: Financial incentives for health care payers are intrinsically aligned with improving quality.

When workers return to health and function faster, employers may experience financial benefits because the employers are responsible for both medical and disability costs under workers' compensation policies. Workers stand to gain not only clinically with a better recovery, but also financially because disability benefits cover only a portion of lost wages.[10] Assuring the quality of care for occupational disorders may, therefore, present a unique opportunity to benefit both workers and their employers. A 2005 study from Spain demonstrated that improving care for musculoskeletal disorders reduced medical care and disability costs.[11] Yet, little is known about the quality of health care provided in workers' compensation systems in the US.

Carpal tunnel syndrome (CTS) is a common work-associated condition that can cause severe functional impairment and lead to sizable medical and disability costs.[12,13] Working with policymakers, payers, and providers in the California workers' compensation system, we sought to measure quality of care for CTS, to assess the value of higher quality of care to workers and employers, and to lay the groundwork for ongoing quality assessment and improvement programs in workers' compensation settings. However, a major challenge to achieving this objective was conducting a rigorous evaluation of the relationship between quality of care for CTS and clinical and economic outcomes. A partnership between Kaiser Permanente Northern California Regional Occupational Health Department (KPNC-ROH), Kaiser Foundation Health Plan, and researchers at the RAND Corporation in Santa Monica, CA, made such a study possible.

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In this article, we explain our study design and research approach, the unique characteristics of KPNC-ROH that were essential to conducting this analysis, and the implications that the study findings may have for the care of future patients with work-associated conditions treated at KPNC-Occupational Health Centers, elsewhere in California, and across the country. This approach can serve as a model for future studies designed to measure quality of care for patients in state workers' compensation systems. If we identify associations of quality of care with key medical, economic, and quality-of-life outcomes, systematic efforts to measure and improve quality would be warranted.

Here, we describe 7 major steps that we have undertaken in our effort to evaluate the value of high-quality care for work-associated CTS: 1) developing quality-of-care measures for CTS, 2) selecting and recruiting the study population, 3) measuring quality of care, 4) assessing patient outcomes, 5) measuring medical care costs, 6) measuring disability benefit costs, and 7) measuring other costs to workers and employers. Steps 4 through 7 are still under way.

DEVELOPING QUALITY-OF-CARE MEASURES FOR CARPAL TUNNEL SYNDROME

To evaluate the quality of care for a condition such as CTS, specific measures were needed. Measure development often considers the framework of Donabedian,[14] wherein quality can be assessed by examining the characteristics of the health care delivery system in which care is provided (its "structure"), the interactions between patients and physicians ("process"), and the changes in health that occur after receiving care ("outcome"). Care processes are widely studied because this focus gives specific information on what types of improvements are needed, and the quality measures are tailored to patient characteristics so case-mix adjustment is less a concern than when assessing outcomes.[15] The National Committee for Quality Assurance (NCQA), for example, monitors how often patients in various health plans receive recommended vaccinations and cancer screenings, among other aspects of care.[7] Before the current endeavor, no CTS-specific process measures existed.

We therefore developed a set of quality measures that could be applied to CTS, including work-associated CTS, meaning CTS that has been ascribed to occupational activities. We used a variation of the well-established RAND/UCLA (University of California, Los Angeles) Appropriateness Method, which incorporates a systematic review of the literature and a quantitative assessment reflecting the judgment of a group of experts.[16,17] This method has good reliability and good content, construct, and predictive validity,[18-21] and it has been used to develop measures of quality and surgical appropriateness for other musculoskeletal disorders as well as other conditions.[2,22-24]

Accordingly, we identified care processes for CTS that may be associated with improved outcomes and then asked content experts and a project advisory board, including the Director of KPNC-ROH, to refine, add, and delete draft measures. An 11-member multidisciplinary panel of experts in CTS reviewed a synopsis of the literature and rated the validity, feasibility, and importance of draft quality measures and the appropriateness of surgery in diverse clinical scenarios. Literature review methods and panel methods for selecting valid quality measures have been described previously.[25-28]

The full set of CTS measures addresses evaluation and monitoring; nonoperative management; electrodiagnostic testing; activity assessment and management; surgical appropriateness; and perioperative care. The current effort focuses on evaluation and monitoring (11 measures), nonoperative treatment (11 measures), activity assessment and management (10 measures), and appropriateness of surgery (13 measures), as shown in Table 1. During analysis, scores on individual measures will be aggregated into these categories. For these 45 measures, we developed a guidance document with detailed specifications for how each measure is to be scored, including eligibility criteria, definitions of terms, and adherence criteria. We also developed a paper data collection tool and pilot-tested it at a large workers' compensation insurance company (California State Compensation Insurance Fund) and at KPNC-ROH. When issues potentially affecting feasibility or reliability were identified, the tool was refined accordingly.[29] We later programmed the tool in Microsoft Access (Microsoft Corp, Redmond, WA) and conducted further pilot testing.

Pilot-testing also suggested that workers' compensation claims for CTS may be filed at variable times in the clinical course of care. Some patients were referred to a KPNC-Occupational Health Center, received a diagnosis, and submitted a workers' compensation claim within a short timeframe. However, CTS had been diagnosed in other patients years before they filed a claim.

Our study design accounted for this issue in two ways. First, the eligibility criteria for each measure included specific timeframes related to specific milestones in the clinical course of care. Physicians should perform certain tasks, for example, when evaluating symptoms that could represent CTS or when making a new diagnosis. Second, the data collection tool included the dates of major milestones related to measure eligibility, including making the first visit to a KPNC-Occupational Health Center for symptoms related to CTS, receiving a diagnosis of work-associated CTS, stopping work because of CTS, having surgery for CTS, and returning to work. Any diagnoses from before study enrollment required a positive electrodiagnostic test or an assessment by a specialist in musculoskeletal disorders.

SELECTING AND RECRUITING A STUDY POPULATION

Identifying a suitable population was the most substantial challenge this study faced. Given that our objectives included informing health care policy, we sought workers with CTS from diverse industries. Also, we needed access to high-quality databases that included diagnosis and treatment codes, medical care utilization, time off work, and disability ratings, among other variables. Many large studies of musculoskeletal disorders have been conducted in countries with national databases,[30,31] offering access to populations of adequate sample size and reducing the time and expense involved in recruiting subjects. Few national databases are available in the US, but some large integrated health care systems have both large patient populations and advanced databases.

Although KPNC is best known for its large regional integrated health care systems and prepaid (ie, capitated) care, KPNC-ROH is a major provider of fee-for-service occupational health care in Northern California. It has been selected by numerous large and small employers, workers' compensation insurance carriers, and

Table 1. Quality measures used in study by aspect of care, type of quality problem, and panelist-rated importance score, and description of provider task

Measure	Aspect of care	Type of quality problem	Importance score	Description of provider task
Evaluation and monitoring: Obtain history, perform physical examination, order tests, and monitor symptoms				
1	New symptoms characteristic of CTS require detailed history	Underuse	8	Obtain history
2	New symptoms characteristic of CTS should lead to suspicion	Underuse	7	Obtain history
3	New hand or forearm pain requires evaluation for "red flags"	Underuse	8	Obtain history
4	New symptoms inconsistent with CTS require evaluation	Underuse	8	Obtain history
5	New CTS diagnosis requires assessment of medical risk factors	Underuse	8	Obtain history
6	New suspicion of CTS requires specific physical examination	Underuse	8	Perform physical examination
7	New suspicion of CTS requires evaluation for excessive weight	Underuse	6	Perform physical examination
8	Imaging should be used selectively for suspected CTS	Overuse	7	Order tests
9	Symptoms should be monitored after new diagnosis of CTS	Underuse	7	Monitor symptoms
10	Work-associated CTS symptoms require prompt follow-up	Underuse	8	Monitor symptoms
11	Preoperative electrodiagnostic testing is required for work-associated CTS	Underuse	9	Order tests
Nonoperative treatment: Prescribe splints, medications, and other treatments correctly				
1	Splints should be placed in neutral position	Underuse	7	Prescribe splints correctly
2	An attempt at splinting should last at least 6 weeks	Underuse	7	Prescribe splints correctly
3	NSAIDs should not be used for CTS	Overuse	7	Prescribe medications correctly
4	Muscle relaxants should not be used for CTS	Overuse	7	Prescribe medications correctly
5	Opioids should not be used for CTS	Overuse	7	Prescribe medications correctly
6	Diuretics should not be used for CTS	Overuse	7	Prescribe medications correctly
7	Corticosteroid treatment requires discussion of risks	Overuse	6	Prescribe medications correctly
8	Discuss benefits of surgery when offering steroids to patients with severe CTS	Underuse	8	Prescribe medications correctly
9	Steroids for work-associated symptoms require follow-up	Underuse	7	Prescribe medications correctly
10	Limit steroid injections to 4	Overuse	7	Prescribe medications correctly
11	Laser therapy should not be used for CTS	Overuse	7	Order other treatment correctly
Activity assessment and management: Assess activity, assess causation, educate patients, recommend activity changes, and monitor activity				
1	New CTS diagnosis requires detailed occupational history	Underuse	6	Assess activity
2	New CTS diagnosis requires assessment of occupational factors: Vibration, force, and repetition	Underuse	7	Assess activity
3	New CTS diagnosis requires assessment of nonoccupational factors: Vibration, force, and repetition	Underuse	7	Assess activity
4	Exacerbating activities should be identified when symptoms limit functioning	Underuse	7	Assess activity
5	Rationale for work association should be documented	Underuse	7	Assess causation
6	Patients with a new diagnosis of CTS should be educated about the condition	Underuse	7	Educate patients
7	Exposures to vibration, force, and repetition should be minimized	Underuse	7	Recommend activity changes
8	Work status should be monitored when CTS appears work associated	Underuse	7	Monitor activity
9	Return to work after CTS-related disability requires follow-up assessment that includes functional limitations	Underuse	6	Monitor activity
10	Prolonged CTS-related disability should trigger evaluation	Underuse	7	Monitor activity
Surgical appropriateness[a]: Assure potential benefits of surgery exceed risks				
1	Compelling indications for surgery when CTS is mild	Underuse	9	Perform necessary surgery
2	Compelling indications for surgery when CTS is moderate, Part 1	Underuse	9	Perform necessary surgery
3	Compelling indications for surgery when CTS is moderate, Part 2	Underuse	9	Perform necessary surgery
4	Compelling indications for surgery when CTS is severe, Part 1	Underuse	9	Perform necessary surgery
5	Compelling indications for surgery when CTS is severe, Part 2	Underuse	9	Perform necessary surgery
6	Compelling indications for surgery when CTS is severe, Part 3	Underuse	9	Perform necessary surgery
7	Avoidance of carpal tunnel surgery during pregnancy	Overuse	9	Avoid inappropriate surgery
8	Compelling contraindications for surgery when CTS is mild, Part 1	Overuse	9	Avoid inappropriate surgery
9	Compelling contraindications for surgery when CTS is mild, Part 2	Overuse	9	Avoid inappropriate surgery
10	Compelling contraindications for surgery when CTS is moderate, Part 1	Overuse	9	Avoid inappropriate surgery
11	Compelling contraindications for surgery when CTS is moderate, Part 2	Overuse	9	Avoid inappropriate surgery
12	Compelling contraindications for surgery when CTS is moderate, Part 3	Overuse	9	Avoid inappropriate surgery
13	Compelling contraindications for surgery when CTS is moderate, Part 4	Overuse	9	Avoid inappropriate surgery

[a] Parts apply to different subpopulations within a given severity of carpal tunnel syndrome.
CTS = carpal tunnel syndrome; NSAID = nonsteroidal anti-inflammatory drug.

third-party administrators of workers' compensation claims. Occupational conditions are referred to KPNC-Occupational Health Center specialists based in 30 clinics. In addition to an electronic medical record system, KPNC-ROH maintains a comprehensive database of workers' compensation claims that includes information on employer, payer, patient characteristics and diagnoses, recommended worksite accommodations, recommended and actual work status, health care utilization and claims (by diagnosis), and prescriptions and pharmacy claims (by diagnosis). Copies of California workers' compensation forms, including Doctor's First Reports, Progress Reports, and Permanent and Stationary Reports, are also included. About 70% of patients treated by KPNC-Occupational Health Centers also have general health insurance through KPNC.

The KPNC-ROH partners in this study used these internal workers' compensation databases to prospectively identify 1009 adults aged 18 years and older who had a primary or secondary diagnosis of CTS that was linked to a workers' compensation claim (July 2011 to February 2013). We included secondary diagnoses of CTS because some patients with claims related to other upper extremity conditions are later found to have CTS. After KPNC-ROH contacted potential subjects, 630 (67.9%) consented to participate; another 81 were found to be ineligible (ineligible subjects included KPNC employees, subjects who did not speak English or Spanish, or subjects who were unable to provide consent), 113 declined to participate, and 185 could not be reached (Figure 1). Given the challenges inherent in making a diagnosis of CTS, subjects remained eligible if the diagnosis was later changed or the workers' compensation claim was dropped or denied, enabling us to evaluate the quality of the initial evaluation and its effects on outcomes.

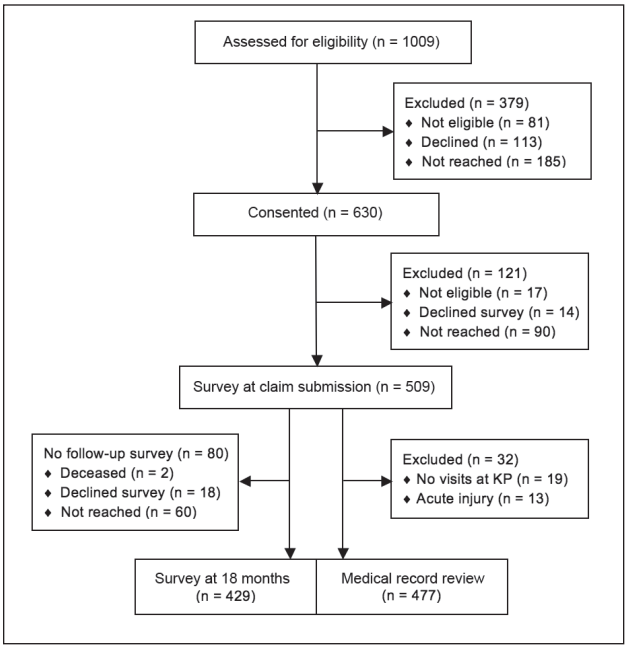

Figure 1. Enrollment of Study Subjects, Survey Responses, and Medical Record Review.

KP = Kaiser Permanente.

MEASURING QUALITY OF CARE

In addition to recruiting an appropriate and sizable population, we needed to assess the quality of care by multiple physicians in different locations, including ancillary services such as physical therapy or imaging. A systemwide electronic medical record system eliminated the problem of legibility and made data from multiple sites and physicians accessible.

Specially trained medical-record abstractors at the KPNC Division of Research with experience collecting data for quality measurement reviewed each subject's electronic medical record and identified visits related to the CTS claim. Abstractors collected data needed to determine eligibility and adherence for each quality measure. After excluding patients with no visits to KPNC-Occupational Health Center physicians (n = 19) or CTS related to an acute injury (acute injuries were excluded from the study; n = 13), abstractors reviewed records for 477 patients. Abstractors also obtained additional variables, including work status at each visit, clinical symptoms and signs, results of electrodiagnostic tests, and the dates of major milestones in the clinical course of care (see section Developing Quality-of-Care Measures for Carpal Tunnel Syndrome).

To ensure that assessments of quality were valid and reliable, abstractors underwent a 2-day training session, including applying the guidance document and Microsoft Access data collection tool (described earlier) to practice cases. Abstractors initially reviewed medical records in pairs, discussed findings, and resolved any discrepancies together and, when questions arose, with the research team. Next, to ensure proficiency, we compared abstractors' reviews for 3 cases against those of an occupational medicine physician. Subsequently, abstractors scored cases independently, except for reliability assessments. Through site visits and phone meetings, an experienced nurse researcher (CR) monitored data validity, clarified definitions of terms and variables, and maintained a log of questions and answers. A total of 58 cases underwent duplicate review, including 35 used to estimate reliability.

ASSESSING PATIENT OUTCOMES

We used a prospective, observational study design to examine the relationship between quality of care for CTS and patient outcomes. Telephone surveys measured changes in each patient's symptoms and functional status between the time of claim submission and 18 months later. Of the 630 subjects initially recruited, 17 were found to be ineligible; 509 (83.0%) of the remaining 613 subjects completed the baseline survey, 14 declined, and 90 could not be reached. For the follow-up survey, 429 (84.3% of the 509 subjects who filled out the baseline survey) responded, 18 declined, 2 were deceased, and 60 could not be reached.

To assess outcomes, we used the Boston Carpal Tunnel Questionnaire and the 12-item Short-Form Health Survey Version 2 because condition-specific instruments tend to be more responsive and general instruments facilitate comparisons across conditions. The Boston Carpal Tunnel Questionnaire is specifically tailored for CTS and has demonstrated validity, reliability, and responsiveness.[32-39] It includes 2 subscales: symptom severity and functional status. Overall scores are obtained by calculating the mean response across component questions; weighting each question according to

the importance to the patient increases responsiveness.[32] The widely used 12-item Short Form Health Survey Version 2 includes physical and mental health component scores, with the former being more responsive in CTS.[33] Finally, we obtained information on any permanent disability via the medical record and Permanent and Stationary Reports completed by the treating physicians.

To enable adjustment for covariates, surveys included questions on prior workers' compensation claims in the study hand (the hand with work-associated CTS included in the study); duration, location, and timing of CTS symptoms; involvement of an attorney; demographic covariates; medical conditions associated with CTS; whether the patient received care for those symptoms before or in addition to being seen at KPNC-Occupational Health Center; and smoking status, alcohol or substance abuse, and anxiety.

MEASURING MEDICAL CARE COSTS

To evaluate the association between quality and costs, detailed information was needed on the costs of medical care related to CTS, including physician visits, physical and occupational therapy visits, medications, diagnostic tests, and surgery. Accordingly, KPNC-ROH provided RAND partners with de-identified datasets containing procedure codes, diagnosis codes, dates of service, and billed amounts for all services billed to workers' compensation. Because many workers' compensation claims involved additional diagnoses, we included only services involving diagnosis codes potentially related to CTS. We adjusted the billed amounts to match California's fee schedule and summed the spending associated with each CTS claim from the time of submission until 18 months later. Of the 477 patients for whom quality of care was assessed, 3 lacked data on medical care expenditures because of having had only a single visit to a KPNC-Occupational Health Center.

MEASURING DISABILITY BENEFIT COSTS

Because of the importance of disability costs when considering the value of high-quality care for work-associated CTS, we needed to estimate the costs associated with temporary and permanent disability benefits. Actual payments were not available to us, so we needed to estimate them based on other information. Physicians at KPNC-Occupational Health Centers document activity restrictions and work status in detail at each clinic visit, and the physicians' Permanent and Stationary Reports with permanent disability ratings are part of the medical record. "Work status" is documented by the physicians as "full duty," "off work," or "work with restriction of activities."

Using work status documented at each visit with a primary treating physician as well as data from the KPNC-ROH workers' compensation database, we constructed event histories that tracked each patient's daily work status throughout the 18-month follow-up period. We estimated statutory temporary total disability benefits using each patient's self-reported monthly personal income before filing the claim, and statutory permanent disability benefits based on patients' permanent disability ratings and statewide data on earnings losses for patients with CTS.

MEASURING OTHER COSTS TO WORKERS AND EMPLOYERS

CTS imposes a variety of costs on workers and employers beyond the financial cost of medical and disability benefits paid by the workers' compensation system during the first 18 months of a claim.[40-43] Employers are responsible for the lifetime cost of medical treatment for occupational injury and illness, and most spending on the average workers' compensation claim occurs well after our follow-up period.[44]

To estimate uncompensated economic losses for workers during the 18-month follow-up period, we used self-reported data from our baseline and follow-up surveys on employment, monthly wages, annual household and personal income, job changes, out-of-pocket medical spending, and out-of-pocket personal care expenditures. We used these data to estimate the effect of higher-quality care on labor income, employment, return to work at the at-injury employer, and out-of-pocket medical costs.

Table 2. Characteristics of study population at submission of workers' compensation claim for CTS (N = 509)

Characteristic category	Value
Demographic characteristics	
Age, years, mean (SD)	47.6 (10.4)
Female sex, %	73.3
Spanish speaking, %	4
Clinical characteristics	
Right hand is study hand (affected hand, or dominant hand if bilateral), %	81.1
Katz hand diagram rating, %	
Classic	5.1
Probable	34.6
Possible	55.4
Unlikely	4.9
Median nerve digit score, %	
2 (most likely)	86.8
1 (intermediate)	8.3
0 (least likely)	4.9
Self-efficacy (1-4, confidence in ability to manage CTS), mean (SD)	2.3 (0.8)
Health status measures	
Boston Carpal Tunnel Questionnaire	
Symptom severity score (1-5, 5 = worst), mean (SD)	2.9 (0.8)
Functional status score (1-5, 5 = worst), mean (SD)	2.5 (0.9)
Short Form Health Survey (12 Item, Version 2)	
Physical component score (1-100, 100 = best), mean (SD)	40.1 (9.7)
Mental component score (1-100, 100 = best), mean (SD)	50.4 (11.5)
Economic characteristics	
Work status, %	
Working full time	63.5
Working part time	11.0
Not working	25.0
Personal income (US$) in last 4 weeks, %	
≤ 1600	24.2
1601-2500	14.9
2501-3750	15.9
3751-5000	19.3
5001-6250	9.2
> 6251	8.6
Data missing	7.9

CTS = carpal tunnel syndrome; SD = standard deviation.

In addition to the costs of reduced employment and earnings that are borne by workers, employers may also bear the cost of absenteeism (time off work) and "presenteeism" (reduced productivity while at work) because of residual disability following recovery from CTS. We estimated costs associated with absenteeism and presenteeism at baseline and follow-up using standardized instruments and monetized the employer costs using data on the daily wage rate and multipliers estimated by Nicholson et al[41] for absenteeism and by Pauly et al[42] for presenteeism.

ANALYSIS

First, we have undertaken descriptive analyses. Table 2 presents key characteristics of the study population obtained from the baseline survey at claim submission. The age and sex of the study population is typical for CTS, including disproportionately affecting women.[45] The personal income in the study population was relatively high, consistent with the geographic area.

Figures 2 through 6 show the timing of major milestones in relation to study enrollment for the 477 patients for whom quality of care was assessed. These milestones include making the first visit to a KPNC-Occupational Health Center for CTS-related symptoms, receiving a diagnosis of work-associated CTS, stopping work because of CTS, having surgery for CTS, and returning to work.

Looking at the timing for when these 477 subjects met the first 2 milestones, most subjects fell into 1 of 4 groups. The most common situation was for both the first visit and the diagnosis to occur within 1 week of study enrollment (267 subjects, 56.1%). For 104 subjects (21.8%), the diagnosis preceded the first visit and enrollment by at least a week, and sometimes by several years: This could reflect later referral to a KPNC-Occupational Health Center, transfer of care, or recurrent symptoms. The first visit preceded both diagnosis and enrollment by a week or more in 48 subjects (10.0%): This could indicate that physicians did not suspect CTS initially or sought additional evidence before making a diagnosis. For 50 subjects (10.5%), the first visit and the diagnosis occurred within a week of each other but more than a week before enrollment. In these cases, the occupational medicine physician may have documented a provisional diagnosis of CTS at the first visit but delayed linking it to a workers' compensation claim pending greater insight into work association. These findings highlight the importance of tailoring eligibility for each measure to the specific clinical circumstances at a given time point. For example, some measures related to the initial evaluation would not apply to patients who already have well-established diagnoses of work-associated CTS at the time of presentation to a KPNC-Occupational Health Center.

Regarding the other 3 major milestones, 178 subjects (37.3%) stopped work because of CTS. The median interval from study enrollment to stopping work was 91 days (interquartile range = 103 days). Most patients who stopped work did so to have surgery, consistent with practices at KPNC-ROH. Of patients who stopped work because of CTS, 147 (82.6%) stopped working within a week of surgery. A few patients stopped work and underwent surgery before presenting to a KPNC-Occupational Health Center. The median duration off work was 41 days (interquartile range = 42 days) among the 163 patients for which this could be calculated.

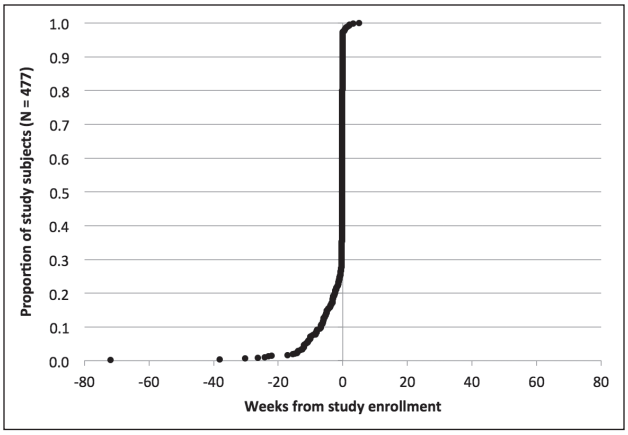

Figure 2. Clinical milestones: Percentage of study subjects achieving each milestone by weeks from study enrollment (time = 0): Making first visit to KPNC-ROH because of symptoms of carpal tunnel syndrome.

KPNC-ROH = Kaiser Permanente Northern California-Regional Occupational Health Department.

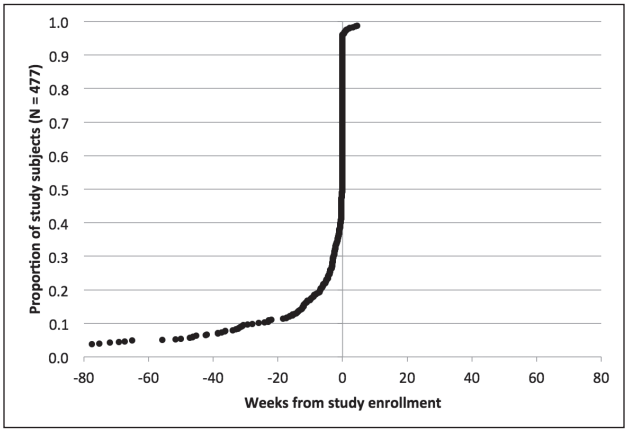

Figure 3. Clinical milestones: Percentage of study subjects achieving each milestone by weeks from study enrollment (time = 0): Receiving a diagnosis of work-associated carpal tunnel syndrome.

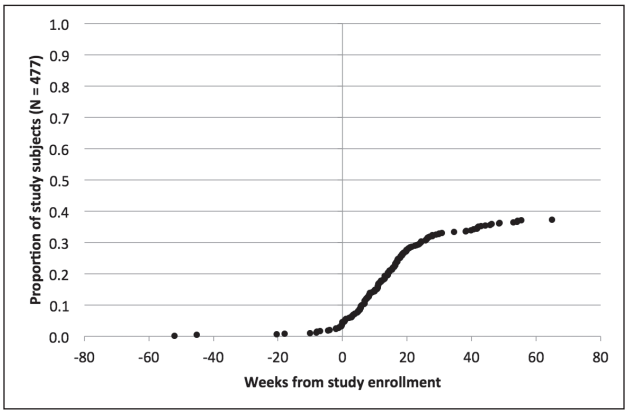

Figure 4. Clinical milestones: Percentage of study subjects achieving each milestone by weeks from study enrollment (time = 0): Stopping work because of carpal tunnel syndrome.

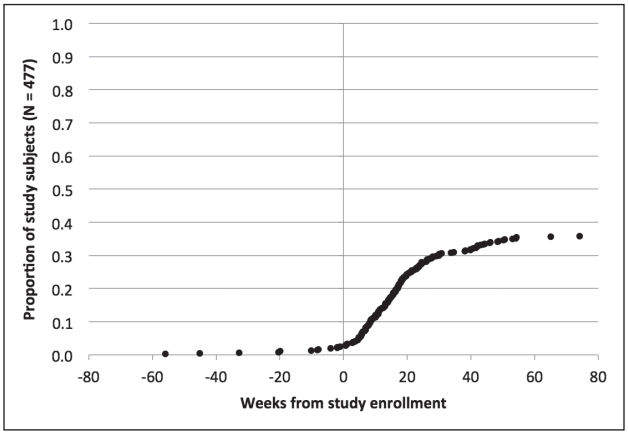

Figure 5. Clinical milestones: Percentage of study subjects achieving each milestone by weeks from study enrollment (time = 0): Having surgery for carpal tunnel syndrome.

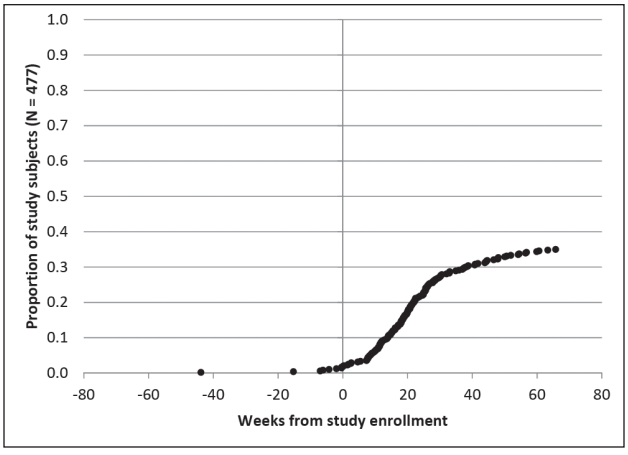

Figure 6. Clinical milestones: Percentage of study subjects achieving each milestone by weeks from study enrollment (time = 0): Returning to work.

After performing these descriptive analyses, we plan to undertake 2 basic types of multivariate regression analyses. The first will involve examining rates of adherence to the measures individually and by aspect of care, and then using multivariate regression models to identify predictors of receiving recommended care. Such predictors will include demographic characteristics, clinical features of the CTS (eg, symptom duration, pattern, timing, and severity; neurologic signs; results of electrodiagnostic testing), characteristics of workers' compensation claims (eg, having a prior claim, involvement of an attorney), clinic characteristics (specifically, volume of patients with CTS treated per year in each of the 30 clinics).

We plan to use a patient-measure-level dataset in this regression analysis. Each patient will contribute 1 observation (ie, row) to this dataset per quality measure for which they are eligible (eg, 10 observations if eligible for 10 measures). Patient-level characteristics (eg, sex and age) will be copied to each corresponding observation, a categorical variable will represent the quality measure for the observation, and a binary variable will indicate whether care for the patient adhered to the recommendation in the quality measure. We plan to use logistic regression with patient-level random effects to control for patient-level heterogeneity and will use measure-level fixed effects to control for variability in the pass rates across the measures.

The second type of analysis will involve examining whether patients who receive higher-quality care, specifically those who have less evidence of underuse and overuse of care, have better clinical outcomes, less disability, and lower costs. Clinical outcomes include changes in scores on the Boston Carpal Tunnel Questionnaire and the 12-item Short Form Health Survey Version 2 from baseline to 18 months. Disability outcomes will include days on temporary disability and the presence of permanent disability under the workers' compensation claim. Cost outcomes will include health care expenditures related to the workers' compensation claim for CTS as well as disability-related costs.

We will also use multivariate regression to assess the relationship between quality of care and clinical and economic outcomes. These analyses must be performed at the patient level, instead of the patient-measure level, because changes in health and costs occur at the patient level. Hence, we will need to develop patient-level indexes that aggregate data on adherence to measure recommendations. For instance, we will create indexes reflecting underuse of care and overuse of care, and indexes for each aspect of care (ie, diagnostic evaluation, nonoperative treatment, activity management, and appropriateness of surgery). Creating each index will involve dividing the number of times care adhered to the recommendations within a group of related measures (eg, related to underuse), by the number of times each patient was eligible for those measures. We will weight the indexes by the measures' importance scores. We will tailor the modeling approach (eg, linear, Poisson) to each outcome of interest. For example, we assume Poisson regression will be needed to determine how days on temporary disability vary with quality of care. All analyses will control for relevant patient-level characteristics, including demographic characteristics, CTS symptoms, clinical signs, electrodiagnostic test results, and characteristics that have been found to influence clinical and cost outcomes for work-associated CTS.

CONCLUSIONS

We have undertaken a comprehensive effort to evaluate the quality of medical care provided to individuals with work-associated CTS, and to assess the associations between quality and both clinical outcomes and diverse costs. However, to achieve our goals, we needed to overcome multiple challenges. These included developing a set of quality measures de novo, recruiting a sizable and diverse population, assessing quality by reviewing medical records from multiple treating physicians over a 12-month period, comparing patients' self-reported outcomes at claim submission and 18 months later, and using diverse sources of data to estimate health care, disability payment, and other costs. Necessary data sources included surveys, medical records, administrative data sets on health care utilization, detailed information on work status, and Permanent and Stationary Reports. In partnership with KPNC-ROH, which provides a high volume of care for

occupational disorders, we were able to recruit and survey 509 adults shortly after submission of workers' compensation claims in 2011 to 2013 and obtain the requisite data. The final stages of data collection and analysis are under way. We hope that this study can eventually provide a model for future efforts to test the association between quality of care and outcomes in workers' compensation for other conditions or in other settings.

Evidence that higher-quality care for work-associated CTS is associated with improved outcomes or lower costs would have important implications for patients treated at a KPNC-Occupational Health Center, elsewhere in California, and in workers' compensation systems across the country. Several prior studies have demonstrated that greater adherence to recommended care processes is associated with improved patient outcomes.[18,19,24] Workers' compensation is unique in the US health care system in that the parties responsible for health care expenditures, employers and workers' compensation payers, are also responsible for disability costs. This creates a natural alignment of incentives such that employers and payers may experience returns on investments in quality. More importantly, individuals with occupational disorders stand to benefit from better health, a more rapid return to work, and reduced economic losses.

If we find that higher-quality care is associated with improved outcomes and lower costs, as hypothesized, systematic efforts to monitor and improve quality would be warranted. To date little has been done to improve quality of care for patients with occupational disorders, in contrast with the myriad efforts in place in other health care settings. For example, the Centers for Medicare and Medicaid Services has instituted various public reporting policies and financial penalties for hospitals, targeting deficient care processes and worse-than-expected outcomes, including readmissions, health care-associated infections, and other problems. For commercial health plans, the National Committee for Quality Assurance has long overseen the Healthcare Effectiveness Data and Information Set, which issues report cards that highlight preventive care and the treatment of chronic diseases. Best practices for incentivizing and improving quality could be adapted from other health care sectors to workers' compensation settings in California and elsewhere.

Our descriptive analyses reveal some potential challenges. In our population, time off work was relatively short and largely limited to patients undergoing surgery. This may make it harder for us to detect associations between quality and time on temporary disability.[46] At least one in five patients were diagnosed with work-associated CTS before presenting to a KPNC-Occupational Health Center—and some even underwent surgery. This could hamper future efforts to improve care for this population. Finally, we detected some delays between presentation to a KPNC-Occupational Health Center and diagnosis of CTS, and between diagnosis of CTS and the filing of a claim. This can be warranted in some patients, such as those with atypical symptoms. However, such delays also can contribute to worse outcomes.[47-49]

This research effort has several limitations. Some patients in our sample who had an initial diagnosis of CTS were found to have other conditions. However, our quality measures were designed to include the challenges in making an accurate diagnosis of CTS. We have so far been unable to include quality measures related to electrodiagnostic studies and perioperative care, which may reduce our ability to detect an association between quality, outcomes, and costs. Finally, because of the unique environment at KPNC-ROH, potential findings may not be fully reflective of conditions in workers' compensation settings nationwide. The quality of care for CTS may also be higher at KPNC-ROH, making it harder to detect an effect at KPNC-ROH on clinical outcomes and costs.

Demonstrating an association between higher-quality care for work-associated CTS and both clinical outcomes and costs has important implications for policy. If associations are detected as a result of the work we have undertaken, systematic efforts to monitor and improve quality of care for patients with CTS will be warranted at KPNC-ROH, across California, and nationwide. ❖

Disclosure Statement

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Girl with a Pearl Earring
oil paint on canvas

Zhanna Vishnevskaya, MD

This oil painting is an original reproduction of the famous painting by Johannes Vermeer (1632-1675), Girl with a Pearl Earring, which is housed at The Mauritshuis in The Hague, The Netherlands. Every artist has been encouraged to copy works by renowned masters to better understand the skill and spirit that inform a great artist's vision.

All medical practitioners know their jobs can be demanding and overwhelming. Recharging daily is necessary for continuing to work like a genius and having a balanced life. Dr Vishnevskaya has found that painting is the best way to refresh her mind. Aside from painting, she enjoys playing guitar, writing, and learning languages.

Dr Vishnevskaya is a Physician in the Department of Family Medicine at Pinole Medical Offices in CA.

CME credits available for this article — see page 128.

ORIGINAL RESEARCH & CONTRIBUTIONS

Special Report

Amniotic Fluid Embolism: Using the Medical Staff Process to Facilitate Streamlined Care

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ABSTRACT

Amniotic fluid embolism (AFE) is a catastrophic consequence of labor and delivery that often results in maternal and neonatal death. These poor outcomes are related largely to the rarity of the event in a population overwhelmingly biased by overall good health. Despite the presence of national AFE registries, there are no published algorithmic approaches to its management, to our knowledge. The purpose of this article is to share a care pathway developed by a multidisciplinary group at a community teaching hospital. Post hoc analysis of a complicated case of AFE resulted in development of this pathway, which addresses many of the major consequences of AFE. We offer this algorithm as a template for use by any institution willing to implement a clinical pathway to treat AFE. It is accompanied by the remarkable case outcome that prompted its development.

INTRODUCTION

Amniotic fluid embolism (AFE) has remained an enigmatic and catastrophic complication of pregnancy since it was initially described in 1926.[1] Anesthesiologists are often the first physicians to recognize the initial signs of impending cardiovascular collapse and to coordinate the care of the critically ill mother and fetus. Maternal death directly attributed to AFE was not well known until the seminal publication by Steiner and Lushbaugh[2] in 1941. To date, the exact pathophysiology of AFE remains incompletely understood. Early reports postulated that the syndrome was embolic in nature.[3] Contemporary thinking suggests an immunologic etiology[4] because amniotic fluid contains proinflammatory, vasospastic, and coagulative substances that cause acute lung injury, ventricular dysfunction, and activation of clotting factors predisposing to disseminated intravascular coagulation (DIC).[5] The syndrome frequently manifests the following symptoms: maternal hypoxia, hypotension, DIC, seizure activity, and fetal distress.[4,6] Mortality rates ranging from 20% to 60% have been reported recently.[7]

The incidence of AFE ranges from approximately 1 case per 15,200 deliveries in North America to 1 per 53,800 deliveries in Europe.[8] The sporadic occurrence of AFE means most anesthesiologists, obstetricians, and delivery units are not prepared for the herculean efforts that are necessary to achieve both maternal and neonatal survival. Table 1 lists the most frequent elements of the clinical presentation that should alert the anesthesiologist and obstetrician to the possibility of AFE. The triad of hypotension, hypoxemia with respiratory failure, and DIC should prompt immediate implementation of the proposed AFE management pathway described later in this article. It was developed following the successful outcome of the case reported here. Clearly, the classic triad is not always present, and milder cases of AFE may not include all common manifestations. A high index of suspicion is critical for a favorable outcome.

CASE ILLUSTRATION

A 33-year-old pregnant woman, gravida 1, para 0, was admitted at 41 weeks gestation for a scheduled induction of labor because she was past her due date. Her medical history included glomerulonephritis during childhood, which resolved after 1 year of prednisone treatment. Her obstetric history was unremarkable with an uncomplicated pregnancy. After admission, the patient was given 2 doses of misoprostol; she experienced spontaneous rupture of membranes and entered active labor. Approximately 2 hours after an uneventful epidural placement, the patient became hypotensive, and fetal monitoring documented severe bradycardia. Fetal distress prompted emergent cesarean delivery. Maternal seizures began during the cesarean delivery, with subsequent

Table 1. Clinical presentation of amniotic fluid embolism[a]

Symptom or sign	Frequency of occurrence, %
Hypotension	100
Fetal distress	100
Pulmonary edema or ARDS	93
Cardiopulmonary arrest	87
Coagulopathy	83
Dyspnea	49
Seizure	48

[a] Excerpted and reprinted with kind permission from: American Journal of Obstetrics and Gynecology, 172(4 Pt 1), Clark SL, Hankins GD, Dudley DA, Dildy GA, Porter TF. Amniotic fluid embolism: analysis of the national registry, p 1158-67: Table V, with permission from Elsevier.

ARDS = acute respiratory distress syndrome.

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cardiac arrest requiring cardiopulmonary resuscitation. This maternal collapse was consistent with AFE.

Five minutes into the resuscitation, a live female infant was delivered via cesarean delivery. After 75 minutes of cardiopulmonary resuscitation, the patient remained in cardiopulmonary arrest and experienced DIC. The massive transfusion protocol was initiated, and a cardiac surgeon was recruited. Appropriate cannulae in the right femoral artery and vein were placed to establish full cardiopulmonary support (CPS) via extracorporeal membrane oxygenation (ECMO). After the initiation of CPS, massive abdominal distention was noted, suspicious for active intraabdominal hemorrhage. Exploratory laparotomy by the obstetrician and on-call general surgeon revealed 3 L of intraabdominal blood. The left uterine artery was ligated, and the abdomen was closed.

In the intensive care unit (ICU), a temperature control protocol for brain cooling was initiated in an attempt to preserve brain function. The patient remained on CPS and a regimen of vasopressors as needed. DIC persisted, as manifested by hemorrhage and progressive abdominal distention. Embolization of the uterine arteries by an interventional radiologist was attempted, but during the attempt, the right lower extremity developed critical limb ischemia as a consequence of femoral cannulation for CPS. The patient was returned emergently to the operating room, where groin cannulation was replaced by ascending aorta and right atrial cannulation for CPS. Arterial flow to the ischemic right lower extremity was reestablished but resulted in compartment syndrome treated with a four-compartment fasciotomy by the vascular surgery team. A total hysterectomy and left salpingo-oophorectomy were necessary to control hemorrhage. Raw bleeding surfaces in the pelvis were treated by packing maneuvers.

The patient returned to the ICU, where transfusion was continued. Once the DIC resolved, packing was removed from the pelvis. After stabilization, CPS was discontinued. During the entire resuscitation, the patient received a total of 154 U of packed red blood cells, 78 U of fresh frozen plasma, 25 U of platelets, 12 U of cryoprecipitate, and 2 doses of Factor VII to control the DIC.

After resuscitation, cardiopulmonary stabilization, and resolution of coagulopathy, the patient recovered. She was discharged from the hospital on postpartum Day 26. The infant was discharged 9 days after birth. Mother and baby are doing well, with no deficits at 3-year follow-up.

DISCUSSION

The successful outcome in this case prompted a post hoc analysis by a multidisciplinary task force to clarify emergent processes that might improve future outcomes. Despite recent advances in prenatal care, AFE remains a most perplexing and frequently fatal consequence of parturition. Major risk factors predisposing to AFE include maternal age older than 35 years, cesarean delivery, vacuum or forceps-assisted delivery, placenta previa or abruption, eclampsia, and fetal distress.[8] There have been previously published reports analyzing complex treatment modalities for maternal support in the immediate postpartum setting when AFE is encountered.[7,8] The proinflammatory pathology of AFE manifests as the clinical scenario of respiratory failure, cardiovascular collapse, coagulopathy, and occasionally seizure activity. The circulatory and respiratory support following maternal collapse can include the use of ventricular assist devices, ECMO, inhalation of nitrous oxide, and cardiopulmonary bypass with or without intra-aortic balloon pump.[4,9,10] This illustrative case demonstrates the benefit of a multidisciplinary approach to the complex care required to treat AFE. Larger multispecialty integrated health care organizations are in a pivotal position to champion refinements in clinical care pathways. Other authors have suggested that multidisciplinary teamwork offers the most effective strategy for maternal and fetal survival.[11] However, an interdisciplinary decision tree is difficult for the anesthesiologist and obstetrician to assimilate in the frenetic environment that accompanies AFE. Rapid information dissemination for recruitment of resources and specialty providers is critical for a successful outcome.

On the basis of the experience with a ruptured abdominal aortic aneurysm and fetal distress protocols already implemented at our institution, an AFE algorithm was developed. The algorithm was vetted through the medical staff process, approved, and promoted in the hopes of clarifying the emergent management of AFE (Figure 1). In this care pathway, the On-Call Nursing Supervisor serves as the initial multidisciplinary coordinator during the "mobilization of resources" phase of treatment. This allows the attending anesthesiologist and obstetrician to focus on the mother with the full knowledge that a previously vetted algorithm will facilitate coordination of all essential aspects of care, including that of the neonate. Separate subalgorithms for anesthesiologists, obstetricians, cardiac surgeons, intensivists, general surgeons, and neonatologists are integrated into the one-page AFE algorithm to streamline the processes and to maximize the chance that smaller but critical decisions are accomplished in rapid sequence. We postulate that a similar AFE algorithm could be easily adopted in any hospital willing to merge the best aspects of its own facility's previously established protocols, such as those for emergent fetal distress, massive transfusion, or ruptured abdominal aortic aneurysm.

… during the period of time required to obtain clinical acceptance of this care pathway by multiple departments, an interval maternal death caused by AFE occurred.

The ultimate goal of the algorithm is to decrease variability in care and to streamline care pathways, which are likely to optimize outcomes. The rarity of this event makes proof of this hypothesis extremely difficult, but we contend that drills similar to mass casualty exercises or treatment of malignant hyperthermia are useful. We note that during the period of time required to obtain clinical acceptance of this care pathway by multiple departments, an interval maternal death caused by AFE occurred. This adverse outcome, which occurred in the absence of a defined

clinical pathway, attests to the need for a streamlined approach to the management of AFE. Our institution is currently in the process of implementing proactive AFE training for our anesthesiologists. We also firmly support the concept of debriefing following each event to modify processes as needed.

Once the anesthesiologist or obstetrician recognizes cardiopulmonary collapse, the AFE algorithm can be implemented by a single phone call to the Nursing Supervisor. Figure 1 outlines in detail the AFE algorithm now in place at our institution. Each subalgorithm provides a checklist to be considered by the individual specialty services. Limiting the document to one page provides simplicity for rapid information transfer and streamlined implementation. This algorithm is not an attempt to comprehensively address each variable that may present in an individual case. It is an overarching document designed to limit major oversights in care. There are areas of controversy in the blood product ratios used to manage massive transfusion, in the use of ECMO for CPS, and in the levels for targeted temperature control (see Figure 1, Blood Bank, Cardiac Surgery, and Anesthesia). Individual institutions can tailor recommendations to regional preferences (practice standards) with appropriate support from the literature.

Intensivists rapidly assume ongoing management of the multiple organ failure and hemodynamic instability on the patient's arrival in ICU. Recruitment of specialists early in the chain of events facilitates the transition from the labor deck to the ICU. The added expertise of those critical care specialists makes it less likely that maternal and fetal stabilization efforts will fail.

While the obstetrician focuses on delivery of the infant and control of maternal DIC and uterine hemorrhage with the assistance of the general surgeon, the anesthesiologist and cardiac surgeon can manage cardiopulmonary failure. In addition to securing the airway, performing advanced cardiac life support on the mother, pediatric advanced life support on the infant, and administering blood products via the massive transfusion protocol, the anesthesiologist(s) may perform transesophageal echocardiography.

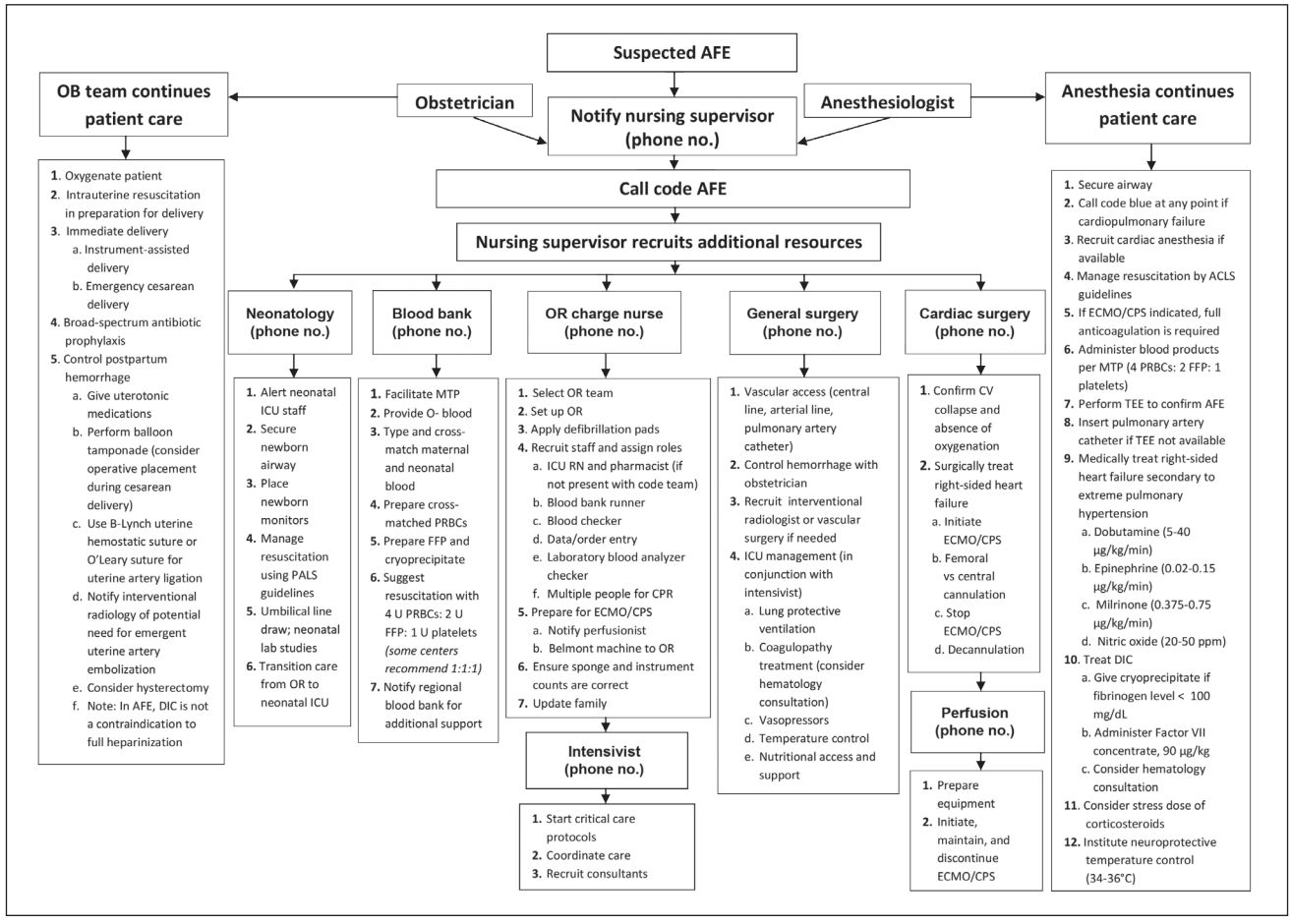

Figure 1. Algorithmic management of amniotic fluid embolism (AFE).

ACLS = Advanced Cardiac Life Support; CPR = cardiopulmonary resuscitation; CV = cardiovascular; DIC = disseminated intravascular coagulation; ECMO/CPS = extracorporeal membrane oxygenation/cardiopulmonary support; FFP = fresh frozen plasma; ICU = intensive care unit; lab = laboratory; MTP = massive transfusion protocol; OB = obstetrics; OR = operating room; PALS = Pediatric Advanced Life Support; PRBC = packed red blood cell; RN = registered nurse; TEE = transesophageal echocardiography.

Transesophageal echocardiography can be useful at identifying amniotic debris in the atrium, facilitating removal on cardiopulmonary bypass.[12] ECMO/CPS using extracorporeal bypass or left ventricular assist devices has been described as a means to treat acute cardiopulmonary failure. Ecker and associates[13] recently reported in the *New England Journal of Medicine* a similar case requiring extensive CPS. Diagnosis and management of AFE is elegantly outlined in their report. The CESAR trial suggested that ECMO for treatment of reversible respiratory failure was superior to conventional ventilation because it increased survival without severe disability.[14] Some investigators have challenged the CESAR trial results and methods. Other articles also promote the use of ECMO for treatment of reversible respiratory failure and acute respiratory distress syndrome, but all suggest that validation and prospective studies are necessary to determine the optimal timing of initiation and specific indications to standardize the use of ECMO in such settings.[15-19] As in this case, the use of ECMO to treat cardiopulmonary failure in the setting of AFE has been described by other investigators.[4,5,7,9,10,13] The cardiac surgeon will determine whether to initiate CPS on the basis of general indications demonstrated in the Sidebar: Extracorporeal Membrane Oxygenation Checklist. In the ICU, the general surgeon or surgical intensivist may adopt management strategies that include use of lung protective ventilation, targeted temperature control for preservation of neurologic function,[20] and early enteral vs parenteral nutritional support.

When such a checklist is in place before the acute event occurs, lessons learned from prior experience are not forgotten in the protracted interim. Each subspecialty can be automatically and seamlessly integrated to provide a unique and critical service in management of the multisystem organ failure associated with AFE. This article combines our experience and knowledge gained from the excellent work of others[5-7,13] into a one-page document that is posted in the labor and delivery suites, in the main operating rooms, and at selected critical locations for easy visibility and accessibility. We are in the process of developing drills to facilitate implementation. Ideally, such drills will be incorporated in periodic training in a manner similar to mass casualty exercises. Regional practice variations in other institutions will mandate changes at the individual hospital level, but the general principles outlined herein constitute a best practice model approved by our institution and based on the current literature. Similar algorithmic decision trees have shown utility in the management of malignant hyperthermia, acute coronary syndromes, and acute stroke.[21-25]

Extracorporeal Membrane Oxygenation Checklist[1]

Algorithmic management of amniotic fluid embolism

(Start ECMO consideration if *Carrico Index:* PaO2/FIO2 < 150)

Indications for ECMO

- Acute Respiratory Distress Syndrome (ARDS) present
- Severe hyoxemia (PaO2/FIO2) < 80 despite PEEP 15 cm-20 cm H_2O
- (PaO2/FIO2) < 50 consider early ECMO
- Uncompensated hypercarbia (pH < 7.15)
- Excessively high plateau airway pressure on ventilator
- Hypercarbic respiratory failure

Contraindications to ECMO

Relative Contraindications

- High-pressure ventilation (peak inspiratory pressure > 30 cm of water) for > 7 days
- High FIO2 requirements (> 0.8) for > 7 days
- Limited vascular access
- Refusal to accept blood products
- Any condition or organ dysfunction that would limit the likelihood of overall benefit from ECMO such as severe, irreversible brain injury or untreatable metastatic cancer

Absolute Contraindications

- Contraindication to anticoagulation
- ECMO as bridge to lung transplantation if transplantation will not be considered

[1] New York Presbyterian Center for Acute Respiratory Failure [Internet]. New York, NY: New York-Presbyterian/Allen Hospital; 2016 [cited 2016 Jun 9]. Available from: http://nyp.org/services/carf/for-physicians/indications-for-ecmo.html.

ECMO = extracorporeal membrane oxygenation; PEEP = positive end-expiratory pressure.

CONCLUSION

The establishment of a multidisciplinary care pathway for the management of AFE is designed to improve maternal and neonatal survival. After a successful maternal and neonatal outcome following a case of AFE at our institution, the course of events and components of care were reviewed, and the parties involved were questioned in an effort to ascertain the elements necessary to reproduce such a monumental success in future cases of AFE. Our analysis suggests that the collaborative effort between multidisciplinary care providers, including early initiation of the massive transfusion protocol and implementation of appropriate CPS, were the critical components for success. Algorithmic treatment is intended to decrease variability, mitigate physician stress, and streamline responses. We offer this report as a template for management of AFE and to encourage other institutions to be proactive in their modifications and implementation of similar algorithmic approaches to AFE. ❖

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A Discipline

Medicine is a discipline, in which the effort is made to use knowledge procured in various ways in order to effect certain practical ends. … It harbors no preconceptions as to diseases or their cure. … It has progressively become less cocksure and more modest. It distrusts general propositions, a priori explanations, grandiose and comforting generalizations. It needs theories only as convenient summaries in which a number of ascertained facts may be used tentatively to define a course of action. It makes no effort to use its discoveries to substantiate a principle formulated before the facts were even suspected.

— Abraham Flexner, 1866-1959, American educator,
reformer of medical and higher education in the US and Canada

Special Report

Integrated Research and the Garfield Memorial National Research Fund—An Unobstructed View

Ed Thomas, RN, MBA

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ABSTRACT

The idea of integrated care has been discussed for many years. It is the belief of those supporting and managing the Garfield Memorial National Research Fund that a similar idea, integrated research, needs to be discussed and tested. This process begins with rethinking the proposal format. This article elaborates on the enhanced proposal format and presents powerful patient stories to demonstrate how integrated research can help deliver better patient care.

INTRODUCTION

Research is only as good as the good it can do. This viewpoint drives the selection of initiatives and projects supported by the Garfield Memorial National Research Fund (GMF), which requires researchers to explain how their investigative efforts will result in operational improvement that will benefit patients and members—either at the point of care or at the systems or processes levels.

The Kaiser Permanente (KP) Board of Directors chartered the GMF in 1987 to honor the research career of Sidney Garfield, MD. His pursuit of innovation based on high-quality, member-focused health care has been a mainstay of the GMF's approach since inception. The GMF funds KP researchers and clinicians, and it has a long history of collaborating with public and private funders and non-KP researchers when they are working with a principal investigator from KP.

INTEGRATED RESEARCH

For decades the GMF approach to requests for proposals has been similar to that of academic models, with a heavy emphasis on methods. The mantra of "research into practice" has great appeal, but the reality is that academic models at times fall short of operational and rapidly changing industry imperatives. Across the health care industry, the idea of integrated care has been discussed and considered for many years. It is the belief and intention of those supporting and managing the GMF that a similar idea—integrated research—must be discussed and tested. The GMF began exploring the concept by redesigning the format of proposals to focus on members, patients, families, and communities. Proposals were then expected to be centered on a story that the people who use and provide health services will easily relate to and understand. Thus the principle of integrated research was born.

THE POWER OF STORY

Story is a compelling approach, as every clinician trained in SOAP (Subjective, Objective, Assessment, Plan) notes knows well. Bringing forward the importance of story fits well within the developing field of precision medicine, wherein individuals' genetics, environment, and lifestyle are taken into account when considering their disease treatment and prevention. Below are several examples of individual stories that shift our discussion toward better understanding of the relationship between patients and the health care delivery system, the system's barriers to access, and what questions drive the research that accelerates improvement.

Prostate Cancer Screening

A 65-year-old man calls the clinic to request laboratory testing before his appointment for a routine physical. His primary care physician (PCP) includes blood tests for prostate-specific antigen (PSA), cholesterol, and glucose. The first of these tests shows an elevated PSA level. The patient does some reading online about the potential complications of prostate cancer treatments and decides he does not want a biopsy. The PSA test result prompts conversations with his PCP in the following months and years.

A 53-year-old man, new to KP, calls his PCP's office, upset that PSA screening was not included in the blood tests ordered at his last office visit. He wants to know why and suspects a cost-cutting initiative. The office schedules a ten-minute telephone appointment with the patient to explain.

Breast Cancer Screening

A 43-year-old woman attends an appointment for a routine Papanicolaou test and asks whether she should undergo a mammogram; her physician recommends screening and signs a mammogram order. After the mammogram, the patient receives a call and is told that abnormalities were detected and additional mammogram views of the areas in question are needed. She calls her PCP's office asking for medication to help her sleep, as her anxiety about the mammogram result is causing insomnia. She looks into purchasing life insurance. The subsequent mammogram shows no abnormalities. She approaches all future screening tests with skepticism.

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Ovarian Cancer

The following excerpt from a consent letter tells a story that is very relevant to the women in a high-risk group and was the driving force behind a specific project's selection for GMF funding: "You are being asked to participate in this research study because you are a woman aged between 30 to 70 years who has a mutation in the BRCA gene and is at risk for developing ovarian cancer." Consider for a moment how this one sentence forever changes a woman's life path and how a health system should respond to women and their loved ones who express concern after receiving such a message.

CONCLUSION

The principle of integrated research requires the investigator to consider, at each step of a patient's care, how the research will do the most good. The answer may be, for example, better communication in the health care system or improvements in decision making by insurance providers. The research may identify barriers limiting the options the health care system can offer or the amount of time that can be dedicated to discussions between clinicians and patients and their families, clarify whether a team care approach offers benefits, or address any other set of questions that will potentially lead to better patient care. ❖

Dislcosure Statement

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So That Few May Reach The Goal

The few who reach the intuitive perception of truth must be preceded by the host of workers, most of them forgotten, whose role it has been to accumulate the facts that constitute the raw material of successful working hypotheses, of the intuitions of discovery. The immense wastefulness of organic life, which demands that thousands of germs perish so that one may live, has its counterpart in the processes of intellectual life; many must run, so that one or a few may reach the goal.

— Robert Platt, Baron Platt, Bt, MD, FRCP, 1900-1978,
British physician who specialized in kidney disease research

Refractory Depression, Fatigue, Irritable Bowel Syndrome, and Chronic Pain: A Functional Medicine Case Report

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ABSTRACT

Introduction: Single-disorder or single-organ-system clinical practice guidelines are often of limited usefulness in guiding effective management of patients with chronic multidimensional signs and symptoms. The presence of multiple long-standing medical problems in a given patient despite intensive medical effort suggests that addressing systemic core imbalances could complement more narrowly focused approaches.

Case Presentation: A 72-year-old man experiencing long-standing depression, fatigue, irritable bowel syndrome, and chronic pain in the context of additional refractory illnesses was assessed and treated, guided by a system-oriented approach to underlying core imbalances termed functional medicine. This patient was referred from a team of clinicians representing primary care, cardiology, gastroenterology, hematology, and psychology. Prior treatment had been unsuccessful in managing multiple chronic comorbidities. Diagnostic assessment included comprehensive stool and nutritional/metabolic laboratory testing.

Results: The blood-, urine-, or stool-based measurements of relevant markers for multiple systemic issues, including digestion/absorption, inflammation, oxidative stress, and methylation, identified previously unrecognized root causes of his constellation of symptoms. These functional measurements guided rational recommendations for dietary choices and supplementation. The patient experienced steady and significant improvement in his mental health, fatigue, chronic pain, and irritable bowel syndrome—as well as the unexpected resolution of his chronic idiopathic pancytopenia.

Conclusion: The success in this case suggests that other patients with chronic, complex, and treatment-refractory illness may benefit from a system-oriented assessment of core imbalances guided by specialized nutritional/metabolic and digestive laboratory testing.

INTRODUCTION

Single-disorder clinical practice guidelines are often of limited usefulness in guiding effective management of patients with chronic multidimensional signs and symptoms. The presence of multiple long-standing medical problems, despite excellent medical care, suggests that new questions or perspectives may be helpful. For example, assessment of underlying key common pathways for all diseases, such as gastrointestinal dysfunction, proinflammatory imbalance, and oxidative stress, could augment the more traditional organ-system-oriented, discipline-focused approach. The organizing principle of the approach taken here, termed functional medicine, is that restoration of health requires defining and addressing seven potential core imbalances that may underlie any given disease state. These seven categories are 1) assimilation (digestion, absorption, microbiomics, respiration), 2) defense and repair (immune function, inflammation, infection), 3) energy (production, regulation), 4) biotransformation and elimination (toxicity, detoxification), 5) transport (cardiovascular and lymphatic systems), 6) communication (hormones, neurotransmitters, cytokines), and 7) structural integrity (membranes, fascia, bacterial translocation). The core belief is that imbalance in one or more of these seven common disease pathways may be the root cause of many seemingly disparate conditions.

This case illustrates how specialized laboratory testing identified previously unrecognized physiologic and biochemical dysfunction in a complex patient. This dysfunction in several common disease pathways was both clinically relevant and inexpensively modifiable. The result was substantial clinical improvement and a markedly improved patient quality of life.

CASE PRESENTATION

Initial Visit (February 2012)

A 72-year-old man was referred to a board-certified internist specializing in complex, refractory illnesses in February 2012. The patient's primary goal, stated at his first visit, was to "walk

Table 1. Medical history timeline

1940s	Heartburn and gastric reflux
1950s	Depression since adolescence
1960s	Began smoking; increased alcohol consumption
1999	Pancreatitis, alcoholic hepatitis, and liver failure (subsequently resolved)
2004	Idiopathic pancytopenia; no alcohol consumption beginning in 2004
2012	Type 2 diabetes mellitus
2012	Specialized digestive and nutritional laboratory testing
2012-2015	Treatment for pancreatic insufficiency, nutritional and digestive imbalances
2013	Resolution of idiopathic pancytopenia and irritable bowel syndrome; decreased depression, fatigue, and pain

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out of the office with more hope." He wrote that it was "very hard to function. I wake after 9 hours of sleep and still feel tired. I don't have the emotional or physical strength to accomplish much. This is frustrating and I am on a cycle of becoming more depressed, more frustrated, and more helpless."

In addition to chronic fatigue and depression, the patient reported 1) heartburn, frequent gas, bloating, and diarrhea alternating with constipation; 2) right lower quadrant abdominal cramping, worsening after bowel movements; and 3) widespread arthralgias and myalgias. See Table 1 through 6 (Tables 4 and 5 available online at: www.thepermanentejournal.org/files/15-242.pdf), and the Sidebar: Important Medical History for a list of the patient's medical considerations.

Initial Clinical Findings

Patient-reported outcome instruments (higher scores indicate worse symptoms):

- Brief Fatigue Inventory: total fatigue interference score of 37/60
- Brief Pain Inventory: total pain interference score 36/70
- Patient Health Questionnaire-9: total score 13 (moderate depression 10-14).

Physical Examination

- Blood pressure 118/54 mmHg, pulse 74 beat/min and regular. Body mass index, 21.6 (calculated as weight in kilograms divided by height in meters squared)
- Anicteric with clear lungs and normal cardiac examination
- Abdomen tender to palpation of the right upper quadrant and epigastric area
- No hepatosplenomegaly
- Palpation in the left lower quadrant resulted in right lower quadrant discomfort
- No ascites present
- No edema in extremities (cool, pale fingers with slow capillary refill)
- No palmar erythema
- No asterixis.

DIAGNOSTIC ASSESSMENTS

The patient's concern of a reduced quality of life secondary to depression, fatigue, and gastrointestinal distress was part of a remarkable medical history as a survivor of end-stage liver failure and alcoholism. However, his depression, fatigue, widespread pain, and gastrointestinal symptoms did not resolve from medical treatments of specific diagnoses and individual symptoms. A clinical decision was made to evaluate the root causes of this patient's symptoms from a functional medicine perspective with comprehensive and structured stool[1,2] and nutritional diagnostic panels. A Comprehensive Digestive Stool Analysis 2.0 (CDSA 2.0) and Nutritional Evaluation (NutrEval) from a Clinical Laboratory Improvement Amendments-certified laboratory (Genova Diagnostics, Asheville, NC) were ordered. These kits offer bundled laboratory tests that provide insight into the function and status of several of the core pathways. Additionally, given the presence of environmental stressors and a decreased sense of personal efficacy, he was referred for Resilience Training or Mindfulness-Based Stress Reduction.

OTHER RELEVANT LABORATORY RESULTS

This patient had previously been found to be vitamin D deficient. However, he was not on vitamin D supplementation at his first visit and supplementation (2000 IU) was begun. In addition this patient's dehydroepiandrosterone-sulfate (DHEAS) level was low normal and DHEA 5 mg sublingually each morning was started.[3]

FOLLOW-UP AND OUTCOMES

The patient was evaluated four times between April 2012 and January 2013. With each subsequent visit, he reported steady improvement in his mood, overall energy, and chronic pain. He was compliant with the dietary recommendations and supplements outlined in Table 3. He elected to not pursue Resilience Training or Mindfulness-Based Stress Reduction.

He experienced minor episodes of dizziness with two near syncopal episodes, for which he was referred to his cardiologist.

Table 2. Medications and supplements at presentation

Medications	Dosage
Lisinopril/hydrochlorothiazide	40 mg/25 mg/d
Trazadone	150 mg/d
Effexor	225 mg/d
Ranitidine	75 mg 2x/d
Cilostazol	1 tablet 2x/d before meals
Atorvastatin	10 mg/d
Cytomel	5 μg/d
Nonsteroidal anti-inflammatory drugs	As needed
Rolaids	As needed
Supplements	
Centrum silver multivitamins	1 tablet/d
Folic acid	400 μg/d
Glucosamine/chondroitin	1500 mg/1200 mg 2x/d
Vitamin B6 (pyridoxine HCL)	50 mg/d

Important Medical History

1. Gastric reflux since childhood
2. Depression since adolescence with persistently elevated Patient Health Questionnaire-9 scores as an adult, consistent with moderately severe depression
3. Twenty pack-year smoking history (quit smoking March 1996)
4. Alcoholism (age 28 to 62 years): alcoholic hepatitis, chronic pancreatitis, pancreatic pseudocyst, and liver failure in 1999—successfully sober since 2004
5. Successful discharge from hospice with resolution of end-stage liver failure, 2004
6. Cardiovascular disease: hypertension, dyslipidemia, coronary stents, and claudication
7. Diagnosed with idiopathic pancytopenia in 2004
8. Type 2 diabetes mellitus since 2012
9. Osteoarthritis
10. Homocysteinemia with homozygous MTHFR (methylenetetrahydrofolate reductase C677T) polymorphism
11. Surgical history: cholecystectomy, tonsillectomy, and anal fissure repair

Repeat testing at his local hospital in December 2012 demonstrated persistent pancreatic insufficiency with an undetectable pancreatic elastase 1 and persistent *Candida glabrata* overgrowth in the stool even though the patient was no longer symptomatic. These findings supported continued prescription of pancreatic enzyme support, probiotics, and a diet rich in prebiotics. The patient's oncologist noted an "inexplicable resolution" of the patient's idiopathic pancytopenia in July 2013 and reported that his physical and laboratory examinations were normal at that time.

In January 2013, patient-reported outcomes had improved significantly:

- Brief Fatigue Inventory: total fatigue interference score of 19/60
- Brief Pain Inventory: total pain interference score 20/70
- Patient Health Questionnaire-9: total score 10.

DISCUSSION

Mental health disorders and gastrointestinal complaints are often components of complex, chronic illnesses that can challenge linear pharmacologic management.[4,5] System-oriented, functional

Table 3. Stool and urine metabolic testing results and therapeutic interventions

Visit no.	Laboratory biomarkers[a]	Diagnostic significance	Therapeutic interventions
1	Pancreatic elastase-1 < 15 (Ref: > 201 μg/g) Fecal fat 50.1 (Ref: 2.6-32.4 mg/g) Long chain fatty acids 43.8 (Ref: 1.3-23.7 mg/g) Phenylacetic acid (PAA) 0.32 mmol/mol creatinine (Ref: ≤ 0.12)	Pancreatic exocrine insufficiency	Pancrelipase 12,000 units with each meal
2	*Candida glabrata* 2+ (Ref: potential pathogen) Arabinose 158 (Ref: ≤ 96) Tartaric acid 66 (≤ 15)	Yeast overgrowth (sensitive to fluconazole)	Fluconazole 100 mg daily for 4 weeks
3	No growth for beneficial bacteria (*Lactobacillus*, *E coli*) 4+ growth (*Citrobacter braakii* and *youngae*) Dihydroxyphenylpropionic acid 6.1 (Ref: ≤ 5.3) Benzoic acid 0.06 (Ref: ≤ 0.05) Hippuric acid 611 (Ref: ≤ 603)	Dysbiosis	Probiotics (multiple: *Lactobacillus* and *Bifidobacteria* species plus *Saccharamyces boulardii*) daily Soluble/insoluble fiber-containing foods in diet
4	Methylenetetrahydrofolate reductase polymorphism Sarcosine 53 (Ref: ≤ 48)	Impaired folate cycle and methylation pathways	Discontinue folic acid supplementation Switch to L-5-methyltetrahydrofolate 400 μg/d plus vitamin B12 as methylfolate 500 μg/d
5	Lysine 39 (Ref: 45-286) α-Aminoadipic acid < detection limit (Ref: 11-73) Glycine 341 (Ref: 639-3306) Histadine 242 (Ref: 271-993)	Insufficient amino acids	Lysine 1000 mg/day for 2 months Glycine 1000 mg/day for 2 months Chew proteins thoroughly (eat slowly)
6	Cystathionine 4 (Ref: 6-33) Glutathione 486 (Ref: ≥ 669 μmol/L)	Impaired trans-sulfuration pathways	Pyridoxal-5-phosphate (vitamin B6) 50 mg/d Molybdenum 75 μg/d (multivitamin)
7	Ethanolamine 71 (Ref: 208-514) Glycine 341 (Ref: 639-3306)	Impaired choline metabolism	Eat lecithin-containing foods (eg, egg yolks, peanuts) Support folate cycle and methylation
8	Adipic acid 3.9 (Ref: ≤ 2.8) Borderline elevated beta-OH-butyric acid 2.0 (Ref: ≤ 2.8) Borderline elevated HMG 12 (Ref: ≤ 15) Borderline elevated ornithine 20 (Ref: 4-21)	Impaired energy production, ketosis Beta-oxidation of fats Pyruvate dehydrogenase (carbohydrate metabolism) Oxidative phosphorylation	Add magnesium glycinate 400 mg/d B vitamin support (multivitamin) Alpha-lipoic acid 200 mg/d Liberalize carbohydrate intake Eat more frequently
9	8-OH-dG 18 (Ref: ≤ 15 μg/g creatinine) Cysteine 82 (Ref: 21-78) Glutathione 486 (Ref: ≥ 669 μmol/L) Pyroglutamic acid 48 (Ref: 16-34) Coenzyme Q10 0.20 (Ref: 0.43-1.49 μg/ml)	Excessive oxidative stress/ overwhelmed defense mechanisms	Coenzyme Q10 (Ubiquinol) 200 mg/d Alpha-lipoic acid 200 mg/d Support glutathione production via transsulfuration Support glutathione production via diet: foods rich in vitamins E and C and sulfur Avoid use of acetaminophen
10	Omega 3 index 3.0 (Ref: ≥ 4.0) Vaccenic acid 1.18 (Ref: ≤ 1.13 wt %) Eicosapentaenoic acid 0.29 (Ref: ≤ 0.26 wt %) Arachidonic acid 22 (Ref: 15-21 wt %)	Long-chain omega-3 fatty acid insufficiency with omega 6 excess	Omega-3 fatty acid: 2 g EPA and DHA/d Cook with olive oil (low heat) or high-oleic acid safflower oil (higher heat)

[a] All biomarkers reported in μmol/L creatinine unless otherwise noted.
DHA = docosahexaenoic acid; EPA = eicosapentaenoic acid; HMG = hydroxymethylglutaryl; Ref = reference; wt % = weighted percentage.

Table 6. Patient-reported outcome instrument scores[a]		
Instruments	**February 2012**	**January 2013**
Brief Fatigue Inventory	37	19
Brief Pain Inventory	36	20
Patient Health Questionnaire-9	13	10

[a] Higher score equals worse symptoms.

medicine approaches, supported by laboratory findings, can help engage patient and clinician in a therapeutic partnership to address genetic, environmental, and lifestyle factors that may be important in complex, chronic diseases.[6]

The intersection of depression, fatigue, widespread pain, and gastrointestinal symptoms in this patient had implications in multiple systems.[7,8] This justified a switch in the diagnostic focus from the customary organ-based systems to whole-body systems. Table 3 delineates the systemic issues important in this case, such as inflammation, oxidative stress, or impaired methylation. The blood-, urine-, or stool-based measurements of the relevant markers for each issue guided rational recommendations for dietary choices and supplementation.

Addressing systemic issues in chronic, complex illness complements a more traditional organ-system approach. In this case, addressing one fundamental imbalance may have addressed several disparate conditions. For example, diagnosing and addressing this patient's digestive dysfunction and the intestinal ecology imbalances not only improved digestive function but also improved several metabolic and nutritional markers known to be correlated with depression, fatigue, and myalgias.

Likewise, the reduction in his myalgias allowed this patient with diabetes with proven atherosclerosis to remain on atorvastatin. HMG Co-A reductase inhibitors (statins) are known to block production of coenzyme Q10; however, supplementation is not routinely recommended. The very low serum coenzyme Q10 measured in this patient suggested that supplementation might be of benefit.[8,9] The reduction in his arthralgias also allowed this patient who presented with low glutathione levels to avoid acetaminophen (which depletes glutathione). His low levels of glutathione were treated with a diet rich in vitamins C, E, molybdenum, selenium, and methionine- or cysteine-containing amino acids. The improved levels of both coenzyme Q10 and glutathione enhanced native oxidative stress management, known to help reduce pain, depression, and fatigue.[10] Finally, correction of all these systemic issues may have contributed to the unexpected resolution of his idiopathic pancytopenia after eight years.

CONCLUSION

David Sackett, one of the pioneers of evidence-based medicine, said "Without clinical expertise, even excellent evidence may be inappropriate for an individual patient."[11] The comprehensive approach outlined here integrated the clinical expertise found in organ-system-based disciplines with the perspective of functional medicine's systems-biology approach. This integration was possible because of external evidence from specialized stool and nutritional diagnostic panels. This combination resulted in effective management of multiple comorbidities that had previously been minimally responsive to treatment. The interference score for this patient's chronic fatigue was reduced by nearly 50% (from 37/60 to 19/60). The interference score for his chronic pain was reduced by nearly 40% (from 36/70 to 20/70). His Patient Health Questionnaire-9 score declined by 25% (13 to 10). His gastrointestinal function improved greatly without significant increases in pharmaceuticals. Therapeutic recommendations were based on measurements of nutritional and digestive status and function. The success in this case suggests that other patients with chronic, complex, and treatment-refractory illness may benefit from a functional medicine, system-oriented approach guided by nutritional and digestive laboratory testing.

Patient Perspective

"I experienced at least a 50% reduction in pain and improvement in my quality of life. My anxiety is reduced, I am more relaxed, and feel stronger. The most helpful has been the work with my gut issues. I am almost like clockwork now." ❖

Disclosure Statement

The author(s) have no conflicts of interest to disclose. Written consent was obtained from the patient for publication of this case report.

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Effectiveness of Cannabidiol Oil for Pediatric Anxiety and Insomnia as Part of Posttraumatic Stress Disorder: A Case Report

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ABSTRACT

Introduction: Anxiety and sleep disorders are often the result of posttraumatic stress disorder and can contribute to an impaired ability to focus and to demonstration of oppositional behaviors.

Case Presentation: These symptoms were present in our patient, a ten-year-old girl who was sexually abused and had minimal parental supervision as a young child under the age of five. Pharmaceutical medications provided partial relief, but results were not long-lasting, and there were major side effects. A trial of cannabidiol oil resulted in a maintained decrease in anxiety and a steady improvement in the quality and quantity of the patient's sleep.

Discussion: Cannabidiol oil, an increasingly popular treatment of anxiety and sleep issues, has been documented as being an effective alternative to pharmaceutical medications. This case study provides clinical data that support the use of cannabidiol oil as a safe treatment for reducing anxiety and improving sleep in a young girl with posttraumatic stress disorder.

INTRODUCTION

Cannabidiol (CBD) oil is a naturally occurring constituent of industrial hemp and marijuana, which are collectively called cannabis. CBD oil is 1 of at least 85 cannabinoid compounds found in cannabis and is popular for its medicinal benefits. After tetrahydrocannabinol (THC), CBD oil is the second-most-abundant component of cannabis. Other names for CBD oil include CBD-rich hemp oil, hemp-derived CBD oil, or CBD-rich cannabis oil. Considered to be generally safe, CBD has been used medicinally for decades. However, CBD is not medical marijuana and should be distinguished from high-CBD strains of medical marijuana, which do contain THC, such as "Charlotte's Web."

The most abundant compound in cannabis, THC is also a cannabinoid. The THC component induces the psychoactive effect, "high." A cannabis plant has different amounts of CBD and THC depending on the strain and thus provides different recreational or medicinal effects. The cannabinoid profile of industrial hemp or medical marijuana is ideal for people looking for the medical benefits of CBD without the "high" of the THC.

The mechanism of action of CBD is multifold.[1-3] Two cannabinoid receptors are known to exist in the human body: CB1 and CB2 receptors. The CB1 receptors are located mainly in the brain and modulate neurotransmitter release in a manner that prevents excessive neuronal activity (thus calming and decreasing anxiety), as well as reduces pain, reduces inflammation, regulates movement and posture control, and regulates sensory perception, memory, and cognitive function.[a2] An endogenous ligand, anandamide, which occurs naturally in our bodies, binds to the CB1 receptors through the G-protein coupling system. CBD has an indirect effect on the CB1 receptors by stopping the enzymatic breakdown of anandamide, allowing it to stay in the system longer and provide medical benefits.[4] CBD has a mild effect on the CB2 receptors, which are located in the periphery in lymphoid tissue. CBD helps to mediate the release of cytokines from the immune cells in a manner that helps to reduce inflammation and pain.[2]

Other mechanisms of action of CBD include stimulation of vanilloid pain receptors (TRPV-1 receptor), which are known to mediate pain perception, inflammation, and body temperature.[5] In addition, CBD may exert its anti-anxiety effect by activating adenosine receptors which play a significant role in cardiovascular function and cause a broad anti-inflammatory effect throughout the body.[5] At high concentrations, CBD directly activates the 5-HT1A serotonin receptor, thereby conferring an antidepressant effect.[6] Cannabidiol has been found to be an antagonist at the potentially new third cannabinoid receptor, GPR55, in the caudate nucleus and putamen, which if stimulated may contribute to osteoporosis.[7]

Since the 1940s, a considerable number of published articles have dealt with the chemistry, biochemistry, pharmacology, and clinical effects of CBD.[8] The last decade has shown a notable increase in the scientific literature on CBD, owing to its identification for reducing nausea and vomiting, combating psychotic disorders, reducing inflammation, decreasing anxiety and depression, improving sleep, and increasing a sense of well-being.[9-12] Findings presented at the 2015 International Cannabinoid Research Society at its 25th Annual Symposium reported the use of CBD as beneficial for kidney fibrosis and inflammation, metabolic syndrome, overweight and obesity, anorexia-cachexia syndrome, and modification of osteoarthritic and other musculoskeletal conditions.[13-16]

Although studies have demonstrated the calming, anti-inflammatory, and relaxing effects of CBD, clinical data from actual cases is minimal. This case study offers evidence that CBD is effective as a safe alternative treatment to traditional psychiatric medications for reducing anxiety and insomnia.[17]

CASE PRESENTATION

A ten-year-old girl presented in January 2015 for a reevaluation of behaviors related to her diagnosis of posttraumatic stress disorder (PTSD) secondary to sexual

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abuse. Her chief issues included anxiety, insomnia, outbursts at school, suicidal ideation, and self-destructive behaviors. Her grandmother, who has permanent custody of the patient and her younger brother, accompanied her.

Our patient had been seen for an initial evaluation in January 2012 and received a diagnosis of PTSD secondary to sexual abuse on the basis of her history, clinical observations, and behaviors (Table 1). Her father had died 6 months earlier in a motor vehicle accident, and our patient's maternal grandparents became her permanent guardians. Before her father's death, our patient had no supervision from her father and very little supervision from her mother. An 11-year-old boy had molested her when she was 3 years old. Her medical history included her mother having methadone addiction, alcoholism, bipolar disorder, and depression. Her mother used marijuana her entire pregnancy with the girl. The patient presented in January 2012 as displaying aggressive, disobedient, impulsive, and sexually inappropriate behaviors. She also demonstrated low self-esteem and anxiety and had poor sleep (restless, interrupted, and unable to sleep alone).

Workup during 2012 included laboratory studies, which ruled out a thyroid dysfunction and an iron or vitamin D deficiency. The patient was started on a

Table 1. Timeline

Date	Presentation	Medications	Supplements	Other
January 31, 2012	New evaluation: 7.5-year-old girl. History of sexual abuse and neglect. Issues: Insomnia, sexual behaviors. Diagnosis: PTSD secondary to sexual abuse.	None	Melatonin, 1 mg/night	February 14, 2012, laboratory values: TSH, 2.46 mIU/L (reference range, 0.47-4.68 mIU/L); ferritin: 21 ng/mL (reference range, 10-150 ng/mL). February 16, 2012, laboratory values: Vitamin D_3: 39 ng/mL (reference range, 20-50 ng/mL)
February 20, 2012	Sleeping 2-3 hours/night. Started counseling; Cooperative and good behavior at counseling session. Anxious, traumatized.	Clonidine, 0.05 mg (half tablet) at bedtime	Inositol, 3 g 3 times/d; EPA fish oil, 500 mg/d	Eye movement desensitization and reprocessing therapy recommended
February 22, 2012	Did not do well with clonidine because of hallucinations, so she discontinued that treatment. Behavior still very rough; sleep poor.	Started imipramine therapy, 25 mg at bedtime		March 7, 2012: ECG was normal
August 8, 2012[a]	Good summer. In play therapy. Overall better sleep and energy with imipramine therapy. Patient's 6-year-old brother also now in therapy.	Imipramine, 25 mg at bedtime		
January 21, 2015	Returned for evaluation and treatment after 3 years. Suicidal ideation; cut self on leg; defiant and stubborn. Had psychotherapy 3 years straight twice a month. Sleeps with brother; can't sleep alone.	Off all medications for past 18 months	Melatonin, 5 mg; St John's wort, 450 mg twice/d; magnesium, 300 mg/d; diphenhydramine, 25 mg/night	
February 16, 2015	Hard to manage. Has outbursts at school.		Magnesium and St John's wort: stopped treatment; EPA fish oil, 750 mg/d; diphenhydramine, 25 mg/night	February 11, 2015: Normal cortisol and DHEA levels
March 16, 2015	Better overall. Started animal-assisted therapy.		EPA fish oil, 750 mg/d; diphenhydramine, 25 mg/night	Started a regimen of CBD oil, 25 mg (1 capsule)/d at 6 pm
April 14, 2015	Sleeping better with CBD treatment. Getting biofeedback. Has stomachaches. Mood is more at ease.		EPA fish oil, 750 mg/d; diphenhydramine, 25 mg/night	CBD oil, 25 mg (1 capsule)/d at 6 pm
May 26, 2015	"Ghosts" waking patient up at night.		EPA fish oil, 750 mg/d	CBD oil, 25 mg (1 capsule)/d at 6 pm
July 22, 2015	Sleeping better; able to sleep in own room 3-4 nights/wk.		EPA fish oil, 750 mg/d	CBD liquid, 12 mg (in 4 sublingual sprays)/night; 12 mg more (in 4 sublingual sprays) during the day as needed for anxiety, typically 3 or 4 times/wk
August 24, 2015	Sleeping well. Handling school well.		EPA fish oil, 750 mg/d	CBD oil, 25 mg (1 capsule)/night; CBD liquid, 6-12 mg (in 2-4 sublingual sprays) as needed for anxiety, typically 2 or 3 times/wk

[a] There were additional visits in 2012 with no substantial changes.

CBD = cannabidiol; DHEA = dehydroepiandrosterone; ECG = electrocardiogram; EPA = eicosapentaenoic acid; PTSD = posttraumatic stress disorder; TSH = thyroid stimulating hormone.

regimen of 1 mg/night of melatonin, which helped her sleep duration. Three grams of inositol 3 times a day and 500 mg/d of eicosapentaenoic fish oil were also helpful in reducing her anxiety. A trial of clonidine was implemented, which resulted in hallucinations and thus was discontinued. The patient was switched to a regimen of 25 mg of imipramine at bedtime to decrease her anxiety, which appeared to be helpful. Counseling sessions were started. The patient continued psychotherapy for 3 years, but she was not seen again in our clinic until the return visit in January 2015, when she was not receiving any of her medications and supplements.

CBD oil can be an effective compound to reduce anxiety and insomnia secondary to PTSD.

At the patient's return in January 2015, she demonstrated the same prominent symptoms as at her initial presentation. At that time, the initial treatment included the following supplements and medications to assist with her sleep and anxiety: melatonin, 5 mg/night; magnesium, 300 mg/d; and diphenhydramine (Benadryl), 25 mg/night. Our patient demonstrated slight gains but was still having outbursts at school and was reportedly difficult to manage at home. In addition, her underlying anxiety continued.

Cannabidiol oil was explored as a potential additional treatment to help her insomnia and anxiety, but we deferred for two months while we waited for a response from other interventions. The grandmother preferred reducing the pharmacologic load given her granddaughter's failure to respond long term to psychiatric medications.

In March 2015, CBD oil was recommended as a potential additional treatment to help her insomnia and anxiety, and her grandmother provided full informed consent. Our patient was administered the Sleep Disturbance Scale for Children[18] and the Screen for Anxiety Related Disorders (SCARED)[19] before taking the CBD oil and each month afterward for the next 5 months. Test scores on the Sleep Disturbance Scale for Children and Screen for Anxiety Related Disorders demonstrated an improvement (Table 2).

A trial of CBD supplements (25 mg) was then initiated at bedtime, and 6 mg to 12 mg of CBD sublingual spray was administered during the day as needed for anxiety. A gradual increase in sleep quality and quantity and a decrease in her anxiety were noted. After 5 months, the patient was sleeping in her own room most nights and handling the new school year with no difficulties. No side effects were observed from taking the CBD oil.

DISCUSSION

Studies repeatedly recognize the prevalence of an anxiety-provoked sleep disorder after a traumatic experience.[20] Our patient was definitely experiencing this phenomenon, which was aggravated by daily stressful activities.

The main finding from this case study is that CBD oil can be an effective compound to reduce anxiety and insomnia secondary to PTSD. A review of the literature suggests some benefits from the use of CBD because of its anxiolytic and sleep-inducing effects.[9] Animal studies support use of this treatment and report that "CBD may block anxiety-induced [rapid eye movement] sleep alteration via its anxiolytic effect on the brain."[21]

The strength of this particular case is that our patient was receiving no pharmaceutical medications (other than nonprescription diphenhydramine) but only nutritional supplements and the CBD oil to control her symptoms. Her scores on the sleep scale and the anxiety scale consistently and steadily decreased during a period of 5 months (see Table 2). She was ultimately able to sleep through the night most nights in her own room, was less anxious at school and home, and displayed appropriate behaviors. The patient's grandmother (her caregiver) reported: "My granddaughter's behaviors are definitely better being on the CBD. Her anxiety is not gone, but it is not as intense and she is much easier to be around. She now sleeps in her own room most of the time, which has never happened before."

Table 2. Patient's clinical progress in sleep and anxiety

Date of visit	Sleep scale score[a]	SCARED score[b]
March 16, 2015	59	34
May 25, 2015	42	24
July 22, 2015	41	19
August 24, 2015	37	16
September 22, 2015	38	18

[a] A score of more than 50 is considered indicative of a sleep disorder on the Sleep Disturbance Scale for Children.
[b] A SCARED score over 25 indicates a high probability of a childhood anxiety disorder.
SCARED = Screen for Anxiety Related Disorders.

Further study will need to be conducted to determine the permanency of our patient's positive behaviors and how long she will need to continue taking the CBD oil. We do not have a reasonable foundation to recommend dosing from the scientific literature. However, in our experience, this supplement given 12 mg to 25 mg once daily appears to provide relief of key symptoms with minimal side effects. Our patient did not voice any complaints or discomfort from the use of CBD. We routinely asked about headache, fatigue, and change in appetite or agitation in addition to conducting a routine psychiatric evaluation. Although CBD is considered generally safe,[17] the long-term effects are yet to be studied.

The ultimate goal is to gradually taper her off the use of CBD oil and transition our patient into lifelong coping strategies such as yoga, meditation, and various other therapeutic activities. ❖

[a] GW Pharmaceuticals is the founder of the Cannabinoid Research Institute, directed by Philip Robson, MD. Further research articles listed.

Disclosure Statement

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

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Marijuana and Medicine

Scientific data indicate the potential therapeutic value of cannabinoid drugs, primarily [tetrahydrocannabinol], for pain relief, control of nausea and vomiting, and appetite stimulation; smoked marijuana, however, is a crude [tetrahydrocannabinol] delivery system that also delivers harmful substances.

— Joy JE, Watson SJ Jr, Benson JA Jr. Marijuana and medicine: Assessing the science base. Washington, DC: National Academies Press; 1999.

CASE REPORTS

A General Pediatrics and Integrative Medicine Approach to Pervasive Refusal Syndrome: A Case Report

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ABSTRACT

Introduction: Pervasive refusal syndrome (PRS) describes children with social withdrawal who become unable to walk, eat, or care for themselves. This case report examines whether an integrative medicine approach is useful for treating PRS.

Case Presentation: A seven-year-old girl with symptoms most consistent with PRS and depression was admitted to a pediatric ward in Germany that integrates conventional pediatric and psychosomatic care with anthroposophic medicine. She was integrated into the structured activities of the ward and received massages, movement therapy, and color light therapy. Her parents were fully integrated into her care. After four weeks, she talked again, showed increased appetite, and supported herself when moved passively. She made a full recovery within four weeks after hospital discharge.

Discussion: Integration of parents and an integrative medicine approach providing a variety of comforting sensory experiences was helpful for this patient with PRS.

INTRODUCTION

Pervasive refusal syndrome (PRS) describes children with dramatic social withdrawal who refuse or are unable to walk, eat, or care for themselves, typically refusing any help.[1] The etiology has been discussed as a sensitivity-stressor spectrum of traumatic experiences.[2] A multidisciplinary, structured, inpatient psychiatric approach that provides persistent, realistic optimism and restricted parent visits has been recommended.[3,4] There is documentation of one child being treated on a general pediatric ward with full integration of parents into her care[5] and one child treated at home.[6] Complementary and alternative medicine approaches seem to have a place in child psychiatry,[7] but there are no reports detailing their use in PRS.

CASE PRESENTATION

Presenting Concerns

A seven-year-old white girl presented with unclear loss of energy and diffuse headaches. Her symptoms worsened during the next four weeks with the addition of loss of appetite. After a viral infection of the upper respiratory tract, she began to experience generalized weakness of the limbs, with increasing gait difficulties (Figure 1).

In her medical history, the patient had colic in early infancy and Stage 1 Lyme borreliosis at age 5 years. Typical child development milestones were met. During preschool she had difficulties detaching from her mother and complained about frequent abdominal pain. The family physician described her as an intelligent, almost overly alert, sensitive, and anxious child. Her weight fluctuated at or above the third percentile for age. She began primary school at age six full of enthusiasm and was well performing and well integrated. A few months into the first school year, she seemed increasingly exhausted, eagerly awaiting each weekend and not wanting to return to school after holidays. The girl lived with her parents and a younger brother. Both parents had been feeling overworked the previous year; the mother had been near burnout and taken time off work.

During a 6-week hospitalization for diagnostic work-up at a pediatric neurology center, the girl became wheelchair bound, refused to eat, and lost further weight, requiring feeding by nasogastric tube. Her speech became slow and poorly pronounced, and she whimpered and cried for hours every day. She was transferred to a child psychiatric ward, where she received diagnoses of moderate depression, mixed dissociative disorder, and separation anxiety. Treatment with haloperidol was started. Her parents interrupted the hospitalization and medication after 16 days because they did not agree with the restricted twice-weekly visits and a pharmaceutical treatment approach. She was then admitted to a general pediatric ward with an integrative medicine approach at the Filderklinik in Stuttgart, Germany, on referral from the family physician.

At physical examination, the girl did not speak but appeared alert and smiled as a positive response to questions. Sitting in a wheelchair with her head hanging to the side, no active movements occurred. There was no spasticity, posturing, or negativism. Muscle tendon reflexes were present and symmetric. Babinski sign was absent. She whimpered even in response to light touch. Findings from examination of the heart, lungs, and abdomen were normal. The child's body mass index was 11.4 kg/m^2 (below the third percentile).

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Extensive diagnostic evaluations for infectious, metabolic, neoplastic, and endocrine causes of her neurologic symptoms were carried out during the initial neurologic hospitalization. All the following parameters were found to be normal: cerebrospinal fluid analyzed for cells, chemistry panel, *Borrelia burgdorferi* serologic analysis, polymerase chain reaction for *Herpes simplex* and picornavirus; complete blood cell count; electrolytes; liver function tests; thyroid function tests; vitamin B_{12} levels; cortisol levels; screening tests for metabolic diseases; copper elimination tests for Wilson disease; and antibodies for gluten intolerance. In addition, magnetic resonance imaging of the head and spine and electroencephalography had normal results. Lively muscle tendon reflexes excluded Guillain-Barré syndrome. No intelligence test was performed.

The working diagnosis on arrival to our service was PRS because her withdrawal affected eating, mobilization, speech, and school attendance and required hospitalization, and because she would react negatively to encouragement and praise.[3,8] Crying and whimpering were atypical for PRS, and depression was considered as an additional diagnosis. Depression could not, however, explain the level of somatic impairment in the absence of depressive stupor, agitation, diurnal variation, or psychomotor retardation.[2] Separation anxiety seemed present but could not explain the extent of the symptoms. Although she had illness gains in the form of paternal attention, her condition fit less with conversion disorder, which more typically affects one organ system at a time; additionally, neurologic inconsistencies that are diagnostic of conversion muscle weakness were missing.[9] A psychotic disorder with predominantly negative symptoms was ruled out because she was always adequate in visual contact and her sense of reality was intact. Although mutism can be part of catatonia, she had none of the motor signs of this condition.[10] It should be noted, however, that some catatonia experts consider PRS a misnomer for catatonia.[11]

Therapeutic Intervention and Treatment

The hospital setting was a pediatric ward that integrates conventional care with anthroposophic medicine.[12] The team included physicians, nurses, special educators, and therapists, offering specialized movement therapy,[13] rhythmic massage,[14] art therapies, and color light therapy.[15] Specific nursing techniques included massages and compresses. Medications in low homeopathic dilutions were used in addition to conventional medications. Elements of Waldorf special education were integrated into the ward routines.[16] A pediatrician experienced in child psychiatry and a senior pediatric neurologist were involved in this patient's care.

The parents were told that, as a sensitive and anxious child, their daughter seemed to have "pulled back" because she had too quickly exhausted her energy with her alert and active approach toward an increasingly demanding environment. The therapy goal was recovery through comforting sensory and whole-body experiences, with initial acceptance of her regression.

We allowed the mother to be present throughout the hospilization to let the girl feel secure, accepting potential reinforcement of the mother-child attachment. An initial four-week stay was agreed to by the parents. All therapies would at least be tried; there was an understanding that a nasogastric tube would be placed if she lost further weight.

The girl was integrated into joint meals with patients, parents, and staff; joint morning and evening gatherings of all children in a circle; and a daily play group for preschool children. She would sit in her wheelchair rather than play, but from her eye expressions she appeared increasingly engaged. She was spoon-fed, progressing gradually from pureed to solid food and eventually a regular diet. A special educator played to her on a harp and read her stories.

The patient received daily gentle abdominal massages with mallow oil (*Malva arborea*), and rhythmic massage of the legs with ointment containing pallasites, a mineral. She had twice-weekly

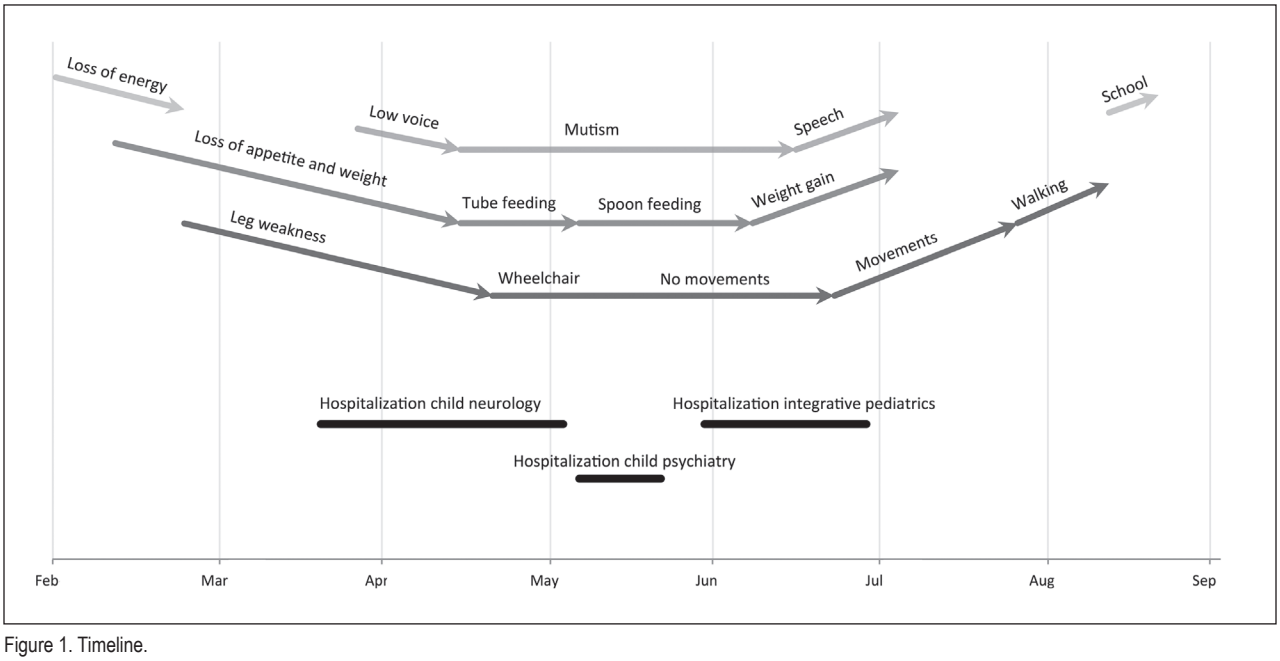

Figure 1. Timeline.

oil-dispersion baths with gold-rose blossom oil and, toward the end, evening mustard footbaths.

In movement therapy (eurythmy therapy), movements were first shown by the therapist and connected to short stories. Later the therapist would move the girl's arms and legs; during Week 4 the patient began giving active support during arm movements.

Color light therapy sessions involved sitting five to eight minutes in front of different metal-colored glasses (manganese-violet, iron-blue, red-gold, and cobalt-blue).

Only one family therapy session took place with both parents.

Anthroposophic medications were administered as follows:

1. *Before admission and continued until hospital Day 9:* Bryophyllum 50% trituration, Bryophyllum argento cultum Rh D3 (D denotes decimal dilution, ie, D2 = 1:10^2, D3 = 1:10^3, etc), and Gentiana Magenglobuli D4.
2. *From hospital Day 9 onward:* "Aufbaukalk 1, Weleda" (containing Apatit D5, Cucurbita pepo D2); "Aufbaukalk 2, Weleda" (containing Conchae, Quercus D3); and Levisticum D4.
3. *Started between hospital Days 12 and 21:* Siderit D6; Argentum metallicum praeparatum D20; Apis D4/Levisticum D3; and Berberis D2/Quarz D19.

Apis/Levisticum and Berberis/Quarz were manufactured by Wala Heilmittel GmbH, Bad Boll, Germany; all other medications were manufactured by Weleda AG, Schwäbisch Gmünd, Germany.

… the pleasurable atmosphere of a general pediatric ward, body and sensory stimulation therapies, as well as a developed structure of group activities were the main "therapeutic agent."

Follow-up and Outcomes

During the course of 4 weeks, the girl began to talk again. Her appetite increased, although she gained only 900 g of weight (still below the third percentile). At the end of the hospitalization, she gave support when moved passively and began moving while asleep. On discharge, she expressed a desire to not be seen in her wheelchair. After discharge, she gradually started walking and within a month made an almost full recovery (except for a stiff walk). A scheduled subsequent hospitalization was no longer needed. A year later, eating habits, weight, body movements, and strength were normal, and she was interacting actively with friends. She now attends a small class in a different school to provide a more socially protected learning environment; she has no academic difficulties.

The parents read the final report and gave signed informed consent for its publication. The mother said of their daughter, "The worst thing was not having a diagnosis for a long time. At the Filderklinik she wanted to avoid being again fed by nasogastric tube and therefore decided to eat. This became her first step toward recovery. In the months preceding her illness, it seemed as if her ambitions were outpacing her energy; this exhausted her. Today she has fully recovered but is less in a hurry to achieve things."

DISCUSSION

PRS and depression appeared the most likely diagnoses in this sensitive, high-achieving girl. Within the spectrum of resistance, withdrawal and regression were dominant rather than refusal.[17] Recovery was exceptionally fast,[18] probably helped by absence of severe trauma or family dysfunction, as well as the maintained level of cooperation with the patient, and the therapeutic approach.

We think that the pleasurable atmosphere of a general pediatric ward, body and sensory stimulation therapies, as well as a developed structure of group activities were the main "therapeutic agent."[19] Full parental integration seemed important too. It is unclear whether enmeshed mother-child relationships in PRS are primary or secondary to the child becoming ill.[3] Our concept worked similarly well for two additional children with PRS who presented to our clinic.

Anthroposophic medicine is an integrative treatment system based on a holistic understanding of humans and nature that considers a close interconnection between body, mind, and spirit in its therapeutic approach.[12,20] Anthroposophic medicine is integrated with conventional medicine in hospitals and medical practices and is most prevalent in central Europe.[12] It is practiced by physicians, therapists, and nurses and is used across a range of medical specialties. A Health-Technology Assessment Report and a 2011 update identified 265 clinical studies on the efficacy and effectiveness of anthroposophic medicine.[21-23]

The integrative treatment approach with anthroposophic medicine seemed helpful in this case, but separating out how the specific therapies contributed to the overall progress is not feasible. Medications play a limited role in treatment of PRS. Because anthroposophic medications were used simultaneously with various other therapies, their benefit cannot be determined for this single case.

By describing therapeutic concept, setting, and all interventions, a whole-systems research approach was taken.[24] A limitation of this report is that no intelligence test was performed, because the girl's intelligence was perceived as above average. Another limitation is that replication requires a multidisciplinary approach and a team with psychiatric experience that few general pediatric departments can offer. Other methods than those used here could be considered to provide comforting sensory stimulation, such as Snoezelen multisensory stimulation therapy.[25]

CONCLUSION

An integrative medicine approach with various complementary therapies focused on comforting and sensory stimulation, were helpful in this case of PRS and depression. ❖

Disclosure Statement

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

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Equal

When the disease is stronger than the patient, the physician will not be able to help at all. When the strength of the patient is greater than the strength of the disease, he does not need a physician at all. But when both are equal, then one needs a physician who will support the patient's strength and help him against the disease.

— Abu Bakr Muhammad Ibn Zakariya al Razi, 854-925, Persian polymath, physician, alchemist, and philosopher

COMMENTARY

Ethical Analysis for Physicians Considering the Provision of Life-Ending Medication in Compliance with the California End of Life Option Act

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ABSTRACT

The End of Life Option Act in California, effective June 9, 2016, permits physicians to prescribe lethal medication to patients confirmed to be terminally ill and capable of independently making and carrying out a decision to ingest deadly medication. Medicine has traditionally excluded the provision of deadly medication from proper practice. Physicians reasonably may hold to that limit. However, honoring a repeated request from a capable, terminally ill patient to receive life-ending medication still can be considered to be a moral and permissible approach to relieve suffering. A physician choosing to expand his/her role within this narrowly defined context allows the patient to assume authority for a deeply personal decision that may belong to the patient more than to anyone else.

INTRODUCTION

This article details an ethical rationale for the physician prescribing life-ending medications for capable, terminally ill patients who will then decide for themselves whether to end their lives this way. It also provides guidance for the physician who wonders whether this service should be offered within the context of an agreement to work collaboratively as physicians. More than one ethical approach may be used to examine this clinical situation. This particular analysis is offered to promote a moral understanding among physicians practicing together within the Southern California Permanente Medical Group (SCPMG). The approach includes those who appreciate the actions permitted in the End of Life Option Act (EOLOA) as useful to Kaiser Permanente (KP) patients and those who may hold an opposing opinion. Physicians who have not yet decided which approach to consider appropriate may benefit from this discussion.

Legislative Highlights

The state of Oregon implemented the Death with Dignity Act in 1997,[1] adopting a process for "Physician Aid-In-Dying." Although commonly referred to as "Physician-Assisted Suicide," many patients were satisfied with receiving the medication without taking it. Numerous attempts to repeal the Act failed. In 2006, the US Supreme Court ruled in favor of Oregon, upholding the law.[2]

KP Northwest adopted procedures to comply with the Oregon law to include participation by physicians within Northwest Permanente.

In California, skilled lobbying efforts, high-profile cases, significant voter support, and precedents from other states led to the proposal of the EOLOA.[3] Initially the California Medical Association (CMA) opposed the legislation, relying on a position statement held since 1987. After a poll and discussion, the CMA changed its position to "neutral" in May 2015.[4] Despite eloquent objections by some physicians reluctant to be placed in a role proscribed by traditional values and after withdrawal of CMA opposition, the EOLOA was signed into law in 2015 and implemented on June 9, 2016.

The CMA position change and the enacted law are at odds with the current American Medical Association position (see Sidebar: American Medical Association Opinion 2.211—Physician-Assisted Suicide), leaving California physicians in a quandary about existing and potential roles.

Since the passage of the law, discussions have included attempts to reverse the EOLOA through referendum or other political processes. A referendum attempt failed for lack of signatures in January 2016.

The California End of Life Option Act

The EOLOA[3] details circumstances under which physicians in California, including those within SCPMG, may legally provide life-ending medications to terminally ill patients. KP has remained neutral on the subject of the EOLOA. After passage of the law, a KP Southern California task force formed to organize efforts to comply with the EOLOA. The task force asked the physician CoDirector of the KP Southern California Bioethics Program to provide an ethical analysis for SCPMG physicians. This article shares that analysis (see Sidebar: Ethical Analysis Summary).

Within the context of the law, a terminally ill patient with access to adequate palliative care, who is capable of making this decision without coercion or impairment from psychiatric illness, may express a persistent wish to consciously ingest, under his/her own power, a physician-prescribed, life-ending medication. That medication allows the dying patient to determine the time and nature of death rather than leaving it to the course of illness.

Provisions of the EOLOA include that the patient must

1. be age 18 years or older; capable of making "medical" decisions as assessed by an attending and consulting physician; and, if needed, as assessed by either a psychologist or a psychiatrist

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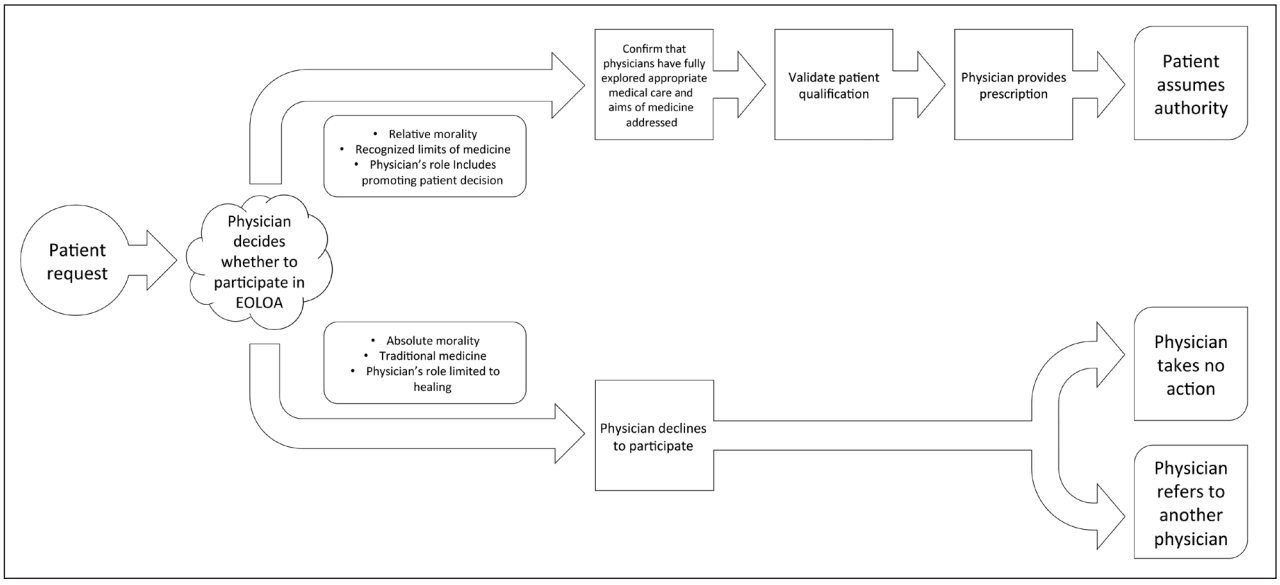

Figure 1. Flow chart of process for physician involvement in the EOLOA.

EOLOA = End of Life Option Act.

2. have a disease that within reasonable medical judgment, and confirmed by a consulting physician, will result in death within 6 months
3. be able to make an affirmative, conscious, and physical act to self-administer and ingest the aid-in-dying medication
4. make two oral requests to an attending physician, separated by at least 15 days and associated with a completed, written request
5. be a California resident.

Once the medications have been secured by the patient, s/he assumes moral authority over whether to take them. California is, to some degree, relieved of the moral implications of disallowing patients to take their lives in this manner and assumes some responsibility to confirm that the process does not result in harm. The EOLOA can be considered to be a legal device necessary in the context of the current California law that allows patients to receive controlled substances only through a physician's prescription. Although individual physician participation in this act is optional, this legal situation requires physician participation for the Act to be operationalized.

Practically, the participating physician takes three steps (Figure 1):

1. confirm appropriate medical care has been fully explored and the aims of medicine have been addressed
2. validate that a patient is qualified to receive the medication under the EOLOA and within the exercise of a physician's best medical judgment
3. provide the prescription to the patient.

AN ETHICAL RATIONALE

Some believe that any step a physician takes toward providing any patient with lethal medication violates traditional prohibitions against offering lethal or poisonous medication.[5,6] This view holds that the physician acting in such a role is either engaging in or is complicit in an immoral act—or at least not practicing medicine in the traditional role of medicine as a healing profession. In this traditional framework, the prescription of life-ending medication could be seen as eroding the credibility and fabric of a social understanding of the practice of medicine. Some may consider that such a serious change might undermine the

American Medical Association Opinion 2.211—Physician-Assisted Suicide[1]

Physician-assisted suicide occurs when a physician facilitates a patient's death by providing the necessary means and/or information to enable the patient to perform the life-ending act (eg, the physician provides sleeping pills and information about the lethal dose, while aware that the patient may commit suicide).

It is understandable, though tragic, that some patients in extreme duress—such as those suffering from a terminal, painful, debilitating illness—may come to decide that death is preferable to life. However, allowing physicians to participate in assisted suicide would cause more harm than good. Physician-assisted suicide is fundamentally incompatible with the physician's role as healer, would be difficult or impossible to control, and would pose serious societal risks.

Instead of participating in assisted suicide, physicians must aggressively respond to the needs of patients at the end of life. Patients should not be abandoned once it is determined that cure is impossible. Multidisciplinary interventions should be sought including specialty consultation, hospice care, pastoral support, family counseling, and other modalities. Patients near the end of life must continue to receive emotional support, comfort care, adequate pain control, respect for patient autonomy, and good communication. (I, IV)

Issued June 1994

1. Opinion 2.211: physician-assisted suicide [Internet]. Chicago, IL: American Medical Association; 1994 Jun [cited 2016 Feb 28]. Available from: www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2211.page.

pillars on which the profession of medicine is founded and damage related provisions for professional conduct. Physicians holding this view may understandably regard those who prescribe life-ending medication as unprofessional and fear that the prescription of aid-in-dying drugs will destroy patient trust in the physician's commitment to cure.

Physicians who choose to participate in the provisions of the EOLOA also uphold key notions of professional responsibility. Particularly important in this view is the practical realization of the worth and centrality of individual human values in every aspect of medical professional activity. For these physicians, it follows that a sensitive and empathic response that honors individual beliefs, dignity, and perceived suffering may, in some contexts, understandably result in the prescription of life-ending medication. The physician fulfills a patient's request, giving the patient a measure of control over an uncontrollable illness, and confirming that a moral community accepts the patient's decision. This view holds further that patients will trust physicians additionally to facilitate a more comfortable end, while addressing perhaps the greatest suffering—physical, emotional, existential—that patients experience.

Although one physician within SCPMG may not accept another's position on this compelling issue, tolerance by physicians of the plurality of opinions and the different social roles of medical professionals that result remains deeply important. Tolerance fosters mutual respect, enhances working relationships, and provides for a broader understanding that physicians who care deeply about their patients may not agree on this particular issue. This ethical analysis is offered to promote understanding among SCPMG physicians and with it, a commitment to professional values that continue to inspire patient trust and appreciation.

Ethical Analysis Summary

Some physicians within California will choose to participate in the End of Life Option Act (EOLOA). They will feel they are doing the right thing when they prescribe life-ending medications for capable, terminally ill patients who will then decide for themselves whether to end their lives this way. Other physicians may feel uncomfortable participating, believing that prescribing lethal medication may be immoral or outside the proper practice of medicine. Undecided physicians may suspend judgment, waiting to be convinced by a particular patient with a terminal illness making an understandable request.

The arguments offered in this article are intended to help physicians make their own decision and to appreciate the decisions of other physicians. Although a physician may disagree with another's position, tolerance is important. Tolerance fosters mutual respect, enhances working relationships, and provides for the broader understanding that physicians who care deeply about their patients on this particular issue may not agree.

Physicians who value traditional medicine: For these physicians prescribing fatal doses of medication to patients is just wrong; it is contrary to the proper practice of medicine as handed down through millennia. Medicine is about healing; ending life can never be considered healing. There must be some absolute moral standard on which medicine is founded. Just as physicians should not participate in torture or the execution of criminals, physicians also should not participate in suicide or encourage patients to kill themselves. Physicians should focus solely on providing sufficient palliative and hospice resources to the terminally ill to reduce the likelihood of such requests.

Physicians for whom the morality of this specific end-of-life decision is relative and not absolute: These physicians feel that, when there is no way to heal the dying patient, the best approach is to allow the patient to decide this issue. When the Hippocratic Oath was written, a dying patient might have received assistance from nonphysicians to obtain life-ending preparations. The traditional practice of medicine did not prevent patients from obtaining these drugs; it only disallowed physicians from providing them. Well-intended modern laws restrict independent patient access to lethal medications without a physician's prescription. The patient may understandably view a physician's refusal to prescribe these medications as being unfairly obstructive. The EOLOA allows a physician to honor a dying patient's request to obtain a life-ending prescription. Although prescribing lethal doses of medication violates the tenets of traditional medicine, it is considered reasonable with the safeguards of the EOLOA. The physician prescribes the drugs, allowing the patient to assume authority for this personal decision. In addition, the physician provides comfort to the patient, giving him/her a measure of control over an uncontrollable illness, and confirming that a moral community accepts the patient's decision. Although many concerns of the dying can be adequately addressed by palliative or hospice care, these have limits with regard to the ability to restore lost autonomy, to promote personal dignity, to make life sufficiently enjoyable, and to lessen a patient's sense of burden on loved ones.

Thus, the act of prescribing a fatal dose of medication is not within the traditional practice of medicine. Physicians may reasonably hold to that limit. However, delivery of life-ending medications to the terminally ill can still be considered an approach to relieve suffering that is both moral and permissible.

EMPIRIC BASIS FOR THE END OF LIFE OPTION ACT

For those patients whose underlying disease has no cure, physicians offer treatment for suffering: the palliation of symptoms. The growth of the specialty of palliative medicine over the last decades is a testimony to the complexity of this treatment. Despite appropriate palliation, some patients facing death will still request life-ending medication. The reasons for this request have been categorized in various ways as seen by those engaged in this activity who poll their particular patient populations. See Sidebar: Euthanasia Research for examples and extracts from one Web site promoting the discussion of euthanasia.

THE MORAL BASIS

Although palliation of symptoms may not be enough for some terminally ill patients to want to continue life, this fact does not oblige physicians to provide the means by which a patient might end it. On what moral basis, then, can physicians participate in the validation of a patient's request for life-ending medications, confirm the patient's access to palliative care, and in the proper situation prescribe deadly medication?

From the *Hippocratic Corpus* comes a direction to know when medicine can no longer be helpful and to know when to step away.[7] This is stated succinctly in the following:

> *First I will define what I conceive medicine to be. In general terms, it is to do away with the sufferings of the sick, to lessen the violence of their diseases, and to refuse to treat those who are overmastered by their diseases, realizing that in such cases medicine is powerless.*[7]

In modern understanding of the above, physicians continue to offer relief of suffering to those overmastered by disease while ceasing attempts that predictably will be ineffective at treating the underlying illness. However, in the context of the time in which the *Hippocratic Corpus* was conceived, the patient, family or persons other than physicians might morally and reasonably seek provisions towards an expedited death through herbal drugs. The Greeks had the knowledge to quickly effectuate a death as evidenced by the death of Socrates, a contemporary of Hippocrates.

Suicide was not uncommon in ancient Greece. Plato and the stoic, Zeno, described the appropriateness of suicide under certain conditions and perhaps the cowardliness of it under others.[8] Hippocrates held the view that physicians should not be associated with this controversial practice and clearly and unequivocally placed it outside the limit of the proper practice of medicine.[8]

Ironically, after hundreds of years of concerned moral and religious argument, the medicalization of suicide transferred some of this controversy into an arena perhaps least equipped to deal with it. The physician's role, circumscribed by traditional prohibitions, was limited to describing and attempting to reverse underlying psychiatric self-destructive motivation. The traditional practice of medicine had no ability to endorse euthanasia or to facilitate suicide. Over time, the involvement of the medical profession may have promoted an inappropriate generalization that all those seeking to kill themselves were mentally ill and its corollary that treatment of underlying mental illness might be the most satisfactory approach for suicidal inclination.

TRADITIONAL MEDICINE AND MODERN BALANCE

The traditional understanding of the proper practice of medicine has been that medicine offers therapeutics through which a process of "healing" or "making whole again" may take place. This is stated eloquently by Edmund Pellegrino[9p40]:

> *Medicine must be concerned with the "good" of the patient. As David Thomasma and I have emphasized elsewhere, the patient's good is a compound notion. It is not synonymous with the patient's medical good. Healing means "to make whole again." Therefore, ascertaining and enhancing all four realms of the patient's good are involved in healing—the patient's biomedical good, his own conception of the good for him as an individual, his good as a member of the human species (ie, the good for humans), and his good as a spiritual being (ie, the good for the soul). The concept of wholeness, together with its asymptotic attainment through relationships between, and among, persons is the specific end of medicine. It is not an end proper to any of the sciences basic to medicine. But without a concept of healing, medicine as such does not exist.*

For some patients, the traditional practice of medicine has limitations. In these

Euthanasia Research[1]

The Oregon Department of Human Services explained in its March 9, 2006 "Eighth Annual Report on Oregon's Death with Dignity Act":

"The most frequently reported concerns included a decreasing ability to participate in activities that make life enjoyable (89%), loss of dignity (89%), and losing autonomy (79%) …"

From: Pearlman RA, Starks H. Chapter 6. Why do people seek physician-assisted death? In: Quill TE, Battin MP. Physician-assisted dying: the case for palliative care and patient choice. Baltimore, MD: Johns Hopkins University Press; 2004. p 91-101:

"Motivating Factor

- Illness-related experiences
  - Feeling weak, tired, and uncomfortable 24 (69%)
  - Loss of function 23 (66%)
  - Pain or unacceptable side effects of pain medication 14 (40%)
- Threats to sense of self
  - Loss of sense of self 22 (63%)
  - Desire for control 21 (60%)
  - Long-standing beliefs in favor of hastened death 5 (14%)
- Fears about the future
  - Fears about future quality of life and dying 21 (60%)
  - Negative past experiences with dying 17 (49%)
  - Fear of being a burden on others 3 (9%)."

From: Ganzini L, Harvath TA, Jackson A, Goy ER, Miller LL, Delorit MA. Experiences of Oregon nurses and social workers with hospice patients who requested assistance with suicide. N Engl J Med 2002 Aug 22;347(8):582-8. DOI: http://dx.doi.org/10.1056/NEJMsa020562:

"According to the hospice nurses, the most important reasons for requesting assistance with suicide, among patients who received prescriptions for lethal medications, were a desire to control the circumstances of death, a desire to die at home, the belief that continuing to live was pointless, and being ready to die. Depression and other psychiatric disorders, lack of social support, and concern about being a financial drain were, according to nurses, relatively unimportant …

Hospice social workers reported that the desire to control the circumstances of death, the wish to die at home, loss of independence or fear of such loss, and loss of dignity or fear of such loss were the most important reasons for requesting prescriptions for lethal medications; the median score for all these reasons was 5 on the 1-to-5 scale. They ranked lack of social support and depression as the least important reasons; the median score for both was 1 …"

1. Why do patients request physician-assisted death (aka physician-assisted suicide)? [Internet]. Santa Monica, CA: ProCon.org; 2008 Jun 10 [cited 2016 Feb 5]. Available from: http://euthanasia.procon.org/view.answers.php?questionID=000199.

uncommon situations, there is no healing that can be accomplished medically, no healing that can be appreciated by the patient, no social understanding of healing, and no spiritual understanding of healing.

Without a concept of healing, the traditional practice of medicine ceases to exist. A physician's determination that the patient has been overmastered by disease and is beyond healing may be the most difficult of the three steps described above that operationalize the EOLOA. Although there is an ongoing role for the medical profession to palliate symptoms, once a patient finds existence within a threat of imminent and unavoidable death to lack meaning, palliation of symptoms cannot return a patient to an acceptable state. At that juncture, although the patient may derive some benefit from palliative therapeutics, those therapeutics can not be understood summarily as "healing."

**… the patient's good is a compound notion …
It is not synonymous with the patient's medical good.
Healing means "to make whole again."
Therefore, ascertaining and enhancing all
four realms of the patient's good are involved in healing …**

In the very distant past, physicians encountering this situation might have stepped aside, leaving patients and families to decide how to proceed, including the possibility of suicide. In the current scenario, with implementation of the EOLOA, the participating physician must detail that for an individual patient, no medical concept of healing, and no promotion of "good" in its compound notion, is understandable by the physician or by the patient. This "diagnosis" that confirms that the patient is "overmastered by disease" and unable to heal or be healed signals the limits of traditional medicine. This stage marks the point where moral authority for a decision regarding dying under this law may be assumed by the patient.

Physicians have elaborated professional values that might guide this expanded role. The relief of suffering has been discussed extensively in the literature.[10] Another professional value is that of humanism. As described by Pellegrino, "Humanism encompasses a spirit of sincere concern for the centrality of human values in every aspect of professional activity. This concern focuses on respect for the freedom, dignity, worth, and belief systems of the individual person, and it implies a sensitive, nonhumiliating, and empathetic way of helping with some problem or need."[9p88] Respect for the individual person may not require ceding to the individual patient authority to ingest deadly medication. The "humane" action, although commonly described as offering life-ending medication, cannot be determined from such an analysis. However, in humanism's explicit call to respect individual freedom and beliefs, some physicians find justification to expand a role for physicians in the specified context of continued patient suffering, in the absence of a known process for healing, and for an individual who repeatedly requests life-ending medication.

The EOLOA details a process intended to protect vulnerable patients and, simultaneously, to preserve the integrity of individual physician moral decision making. The EOLOA mandates that each physician be allowed to decide whether participation for that physician is ethically acceptable and to be protected from social or professional consequences of that assessment. Both physician and patient are permitted to participate in the legal process or to decline involvement. Although the physician and patient are both granted legal permission to engage in this action, each must also grant permission to the other for the process to move forward. Although permissions are essential to procedure, this approach is morally unsatisfying in that permission cannot make a morally wrong act right. The hope is that in areas of moral uncertainty and lack of clear social guidance, vetted agreements by those involved will provide safeguards against abuse.

When a physician first receives a request from a patient for life-ending medication, the physician should explore the request in sufficient detail to determine whether the request is valid. To confirm the diagnosis and prognosis, additional opinions may be required. The physician should confirm the patient's understanding of current medical care to ensure that the request does not come as a result of end-of-life treatment that can be improved. Maximizing the palliation of symptoms including pain, incontinence, and nausea may make the patient more comfortable. In addition, improving issues of independence, autonomy, spiritual distress, and dignity may be essential for some patients.

The physician must confirm that the patient has decision-making capacity, free from the coercive influence of others, and can self-administer and ingest the medication. The patient must be emotionally and psychologically prepared. Over time, the physician reassesses a judgment by the patient that current and foreseeable life lacks meaning. Once the physician has confirmed the validity of the request, the physician delivers the prescription to the pharmacy. The patient then receives the drugs from the pharmacy and assumes the moral authority to choose whether to take the medication.

Today, previously open avenues to obtain optimal deadly drugs without a physician's prescription are largely closed to patients. Only physicians licensed within the state of California may place optimal lethal prescriptions within legal reach of the California patient. Advising terminally ill patients requesting lethal medication to find nonprescription means to their death remains irresponsible practically and socially.

Once a capable patient has been determined to be terminally ill, no interest of the state or claim of the medical profession, religion, or any other individual overrides a patient's request to own a decision whether to take life-ending medication. In the past, state laws intended to protect patients from unsafe prescriptions have placed physicians in the position of denying patients this option.

With the EOLOA, physicians may opt out of a position that obstructs a dying patient's request to assume moral authority for this decision. To do so, such a physician must violate traditional medical prohibitions against the prescription of deadly

medications as detailed above. A diagnosis of terminal illness signals the time that for the patient seeking aid in dying, a physician can consider validating such a patient request. After validation, the participating physician then may decide to act in a role expanded beyond traditional medicine to include the prescription of medications to assist in dying.

CONCLUSION

Thus, the act of prescribing a fatal dose of medication is not within the traditional practice of medicine. Physicians reasonably may hold to that limit. However, honoring a repeated request from a capable, terminally ill patient to receive life-ending medication still can be considered to be a moral and permissible approach to relieve suffering. A physician choosing to expand his/her role within this narrowly defined context allows the patient to assume authority for a deeply personal decision that may belong to the patient more than to anyone else. ❖

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Friend

I have come to believe that a content life is one that gracefully carries death on its shoulder as a friend and not a feared adversary.

— The Least of These Brethren: A Doctor's Story of Hope and Miracles on an Inner-City AIDS Ward.
Daniel J Baxter, MD, American author and physician

COMMENTARY

An Ethics of Permission: A Response to the California End of Life Option Act

Craig Nelson, PhD, CLS

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ABSTRACT

An ethics of permission can be helpful in framing a response to the ethical differences surrounding the California End of Life Option Act. Law does not define morality, and reaching a moral understanding demands thorough reflection. An ethics of permission examines the ethical demands of a permissive law for both clinician and patient. Serving the good of the patient, respecting professional conscience, and following the law are three ethical elements. Although developing an ethics of permission includes these three elements, these elements do not exhaust all the moral implications involved. An ethics of permission also includes the importance of exercising professional tolerance in the honoring of clinicians who choose to participate or refuse to participate. In addition, an ethics of permission also provides insight in implementing just and fair behavior among medical professionals.

INTRODUCTION

On October 5, 2015, California Governor Jerry Brown signed into law the End of Life Option Act (EOLOA),[1] legalizing physician aid in dying in that state. The law took effect June 9, 2016. Before the enactment of this law, a physician who provided a lethal agent would be liable to criminal charges of homicide or of assisting suicide. The law specifies the process a physician must follow to prescribe any aid-in-dying medication, including referral to another physician for medical confirmation of diagnosis, prognosis, and capacity. The process is entirely voluntary, with liability protections for both those who choose to participate and for those who decline to participate. Eligible patients must be age 18 years or older, residents of California, and of sound mind, and have a diagnosis of a terminal illness that, subject to reasonable medical judgment, will prove fatal within 6 months. These patients also must be capable of self-administering the aid-in-dying drug. In addition, eligible patients must make 2 oral requests to a physician separated by a 15-day waiting period, which must be followed by a witnessed written request. The prescribing "attending physician" must be appropriately licensed and registered with the Drug Enforcement Administration. It is the responsibility of this physician to inform the patient of alternatives such as palliative care. A "consulting physician" must certify the diagnosis and reassess the mental competence of the patient in question. If either physician deems the judgment of the patient to be impaired, the patient must be referred for a psychiatric evaluation. An important distinction should be made between the anticipatory grief of finality and depression.

The State of California is continuing to walk through a new legal and moral threshold but not without ethical questions. Ethical questions existed before the law was written. Physicians have prescribed medications that may relieve pain and have the double effect of sedating or diminishing respiratory function under the common practice of palliative sedation. Questions that recur include themes such as providing compassion and beneficence in the presence of terminal physical pain and disability; the right of patients to exercise free choice and autonomy; and deeply held views on the sanctity of life, faithfulness to the healing, and the "first do no harm" imperative of medicine. Other ethical questions include the professional autonomy of clinicians, the risk of coercion for the elderly and the debilitated, and the ethical obligations of those who opt out of participating.

Terminally ill Californians are now able under law to request life-ending drugs. Is there a helpful way to describe an ethical approach to recurring ethical questions? Ethical expertise in the work of clinical ethics has been both principle centered and context centered.[2] This knowledge of ethical conversation has historically relied on theories and principles such as teleology (describing which action would bring about the goal being sought), deontology (defining what one's duty is), justice, autonomy and beneficence, and casuistry (adapting ethical principles to circumstances and emphasizing sensitivity to particular cases).[3] These theories and principles all help us focus more clearly on patient preferences, quality-of-life questions, contextual issues including patient and family values, monetary resources, religious beliefs, and cultural factors.

The questions surrounding the EOLOA represent moral diversity; because universally accepted normative answers are unreachable, we should not expect to discover a monolithic right or wrong answer. It is important to describe a reflective approach that is capable of providing direction in forming a moral understanding for the recurring ethical questions. The adversarial issues around physician-assisted death ultimately are of primary concern to the patient, the family, and the local community. Political debate at the state level is less important than are religious and cultural attitudes confronting patients asking permission of their family and their God to take life-ending medication.

ETHICS OF PERMISSION

In California, how can clinicians begin to talk about the EOLOA with respect for diversity and still embrace a personal moral position? I propose exploring what we mean by an ethics

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of permission. An ethics of permission is not advocating for a "permissive society" but provides a common understanding that shapes some basic ground rules for coexisting ethical positions. An ethics of permission used in this commentary is not championing the permission to engage in the EOLOA. I am not trying to defend the rationale of the EOLOA. Rather, an ethics of permission is describing how to treat one another regarding the EOLOA. A permissive law creates an ethical demand. This demand is both the recognition that there is an ethical obligation for all because of the existence of the law and a particular ethical behavior because the law affects those individuals who appreciate the actions permitted in the aid-in-dying statute and those who may hold a different moral position. In other words, regarding the EOLOA, how should professionals act toward one another and toward their patients?

Because the EOLOA was created as a permissive law, no one is obligated to engage in its formal activity. Clinicians to one degree or another become materially involved in its activity. But how? Should health care professionals answer questions about the EOLOA and even refer patients interested in it to a health care professional who may have a comfortable conscience in participating in what the law outlines? Is it ethical to be a barrier to a patient wanting referral to a health care professional who is comfortable in participating in what the law permits? Is it an ethical obligation to refer a patient to a willing clinician? Is there an implied obligation to refer patients interested in exercising their right to participate in the EOLOA that should be an essential component of the conscientious objection process? An answer to these questions should never produce actions that legitimate patient abandonment.

… health care professionals coming from different moral viewpoints must find a way of relating to each other without primarily saying that those embracing the opposing viewpoints are morally suspect.

In a culture of diversity, such as in California, health care professionals coming from different moral viewpoints must find a way of relating to each other without primarily saying that those embracing the opposing viewpoints are morally suspect. It is important to work together by creating an approach to moral diversity that will preserve teamwork, collaboration, and communication. This is not advocating for a broad brushstroke of ethical relativism and that anything is morally acceptable as long as it is what you say you believe. An ethics of permission for physician-assisted death emphasizes the importance of understanding professional tolerance, the value of honoring conscientious refusal to participate, and the goal of promoting fairness and justice. In reviewing the potential adversarial nature of discourse surrounding the ethics of physician-assisted death, being in favor or against physician-assisted death is not simply divided into two opposing positions. People may be in favor of it for others but not for themselves or vice versa, or under some circumstances but not others. The downside of not employing an ethics of permission can hinder a realization of moral understanding and lead to moral cacophony in the delivery of compassionate, integrated health care.

Once a patient enters a clear trajectory of clinical decline caused by a terminal disease that includes a likely prognosis of death within six months, the limits of medicinal cure are realized. Some patients may want to avoid living in such a state of clinical decline and believe that the burdens of treatment outweigh the probability of life extension.

The conceptual balance dwells between questions of how patients survive and thrive with illness and how they minimize the prolongation of their dying process by taking aid-in-dying medication in the face of terminal and severely disabling illness. The distinction between treating the disease and relieving suffering is important. Healing moves into more of an existential expression when palliation can help minimize the suffering from disease and help the patient search for peace and meaning for the quality of life that remains.[4] Sometimes the reach of effective palliation is perceived as falling short of realizing its goal.

The good of the patient must be sought in one's own particular existential circumstance through both curing and healing,[5] but healing involves the whole person, not just his/her physiologic condition. An ethics of permission applies to those clinicians in good conscience who believe participating in the law helps terminal patients deal with existential suffering in their specific context in the only possible way they can,[5] and there seems no other way for a quality of life to be experienced that honors their lived values.

An ethics of permission should nurture fairness, tolerance, and justice. For an ethics of permission to be fair, it should uphold professional tolerance for all involved. In other words, to adopt fairness as a procedural notion hinges on choosing to adopt a shared moral point of view.[6] This can mean that those who choose to participate and those who choose not to participate are both enjoined to exercise professional tolerance toward the other. Fairness is a key concept in social and professional tolerance as we all perform our duties in a social context in which we are affected by the opinions and actions of other decision makers. These have been noted as "interdependence situations,"[7] and the intent to be fair is important to uphold.[8] Some research indicates that when people from different ages, cultures, religions, and educational backgrounds judge cases involving helping or harming others, they do so in a universally informed and shared way.[9] The key, however, is discerning how to define help and how to define harm. This is an important distinction involved in physician aid in dying. This will be perspectival, and a specific and contextual understanding of the "good of the patient" from the patient's perspective will always play a major role in the distinction.[10]

Physicians who decide not to formally participate in the EOLOA should exercise tolerance toward those who in good conscience participate in the law believing that they are serving the good of the patient from the patient's perspective. Physicians who do opt to participate should exercise tolerance toward physicians who decide not to participate. This tolerance does not imply that they are accepting their colleague's moral posture as their own. Tolerance allows for plurality of belief and can be the ingredient of reciprocal exchange; tolerance and goodwill are exchanged

in a cooperative act between individuals who possess different moral positions.[11]

For an ethics of permission to be just, it must treat all professionals as they deserve, whether they choose to participate in the law or choose not to participate in validating a patient's request for life-ending drugs. Justice should also facilitate social cooperation.[12] Hayek[13] reminds us that an objective standard of justice must not make one either too powerful or too weak and should be embedded in a dialogue of human experience and reflection. This means that each clinician has a specific human experience and moral reflection that should be allowed expression, while refraining from believing that s/he possesses proprietary knowledge about what is morally acceptable for all. Justice hinges on accepting difference with respect.

All clinicians deserve to exercise their professional conscience. This conscience can cause a physician to find merit in participating in the validation described within the law or to find merit in abstaining from providing such validation. The law allows for restitution for those physicians who find their moral posture to differ from that of physicians who choose to participate. Their conscientious refusal to participate should be tolerated by physicians who believe in participating in the law. In this way, those physicians from each moral position receive what they deserve: tolerance and respect. Forrester[14] emphasizes that justice must remain robust enough to face real conflicts of interest and understanding, and visionary enough to call forth a passionate commitment to thoroughly examine one's self-interest while being mindful of the other.

CONCLUSION

This brief commentary introduced an ethical approach to questions surrounding the enactment of the EOLOA. It suggested that an ethics of permission should be considered as a lens and guide for those who have different ethical positions.[15,16] An ethics of permission is one step in developing a more practical understanding of professional tolerance, of how to encourage conscientious refusal, and how to provide a fervent commitment to promote justice and fairness that maintains a focus on the good of the patient. ❖

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Wisdom

To die well is the height of wisdom of life.

— Søren Kierkegaard, 1813-1855, Danish philosopher, theologian, poet, social critic, and religious author

EDITORIAL

Form Follows Function: A Functional Medicine Overview

Patrick Hanaway, MD

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Editor's note: This Commentary is a companion to *Refractory Depression, Fatigue, Irritable Bowel Syndrome, and Chronic Pain: A Functional Medicine Case Report* on page 104 (available at: www.thepermanentejournal.org/issues/2016/fall/6239-ibs.html). Also note that material describing the foundation and practice of Functional Medicine has been excerpted, with permission, from *Introduction to Functional Medicine* by David S Jones and Sheila Quinn, ©The Institute for Functional Medicine, 2016.

In this issue, Plotnikoff[1] presents a case report using an innovative systems-biology approach known as Functional Medicine to improve the overall health status of a 72-year-old man with multiple complex, chronic, comorbid conditions. Expensive technology was not required, and treatment focused on the correction of common physiologic imbalances, along with lifestyle modifications in diet and nutrition. It is noteworthy that this relatively low-cost intervention was able to reverse long-term symptoms and diseases, while decreasing utilization of health services. This case highlights a significant opportunity to move the focus of care toward root cause analysis, which, when combined with the power of lifestyle modification, can help to bend the cost curve and improve the value of care.

In 2010, 86% of all health care spending was for people with one or more chronic medical conditions.[2] In 2014, national health expenditures grew to $3.0 trillion or $9523 per person, and accounted for 17.5% of gross domestic product.[3] If we do not adopt new approaches by 2022, annual health care costs in the US will rise to more than 20% of gross domestic product,[4] making the cost of care in our current care model economically unsustainable. The current focus in health policy is on value-based care, which can be thought of simply as outcomes divided by cost.[5] One would like to think that increased costs produce improved outcomes, but this is not the case. The US spends 1.5 times to 2 times more per person on health care than other industrialized countries (per Organization for Economic Cooperation and Development),[6] but falls last in most categories of health outcomes, including infant mortality, percentage with multiple chronic diseases, and life expectancy.[7]

Our current health care model fails to address the causes of and the solutions for chronic disease. We segregate lifestyle medicine from clinical care and fail to recognize the urgent need for a continuum-of-care model that reverses illness, promotes health, and optimizes function. This type of transformation requires a perspective different from what is currently present in our costly health care system.[8] Randomized controlled trials comparing Functional Medicine, a systems-biology approach, with the current standard of care are underway at the Cleveland Clinic, along with unique approaches to measure global patient outcomes (with National Institute of Health's PROMIS [Patient-Reported Outcomes Measurement Information System] measures) and total cost of care (with insurers' claims-based data).

Functional Medicine provides a new operating system for 21st-century medicine.[9] This transformation will require us to validate appropriate clinical models and support clinical practices with tools and compensation to promote behavior change, especially in nutrition. According to the Milken Institute,[4] opportunities for improving value within our health care system can be found in many areas: behavioral changes, innovations in technology, improved delivery of services and communication, health education, and wellness programs.

The Gordian knot of chronic disease will be solved by shifting our focus from suppression and management of symptoms to addressing their underlying causes. Specifically, we must integrate what we know about human biochemistry, physiology, and behavior change with scientific, personalized care that addresses the causes of complex, chronic disease—which are rooted in modifiable lifestyle choices, environmental exposures, and gene expression. This fundamental principle has fostered rapidly growing interest in Functional Medicine.

Definition: Functional Medicine is a systems-biology-based model that empowers patients and practitioners to work together to achieve the highest expression of health by addressing the underlying causes of disease. Functional Medicine uses a unique operating system and personalized therapeutic interventions to support individuals in achieving optimal wellness.

Functional Medicine can be described as the clinical application of systems biology. Chronic disease is usually preceded by a decline in function of the body's systems. Functional Medicine sees health and illness along a continuum that changes over time as we interact with our environment. Additionally, Functional Medicine improves patient health by helping clinicians to identify and reverse dysfunction in biochemistry, physiology, and behavior.

Each patient represents a unique, complex set of inter-related environmental and lifestyle influences on function (including genetic vulnerabilities). These factors create opportunities for health maintenance or disease progression. Lifestyle choices and environmental exposures can push us toward (or away from) disease by turning on—or off— certain genes. This, in turn,

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may impair certain biological functions: assimilation, defense and repair, energy production, biotransformation, communication, transport, and structural integrity—the seven core clinical imbalances.

Lifestyle choices and environmental exposures can push us toward (or away from) disease by turning on—or off— certain genes.

To assist clinicians in understanding and applying Functional Medicine, The Institute for Functional Medicine[9] has created a highly innovative way of representing the patient's signs, symptoms, and common pathways of disease. Organizing the seven biological systems and clinical imbalances into the Functional Medicine Matrix Model creates an intellectual bridge between the basic science literature on physiologic mechanisms of disease and the relevance of clinical applications. Functional Medicine posits that, with scientific rigor, clinical wisdom, and innovative tools, we can identify many of the underlying drivers (both triggers and mediators) of chronic disease, allowing us to reverse these clinical imbalances, often before overt disease is present.

In Plotnikoff's case study,[1] overt disease is already present. Through the lens of Functional Medicine, the author is able to identify underlying drivers of dysfunction—recognizing pancreatic insufficiency and alterations in the microbiome; nutritional depletion, with need for methyl support and omega-3 fats; and severe oxidative stress. These imbalances in assimilation, energy production, and nutrition are activators of overall imbalance, manifesting as symptoms and multiple comorbidities. In this case, one expression of disease may arise from the interconnection of multiple clinical imbalances, whereas one clinical imbalance may be the root cause of multiple, seemingly different conditions. An essential precept in Functional Medicine is that restoring balance—in the patient's environmental inputs and in the body's fundamental physiologic processes—is the key to restoring health.[9] As John F Kennedy stated, "A rising tide lifts all the boats."[10]

Functional Medicine treatment usually involves a broad array of therapies, from dietary interventions and lifestyle changes to high-quality nutraceuticals and targeted pharmaceuticals. The hierarchy of approach moves from fundamental lifestyle and nutritional interventions to a prioritization of the aforementioned clinical imbalances, then iterative follow-up of symptoms and assessment of patient-reported outcomes measures. Ultimately, we find that when patients embrace these foundational principles, they have improvement in function and decreased health care utilization. The bottom line for patients is to achieve outcomes that encompass the entire continuum of care—especially the health status achieved, including survival, functional status, and quality of life.[11]

The Functional Medicine approach is done within the context of a therapeutic relationship. The role of connection, deep listening, reflection, presence, humility, vulnerability, trust, and gratitude are essential for healing to occur.[12] The skills to assess a patient's readiness to change and provide appropriate coaching are as important as understanding the underlying clinical imbalances and treating with the correct therapies.

Functional Medicine practice highlights these four essential components

1. Listening to the patient's illness narrative on the initial intake
2. Evaluating, prioritizing, and focusing on the patient's modifiable lifestyle factors
3. Organizing the patient's clinical imbalances by underlying causes into a systems biology matrix framework; and
4. Creating a therapeutic partnership between doctor and patient.

Functional Medicine is relevant to all health care disciplines and specialties, all of which can apply this approach using the Functional Medicine Matrix Model as a template for organizing data and uncovering new understanding. The Functional Medicine operating system and approach build a cross-disciplinary model and provide effective clinical tools to prevent, treat, and reverse complex chronic disease. As we move from Case Reports to randomized controlled trials and population-based trials, Functional Medicine research will offer insight into the best ways to improve the value of the care we offer. ❖

Discosure Statement

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Her Glistening Eyes

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It all started with a clot. Large portions of our patient's dominant hemisphere were damaged. She was intubated and too sleepy to even open her eyes. Her family gathered around her, anticipating a moment of life. Together we reviewed her brain images. "It was a large stroke that deprived segments of her left brain of oxygen and nutrients," I said.

Her family craved answers. They asked, "Will she ever wake up?" "Will she recognize us again?" "If she does, will she talk, walk, eat, or be able to live on her own?"

"It is too early to know. Let's give her some time," I replied.

A few days after her admission to the hospital, she opened her eyes and was successfully extubated, but she was not moving her right side, and her eyes were looking to the left. She was unable to vocalize or engage with her surroundings. Her family was starting to accept the minimal chance of her recovery. However, they remained at her bedside all the time, talking to her as if she could respond.

My mother became a night person after her stroke.

One morning, as part of my daily checks on her, I walked into her room and greeted her son who was sitting on a bed next to her. He had a smile on his face and said, "She is improving. Last night she appeared more awake; she opened her eyes and seemed to be 'mindful.'" I was excited as I performed my neurologic exam. The results were largely unchanged, however, with the exception of a new look in her eyes, I read it as an expression of life. That same day, she was transferred from the intensive care unit to the regular floor. I continued to check on her every morning. She remained sleepy and poorly interactive, but she started to move her right forearm in a sporadic and frail manner. I noted that despite her somnolence and continued silence, she started to follow some instructions. In spite of my perception of her slight improvement, she could not participate in physical therapy and remained too sleepy to swallow. Chart notes continued to describe her as drowsy and at high risk of aspiration. Her nasogastric feeding tube was not a permanent access, and we planned for the placement of a gastrostomy tube. The Social Work Department had found her a place at a nursing home near her family residence, and her discharge from the hospital was imminent.

One day, as the end of our patient's hospital stay neared, her son grasped my attention with these words: "Last night, she mentioned my name, touched my head, and pulled me close to her heart as if I were her baby again. She smiled and followed my steps around the room." I was surprised to hear that she was so different at night—she kept her eyes closed during most of my morning visits and could hardly move her unaffected side. I inquired about that. Her son answered, "My mother became a night person after her stroke."

That night I felt guilty and stayed up late thinking about her. "Is she more awake?" "Shall we reassess her now?" "Shall we repeat the swallow evaluation at night?" "What if she is able to?" "What if she qualifies for rehabilitation?" I felt like I should do something. I wanted her to go to rehabilitation. I wanted her to go home. I wanted her taste buds to enjoy food again. I could see hidden potential beneath her glistening eyes.

The next morning, I expressed my concerns to the team. We all agreed to do our best to wake her up. To help her, we administered amantadine and asked all other teams to reassess her as late as possible that day. I was pleasantly surprised to witness her gain a soft diet and participate in physical therapy. In fact, she was evaluated by our Physical Medicine and Rehabilitation Department, passed their assessment, and was transferred to a rehabilitation center on the basis of their recommendation. There, she participated in an intensive exercise plan and was later discharged home in good condition. Her glistening eyes were inspiring. Her great family support and our teamwork had indeed been successful.

I believe that this case made me a better physician—I learned that patient recovery is far beyond a signed daily progress note. I now check on all my patients at least twice, in the morning and later in the evening just before I leave work. Being a busy resident doesn't justify overlooking such details in patient recovery. Brain pathologies can affect sleep patterns and distort arousal.[1] These changes can indeed confound the journey toward true recovery and can result in suboptimal outcomes.

Finally, I wonder how many patients are just like her. Being sleepy is one thing, but failing the poststroke assessment is another. Daytime hypersomnia has been described in patients following acute stroke.[1] Several mechanisms for hypersomnia have been proposed, ranging from alterations in sleep physiology to changes in respiratory function including central sleep apnea.[1]

This case serves to remind us of the possibility of a sleep-wake inversion following acute stroke and the potential impact of this change on patient disposition and ultimate outcomes. Further prospective studies aiming to investigate an association between acute hypersomnia, posthospitalization disposition, and functional outcomes are likely to unravel novel interventions to improve poststroke recovery. ❖

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Physicians', Nurses', and Medical Assistants' Perceptions of the Human Papillomavirus Vaccine in a Large Integrated Health Care System

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ABSTRACT

Context: Vaccination against the human papillomavirus (HPV) decreases risks of cancer and genital warts and the need for gynecologic procedures, yet nationwide vaccination rates are low. Previous surveys exploring this phenomenon have not included input from nurses and medical assistants, who play integral roles in HPV vaccine delivery.

Objective: To understand perceptions of HPV vaccine delivery among physicians, nurses, and medical assistants in a large integrated health care system in Southern California.

Design: Online surveys were sent to 13 nurse administrators and 75 physicians. Physicians were instructed to forward the survey to nurses and medical assistants with whom they work.

Results: A total of 76 surveys were completed, consisting of 52 physicians, 16 clinical nurses and medical assistants, and 8 nurse administrators. Physicians' perceptions of vaccine safety or strength of recommendation did not differ by specialty department. Physicians reportedly perceived the HPV vaccine as safer than did clinical nurses and medical assistants ($p < 0.001$), who indicated they wanted more education on the safety and efficacy of the vaccine before being comfortable strongly recommending it. Respondents advised that all clinicians could improve in their roles as HPV vaccine advocates through patient counseling and providing informational literature and that workflow standardization was needed to minimize missed vaccination opportunities.

Conclusion: Physicians reportedly perceive the HPV vaccine as safer compared with nurses and medical assistants. Both groups think that more education of nonphysician staff is needed. Having proper systems in place is also vital to improving vaccination compliance.

INTRODUCTION

The Centers for Disease Control and Prevention (CDC) reports that 79 million Americans are infected with the human papillomavirus (HPV), with 14 million new cases detected each year; plus, HPV contributes to an estimated 26,200 new cancers each year in the US.[1] In addition to malignancy, HPV causes premalignant diseases, anogenital warts, and laryngeal papillomatosis, which makes it the most common sexually transmitted infection and the cause of a substantial economic burden on the US health care system.[2]

Vaccination against HPV has been available for girls since 2006 and boys since 2011 as 2 inactivated vaccines. Gardasil (Merck & Co, Kenilworth, NJ) is a quadrivalent vaccine against HPV Types 16, 18, 6, and 11, and Cervarix (GlaxoSmithKline, Brentford, Middlesex, UK) is a bivalent vaccine for HPV Types 16 and 18. Currently, HPV vaccination consists of a 3-dose series approved by the US Food and Drug Administration and endorsed in the US by the Advisory Committee on Immunization Practices.

HPV vaccination provides both clinical effectiveness and economic benefits to all international health care systems, and statistical models consistently show the cost and quality benefits that will be achieved.[3] Vaccination against HPV has already demonstrated decreased risks of cervical cancer and genital warts and the need for fewer gynecologic procedures, including colposcopy and the loop electrosurgical excision procedure.[4] Despite the reported safety and efficacy of HPV vaccines as well as the potential impact on the eradication of preinvasive and invasive carcinomas associated with HPV, a national problem exists in the initiation and completion rates of the vaccine series.

The CDC estimates that only one-third of eligible women have initiated vaccination, and the initiation and completion rates have varied from 14% to 56% and from 24% to 56%, respectively.[5-7] In 2012, according to the CDC,[1] 53.8% of girls received the first dose of the series, and 33.4% completed all 3 doses of the series; most HPV vaccines are delivered in the primary care setting.[8] Between 2007 and 2009, HPV uptake in a university-based primary care system among 11,535 eligible women was only 18%,[9] and only 10% of this group received all 3 doses. In addition, a 2010 survey of 1741 men aged 18 to 26 years reported that 51.8% had heard of HPV, but only 34.8% had heard of the HPV vaccine.[10] A university-based pediatric practice reported that 82% of adolescents had missed opportunities for HPV vaccination during preventive care visits between 2006 and 2011.[11]

The struggles of national HPV vaccination programs are not limited to health care systems outside Kaiser Permanente (KP). Although KP is an integrated health care system with a proven track record in vaccination programs such as influenza

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and is a participant of the CDC program, Vaccine Safety Datalink, KP's success with HPV vaccine initiation and completion rates has been limited. In 2007, a Southern California Permanente Medical Group study of 34,193 women reported only a 41.9% series completion rate.[12]

Multiple issues hinder the success of HPV vaccination programs in the US. This vaccination touches on issues of sexuality, parental autonomy, and cost.[6] The main barriers identified are the education of parents and clinicians, financial limits related to access to care, and lack of clinician recommendation. Among parental issues, it was found that lack of personal knowledge and lack of perceived need for the vaccine was reported in 19.4% and 18.8%, respectively.[6] In addition, 18.3% of parents believed their daughters were not sexually active and did not need to be vaccinated, whereas 13.1% of the time they reported not being informed by their clinician of the importance of the vaccine.[6] Moreover, mothers' attitudes toward prevention appear to influence HPV vaccine uptake in adolescent girls, and maternal utilization of preventive care and maternal history of genital warts may influence HPV vaccine uptake in adolescent boys.[13,14] Threats to parental autonomy regarding sex education and concerns that education programs may undermine abstinence messages or condone risky sexual behavior have been unfounded concerns.[15]

Barriers to vaccine uptake have been addressed in patient and clinician surveys, which have thus far been limited in scope. Previous surveys have either omitted specialties in which the HPV vaccine is given routinely or included only physicians, without attempting to understand the perceptions and experiences of nonphysician staff who may have strong influences on HPV vaccine uptake. In the current study, we aimed to understand perceptions of HPV vaccine delivery in a large integrated health care system in Southern California through a survey of physicians, medical assistants, clinical nurses, and administrative nursing staff in the Pediatrics, Obstetrics and Gynecology (OB/GYN), Family Medicine, and Internal Medicine Departments.

METHODS

KP Southern California is a large integrated health care organization serving more than 4 million members. The Orange County Service Area includes 2 hospitals and 16 primary care clinics and is located in a primarily suburban area of Southern California. The clinics are staffed by registered nurses (RNs), licensed vocational nurses (LVNs), and medical assistants (three groups considered collectively as ancillary staff) who assist physicians with determining which vaccines are needed at any given visit and often communicate this information to patients and their caregivers. The department administrators help set the policies and procedures for the ancillary staff regarding how to communicate with physicians and patients.

A 12-question open- and close-ended survey, developed from previously published clinician surveys,[16,17] was e-mailed directly to selected physicians and department administrators to complete via an online survey tool (SurveyMonkey, Palo Alto, CA; Figure 1 available at: www.thepermanentejournal.org/images/2016/15-205Fig1.pdf). Physician recipients were asked to forward the survey to the team's lead RNs or LVNs and medical assistants they work with most frequently.

One or two physicians from each of the clinic locations in each subspecialty were selected to participate. Selection was based on the physician's length of tenure with KP, to leverage physician familiarity with KP vaccination protocols and to generate actionable information. Thus, this was a purposive sample rather than a random selection. All

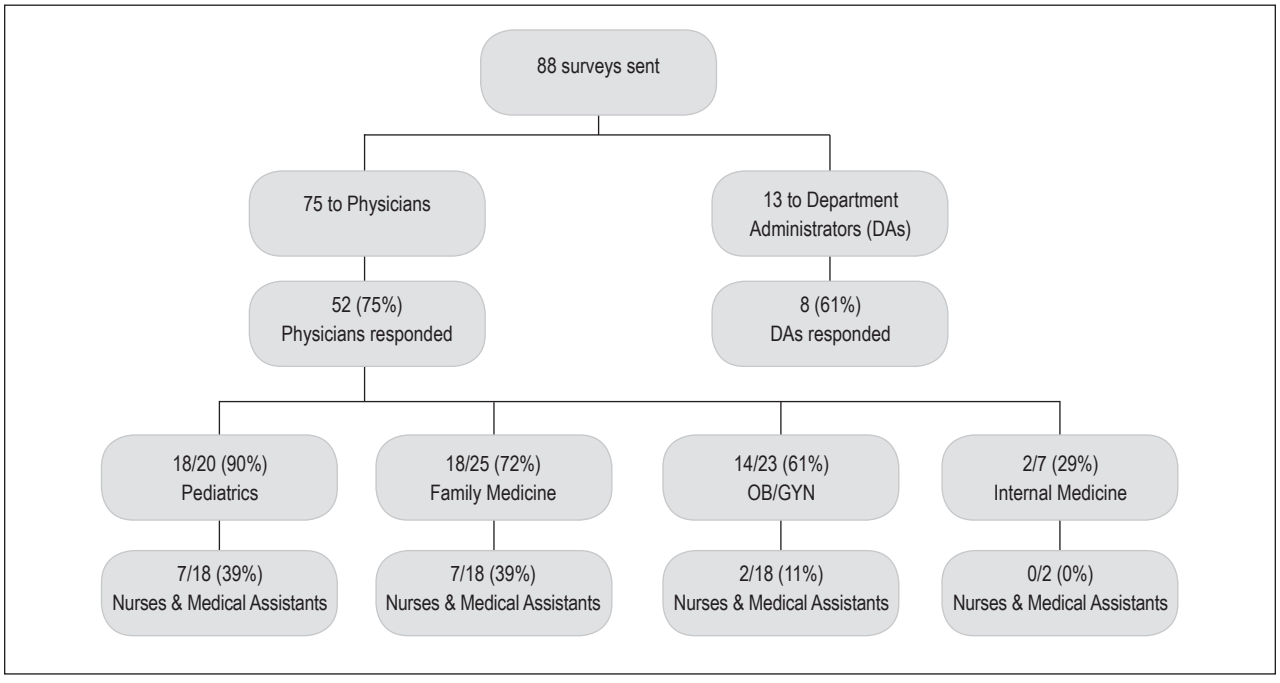

Figure 2. Algorithm of analysis of survey respondents.[a]

[a] Physicians sent the survey to their medical assistants and clinical nurses at our request; we did not send the survey directly to the staff.

OB/GYN = Obstetrics and Gynecology.

department administrators from primary care clinics involved in the administration of the HPV vaccine were selected to participate. (Each clinic has a single department administrator.)

Surveys were sent via a SurveyMonkey link in an e-mail message on October 20, 2014. Recipients were given until December 1, 2014, to complete the survey. At the end of November, an additional e-mail was sent as a reminder to recipients who had not yet completed the survey. Responses were coded independently by 2 members of the research team and then consolidated and entered into a spreadsheet (Microsoft Excel, Microsoft, Redmond, WA).

Chi-squared tests were conducted to compare categorical response rates regarding respondents' perceptions of vaccine safety and reported strength of recommendation to patients by specialty department (OB/GYN, Pediatrics, Family Medicine, and Internal Medicine) and by respondent role (physician, clinical nurse, and medical assistant). Data were analyzed with statistical analysis software (SAS [Statistical Analysis System] Version 9.2, SAS Institute Inc, Cary, NC). Statistical analyses were 2-sided, and $p < 0.05$ was considered significant. Nonclinical nurses were excluded in the statistical analysis because of low sample size (n = 8). Responses from family medicine and internal medicine physicians were combined for categorical comparisons because of the low number of internal medicine responses (n = 2).

RESULTS

A total of 76 respondents returned completed surveys, most of whom were physicians (n = 52, 75% response rate). Physicians in the Family Medicine Department (n = 18) and the Pediatrics Department (n = 18) were the most responsive. Response rates were lower for clinical nurses and medical assistants (31%) and for nonclinical nurses (administrators; 61%; Figure 2).

Perceptions of Vaccine Safety

Perceptions of vaccine safety between physicians in different departments and between physicians and clinical nurses and medical assistants are shown in Tables 1 and 2, respectively. There was no significant difference in perceptions of vaccine safety between physicians by specialty department, but overall physicians did perceive the vaccine to be safer than did clinical nurses and medical assistants.

Two pediatricians cited concerns regarding adverse neurologic effects of the vaccine. They reported: *"Some neurologic concerns have surfaced regarding this vaccine. I am a little concerned"* and *"I have some hesitation because anecdotally I have had patients who have experienced neurological symptoms and refuse beyond their first dose."* The author of the first quotation reported perceiving the vaccine as very safe and recommending it somewhat strongly to patients, whereas the author of the second quote reported perceiving the vaccine as somewhat safe and recommending it very strongly to patients. Thus, only a small number of physicians were concerned specifically about neurologic effects of the vaccine, and they still tended to recommend it to patients. In addition to neurologic concerns, 5 respondents cited concerns about dizziness/fainting after vaccine administration; 4 reported witnessing this in their patients. Interestingly, despite this concern, 2 of the 5 reported somewhat strongly recommending, and 3 of the 5 reported very strongly recommending the vaccine to patients.

Reported Strength of Recommendation

There was no significant difference in strength of recommendation of the vaccine between physicians by specialty department (Table 1) or between physicians and clinical nurses/medical assistants (Table 2).

Table 1. Physicians' perceptions of vaccine safety and strength of recommendation by subspecialty department[a]

Perception	Pediatrics (n = 18), no. (%)	OB/GYN (n = 14), no. (%)	Family and internal medicine (n = 20), no. (%)	p value
Vaccine safety				
Very safe	16 (89)	14 (100)	20 (100)	0.14
Somewhat safe	2 (11)	0 (0)	0 (0)	
Somewhat unsafe	0 (0)	0 (0)	0 (0)	
Very unsafe	0 (0)	0 (0)	0 (0)	
Strength of recommendation				
Very strong	15 (83)	12 (86)	13 (65)	0.35
Somewhat strong	3 (17)	2 (14)	5 (25)	
Somewhat weak	0 (0)	0 (0)	2 (10)	
Weak	0 (0)	0 (0)	0 (0)	

[a] χ^2 analysis by physician specialty department.
OB/GYN = obstetrics and gynecology.

Table 2. Perceptions of vaccine safety and strength of recommendation by provider type[a]

Perception	Physicians (n = 52), no. (%)	Clinical nurses and medical assistants (n = 16), no. (%)	p value	Nonclinical nurses (n = 8)[b], no. (%)
Vaccine safety				
Very safe	50 (96)	8 (50)	< 0.001	3 (38)
Somewhat safe	2 (4)	8 (50)		2 (25)
Somewhat unsafe	0 (0)	0 (0)		2 (25)
Very unsafe	0 (0)	0 (0)		1 (13)
Strength of recommendation				
Very strong	40 (77)	9 (56)	0.11	5 (63)
Somewhat strong	10 (19)	7 (44)		1 (13)
Somewhat weak	2 (4)	0 (0)		1 (13)
Weak	0 (0)	0 (0)		1 (13)

[a] χ^2 analysis compared responses of physicians vs clinical nurses and medical assistants. Nonclinical nurses were not included in the statistical analysis because of low sample size.
[b] Percentage does not total to 100 because of rounding.

Five respondents (2 physicians and 3 nurses and medical assistants) reported a perceived need for more education on the safety and efficacy of the HPV vaccine for nonphysicians. Sample comments were as follows: *"With better understanding of [the] topic, staff can do more patient teaching,"* and *"Educate back-office staff so they feel stronger in recommending the vaccine."*

Respondent-Reported Reasons Given by Patients and Parents for Declining Vaccine

The most common reason for refusing the HPV vaccine identified by parents to the respondents was that the vaccine is not safe because it is too new (n = 22), or the patient is too young and thus vulnerable to side effects (n = 11). Specifically for males, 11 respondents reported that parents think the risk of HPV for males is low; thus, there is no need for the vaccine. For instance, one respondent said, "*[Parents think] that it does not 'affect' males so there is no reason to get it."*

Another common reason given for not wanting the vaccine is because the virus is transmitted sexually. Most respondents reported that patients and parents deny sexual activity and thus perceived no need for the HPV vaccine. Comments reportedly heard from parents included the following: "*My child is not having sex"*; *"We don't believe in premarital sex"*; *"My daughter is not sexually active [or] promiscuous; we go to church [and] she is not that kind of girl."* This link between the vaccine and a sexually transmitted disease (STD) was inherently part of the language used by respondents to illustrate their patients' perceptions and beliefs. Another said, *"They don't need an STD vaccine at their age."*

Counseling Topics

The most common point that respondents reported discussing with female patients in relation to the HPV vaccine was the decreased risk of cervical cancer (n = 50), followed by the decreased risk of genital warts (n = 17). The most common point that respondents reported discussing with male patients was decreased risk of anogenital cancer (n = 32), followed by decreased risk of anogenital warts (n = 19). For both female and male patients, the third most common topic discussed by respondents was the ubiquitous nature of the virus as a sexually transmitted infection with no cure that can be asymptomatic and easily transmitted (n = 29 for males and n = 22 for females). Nine respondents reported that they emphasize the decrease in risk of abnormal results of Papanicolaou tests and thus the need for additional procedures such as colposcopy.

Eleven respondents thought that both physicians and ancillary staff could improve in their respective roles as HPV vaccine advocates. Specific areas for improvement identified included consistency of message (*"Train providers to have [a] consistent message regarding benefits"),* assertiveness (*"Physicians [need] to be more engaged in explaining the vaccine"),* and completeness (*"I find the parents who refuse never got a full explanation").* One OB/GYN reported regularly using self-disclosure to advocate for the HPV vaccine: *"I let everyone know I vaccinated my own child."* Ten respondents reported that they emphasize the nature of the HPV vaccine as a three-dose series.

Workflow/Institutional Procedures

Thirteen distinct workflows were reported by respondents to describe the events of an office visit in which the patient is identified as eligible for the initial HPV vaccine dose. There was no clear pattern when evaluated by department specialty or role as physician, nurse, or medical assistant. Three physicians reported that they teach their medical assistants to put the vaccine in the chief complaint section of the patient encounter. Moreover, two of the three physicians indicated that this is an established protocol but that the medical assistants do not routinely do it.

KP Orange County uses Epic software (Epic Systems Corp, Verona, WI) for its electronic medical records in the inpatient and outpatient settings. During a clinic encounter, ancillary staff are taught to "pend" certain orders (including the HPV vaccine) in the order entry section of the encounter. Physicians can then simply sign the order with a click of the mouse. In our sample, 2 physicians saw a need for improvement in this practice by ancillary staff. For example, one stated, "*If my medical assistant doesn't pend [the HPV vaccine order], I forget to look.*"

Nearly all respondents reported that after administration of the first HPV dose, the patient is advised verbally to get the second and third doses by the physician (n = 35), nurse or medical assistant (n = 38), or both (n = 28). Thirty-one respondents reported including some type of recommendation in the printed handout given to patients at the conclusion of the encounter. Five reported that often 1 or all of these steps are overlooked during the visit. Twenty-nine respondents indicated that an effort is made to schedule a follow-up appointment with a nurse for the next HPV vaccine dose before the patient is discharged home from the encounter. Half of the respondents recommended some kind of reminder system after the first HPV vaccine dose, by text message, e-mail, phone, or postal mail (n = 38). Eleven respondents recommended contacting patients who do not come for follow-up visits with a nurse for their second and third doses to reschedule.

Nine respondents emphasized the importance of initiating the vaccination series before the advent of sexual activity. Four respondents recommended that physicians broach the subject of the HPV vaccine with parents well before the patient reaches age 9 years by providing information on HPV and the vaccine via mail, e-mail, or phone or through direct discussion at well-child examinations. One pediatrician recommended routinely starting the series at age 9 rather than age 11 years.

DISCUSSION

Common Themes of Survey

In the current survey, all physicians reported perceiving the HPV vaccine as somewhat safe or very safe. Such a strong testament to the safety of the vaccine has not been observed in previous surveys, in which at least a few physicians have considered the HPV vaccine unsafe, with some even choosing to not recommend it for eligible patients.[18,19] Proportionally more of these clinicians have been family physicians rather than pediatricians or OB/GYNs. In a survey of 1013 physicians, the pediatricians and OB/GYNs were more likely than family physicians were to "always" recommend the vaccine.[20] In contrast, we found no difference in perception of vaccine safety or strength of recommendation between family physicians, pediatricians, or OB/GYNs. Possible explanations for this include our relatively small sample size, the emphasis placed on preventive medicine at KP as an integrated health care system, and

mounting data providing reassurance that the vaccine is safe.[6,7] Surveys continue to identify safety as the predominant concern among patients and parents.[17,21,22]

The most commonly reported safety concern by physicians and ancillary staff in our survey was the potential for adverse neurologic effects associated with the HPV vaccine, specifically fainting immediately after vaccine administration. This adverse effect was found to be so common after vaccine licensure that the US Food and Drug Administration changed prescribing information to include information about preventing falls and possible injuries from fainting after HPV vaccination, although the vaccine benefit-risk profile was still considered acceptable in adolescent girls and women.[23] A few respondents cited general neurologic disease as an additional concern. A recent study of almost 4 million women in Denmark and Sweden followed-up from 2006 to 2013 showed no association between the HPV vaccine and the development of multiple sclerosis or other demyelinating diseases.[24]

Besides physician input, there is potential value in the thoughts of nonphysician staff who interact directly and indirectly with patients and parents to influence decision making, which previous surveys have not explored. We observed that physicians reportedly perceive the HPV vaccine as safer than do clinical nurses and medical assistants. Several respondents, including clinical nurses and medical assistants, reported a need for more education for ancillary staff about the safety and efficacy of the HPV vaccine. Medical assistants, nurses, and possibly even receptionists involved in direct patient care may greatly influence the decision making of parents and patients, and their role in the advocacy for the HPV vaccine deserves further study. A follow-up study with a larger sample size of medical assistants and nurses with assurance of anonymity is needed.

Although 100% of physicians and clinical nurses/medical assistants in our sample reportedly considered the HPV vaccine as somewhat or very safe, one-fourth and one-eighth of nonclinical nurses reportedly considered the HPV vaccine as somewhat and very unsafe, respectively. Additionally, 1 nonclinical nurse (administrator) reported weakly recommending the vaccine compared with no physicians or clinical nurses/medical assistants. Nonclinical nurses at KP are largely involved in establishing workflows used by clinical nurses and medical assistants, in governing how and when to discuss the vaccine with patients, and in facilitating the utilization of the vaccine for the physician (eg, providing the HPV vaccine in the chief complaint of the encounter and/or pending the order for the physician). Because of the integrated and streamlined nature of vaccine delivery at KP, a negative perception of the HPV vaccine among nonclinical nurses may actually impede vaccination efforts to a larger degree than negative perceptions held by clinical nurses and medical assistants involved in direct patient care. This finding highlights the need for education of nonclinical nurses as well as clinical nurses and medical assistants about the safety and efficacy of the HPV vaccine to improve coverage rates as well as the need for workflow standardization for vaccine delivery.

Respondents identified timing as a critical aspect of vaccine delivery, emphasizing the nature of the HPV vaccine as a 3-dose series. In a 2008 KP Northwest survey of 3490 females between ages 11 and 26 years, 899 (26%) responded. Emphasis of the 3-dose schedule from the clinical care team to the patient was predictive of improved rates of series completion.[25]

Another commonly reported counseling point relating to the timing of the vaccine was the importance of initiating the vaccination series before the advent of sexual activity. Second only to safety concerns, parental denial of the patient's sexual activity and the perception of the HPV vaccine as an STD vaccine were cited as major barriers to vaccine uptake, consistent with previous surveys.[26] A recent study of a large cohort of female adolescents found that HPV vaccination was not associated with increases in sexually transmitted infections after one year, suggesting that vaccination is unlikely to promote unsafe sexual activity.[15] Clinicians can use this data to address the STD-vaccine barrier with parents.

Another crucial aspect of vaccine timing—when to give the vaccine—was addressed by survey respondents, yielding novel proposals to help overcome HPV vaccination barriers. Some respondents recommended that the subject of the HPV vaccine be discussed with parents well before the patient reaches age 9 years, with a single pediatrician recommending starting the series at age 9 years rather than age 11 years, which is still within the CDC recommendations. Adopting such recommendations could serve to educate parents on HPV vaccine safety and efficacy and thereby dispel common myths.

Given the major challenges to improving HPV vaccination coverage, we must be open to trying novel approaches that pose no obvious risk, even if they are not yet validated by large-scale studies. Several specific intriguing recommendations were made by at least one respondent of the current survey, including the practice of self-disclosure (ie, providers advising patients and parents that they give the HPV vaccine to their own children), which has been demonstrated to be a powerful motivational tool in patient-clinician interactions.[27] Other specific suggestions included incentivizing vaccination uptake and completion either financially or in some other way and using presumptive recommendation strategies when discussing the vaccine—"*We have to do some shots*"—instead of "*What do you want to do about shots?*"

Limitations

The objective of the current study was to obtain sufficient input from physicians, medical assistants, and clinical and nonclinical nurses to compare safety and efficacy perceptions between physicians and ancillary staff and across specialties. Because of the low response rate for clinical nurses and medical assistants (31%), the statistical analysis was not as robust as originally intended. The low response rate was caused by either the physician not sending the survey as requested or the nurses and medical assistants failing to complete the survey after receiving it from the physician. Future surveys should be sent directly to all potential respondents, facilitating direct follow-up for nonresponders. Additionally, the survey did not distinguish between clinical nurses and medical assistants. Both positions involve direct outpatient care but in slightly different capacities. It is certainly possible that individuals from these groups hold different views that could have been overlooked.

Our survey did provide a good mix of responses from Family Medicine, OB/GYN, and Pediatric Departments, but the response

rate from the Internal Medicine Department was low. Most internal medicine physicians in KP Orange County work exclusively or predominantly in the inpatient setting and thus do not have the opportunity to discuss the HPV vaccine with patients, as do family medicine physicians, who work predominantly in outpatient clinics. The two internal medicine physicians who responded do routinely work in the outpatient clinic and occasionally see patients eligible for the HPV vaccine. Statistical analyses were conducted with and without addition of the internal medicine physician responses to those of family medicine physicians, and the results were unchanged.

CONCLUSION

Physicians perceive the HPV vaccine as safer than do clinical nurses and medical assistants and purport to recommend it more strongly compared with nonclinical nurses. Medical assistants and clinical nurses who serve on the front lines of vaccine advocacy report that they need more education on the safety and efficacy of the HPV vaccine. Concerns about safety and possible promotion of sexual activity are the most frequently reported barriers limiting HPV vaccine coverage. Vaccination uptake may increase through improved advocacy by physicians and ancillary staff, predicated on improved provider and patient education. Workflow standardization is needed to ensure minimization of missed vaccination opportunities. ❖

Disclosure Statement

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

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Trends in Type of Original Psoriasis Publications by Decade, 1960 to 2010

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ABSTRACT

Context: Research investigating psoriasis has spanned decades, and as our understanding of the disease has evolved, the focus of publications has changed.

Objective: We sought to characterize the trends in original psoriasis-related research from 1960 to 2010 chronologically by decade.

Methods: A literature review was performed using the keyword *psoriasis* in the MEDLINE database. All original psoriasis-related articles published at the beginning of each decade were searched and categorized by study type and topic.

Main Outcome Measure: Number of articles per topic.

Results: A total of 869 original psoriasis-related articles were found. The number of publications increased 18 fold over 5 decades. The immunology and pathogenesis of psoriasis was the most frequently researched topic (36%), and retrospective studies were the most common study type (37%). Recent highly published topics included biologic therapy, genetics, and psoriasis-associated cardiovascular disease.

Conclusion: Original psoriasis-related publications have grown substantially since 1960. Basic science research into the immunology and pathogenesis has been and continues to be the mainstay of psoriasis research. Recent research trends suggest the focus has expanded to topics such as psoriasis-associated cardiovascular disease, genetics, and biologic therapy.

INTRODUCTION

Psoriasis is a chronic inflammatory skin condition affecting 2% of the population, and it can be physically and psychologically debilitating.[1] Although psoriasis was first described in 1841, it was the 1960s that first saw a surge in psoriasis-related research. Initial studies focused on the keratinocyte, and nonmalignant proliferation and reduced differentiation were found to be hallmarks of psoriasis.[2]

Since then, considerable achievements have changed the way psoriasis is viewed. Advances in technology have allowed researchers to gain an understanding of the molecular mechanisms driving the disease. Breakthroughs in biologic therapy have revolutionized the way psoriasis is managed. Recent research suggests that patients with psoriasis have a systemic inflammatory state, putting them at increased risk of cardiovascular complications, including metabolic syndrome, peripheral vascular disease, stroke, myocardial infarction, and cardiac death.[3,4] Some articles suggest that tumor necrosis factor inhibitors may decrease the risk of stroke and myocardial infarction in patients with psoriasis.[5,6]

As understanding of the disease has continued to evolve over five decades, research interests have expanded. Our goal is to identify these new components to gain a better understanding of the current landscape and future direction of psoriasis-related research. On the basis of recent study findings, we hypothesized that there would be a higher proportion of recent publications investigating psoriasis-associated cardiovascular disease and biologic therapy. To our knowledge, no study has systematically examined research trends in this field. We sought to accomplish this through a literature review, wherein all original psoriasis-related articles published at the beginning of each decade, starting in 1960, were categorized by study type and topic.

METHODS

To evaluate trends in psoriasis research, we extracted articles from the MEDLINE database using the keyword *psoriasis* for the calendar years of 1960, 1970, 1980, 1990, 2000, and 2010. We excluded articles that were not original research, were not available in English, or were not primarily focused on psoriasis. Systematic reviews, meta-analyses, case reports, literature reviews, and editorials were excluded.

Articles that met inclusion criteria were classified by study type as follows: clinical trial, basic science, retrospective, and cross-sectional. The clinical trials topic included randomized trials and prospective nonrandomized trials. Basic science studies were defined as studies that required specialized or extensive laboratory testing outside a clinical trial or animal models. Retrospective studies included observational studies. Cross-sectional studies were generally time-independent, questionnaire-based studies.

These articles were then linked by their subject matter to 1 of 13 topics: topical therapy, oral therapy, phototherapy, biologics, other therapy, genetics, immunology and pathogenesis of psoriasis, cardiovascular comorbidities, other comorbidities, infection, cancer, quality of life, and epidemiology and cost. These topics were thought to capture the variety of broad research topics that have been covered in psoriasis research. Therapy-based topics such as topical therapy encompassed studies that evaluated any aspect of the treatment, including but not limited to cost, efficacy, side effects, and pharmacology. Genetics articles focused on the hereditary nature of the disease. Immunology and pathogenesis of

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psoriasis was a broad heading that covered the mechanisms and manifestations of the disease. Publications dealing with cardiovascular comorbidities, infection, or cancer looked at the association between psoriasis and each of these entities. Studies of other comorbidities investigated the association between psoriasis and other diseases. Quality of life included studies that investigated the impact psoriasis has on the patient's well-being and emotional state. Epidemiology and cost consisted of studies that analyzed the pattern of disease or the financial impact. If an article's subject matter covered multiple topics, the article was categorized into the topic that fit best.

Percentages for topic type were calculated by dividing the number of articles by the total number of articles that year. Percentage increase from decade to decade was calculated by dividing the number of articles in a given decade by the number of articles in the comparative decade then subtracting 1 and converting to a percent.

RESULTS

Original Psoriasis Research

Our search yielded 869 original psoriasis-related publications (Table 1). There was a linear increase in the number of original articles from 1960 to 1980, with 7 times more articles published in 1980 than in 1960. Although the years 1990 and 2000 experienced a modest increase in publications, 2010 saw a 101% rise compared with the previous decade.

Trends in Study Topic

Immunology and pathogenesis of psoriasis was the most-researched topic, totaling 300 articles and comprising 35% of the total research found, followed by studies in topical therapy (n = 102, 12%) and phototherapy (n = 102, 12%; see Table 1). The least-researched topics overall were cancer (n = 8, 1%), infection (n = 10, 1%), and other comorbidities (n = 23, 3%).

Immunology and pathogenesis of psoriasis comprised 47%, 40%, and 26%

Table 1. Original psoriasis articles by study type and topic

Decade	Study type	Topical	Oral	Photo	Biologics	Other	Genetics	IP	CV	OCM	Infection	Cancer	QOL	EC	Total
1960	Clinical trial	2	3	1	0	0	0	1	0	0	0	0	0	0	7
	Basic science	0	0	0	0	2	0	6	0	0	0	0	0	0	8
	Retrospective	0	0	0	0	0	0	2	0	0	0	1	1	0	4
	Cross-sectional	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Subtotal	2	3	1	0	2	0	9	0	0	0	1	1	0	19
1970	Clinical trial	11	10	1	0	0	0	0	0	0	0	0	0	0	22
	Basic science	3	4	0	0	0	4	26	0	0	0	0	0	0	37
	Retrospective	5	1	1	0	0	0	5	2	0	1	0	1	0	16
	Cross-sectional	1	1	0	0	0	0	0	0	0	0	0	0	0	2
	Subtotal	20	16	2	0	0	4	31	2	0	1	0	1	0	77
1980	Clinical trial	3	6	12	0	1	0	0	0	0	0	0	0	0	22
	Basic science	1	1	15	0	0	1	44	0	0	0	0	0	0	62
	Retrospective	4	4	15	0	1	6	10	3	4	0	0	0	1	48
	Cross-sectional	0	0	0	0	0	0	0	0	0	0	0	2	0	2
	Subtotal	8	11	42	0	2	7	54	3	4	0	0	2	1	134
1990	Clinical trial	19	6	6	2	5	0	0	0	0	0	0	0	0	38
	Basic science	7	5	3	0	1	2	39	0	0	0	0	0	0	57
	Retrospective	4	3	4	0	0	2	14	0	3	0	2	0	1	33
	Cross-sectional	0	0	0	0	0	0	0	0	0	0	0	1	3	4
	Subtotal	30	14	13	2	6	4	53	0	3	0	2	1	4	132
2000	Clinical trial	14	4	12	4	7	0	0	0	0	0	0	0	0	41
	Basic science	5	0	1	1	1	7	46	0	2	1	1	0	0	65
	Retrospective	4	3	1	1	1	9	19	0	5	2	1	0	7	53
	Cross-sectional	0	0	0	0	0	0	0	0	0	0	0	9	0	9
	Subtotal	23	7	14	6	9	16	65	0	7	3	2	9	7	168
2010	Clinical trial	15	7	14	30	4	0	0	0	0	0	0	0	0	70
	Basic science	3	1	4	0	1	4	58	0	0	0	0	0	0	71
	Retrospective	1	2	12	26	8	24	30	25	9	6	3	2	15	163
	Cross-sectional	0	0	0	0	0	0	0	0	0	0	0	21	14	35
	Subtotal	19	10	30	56	13	28	88	25	9	6	3	23	29	339
Total		102	61	102	64	32	59	300	30	23	10	8	37	41	869

CV = cardiovascular comorbidities; EC = epidemiology and cost; IP = immunology and pathogenesis of psoriasis; OCM = other comorbidities; oral = oral therapy; other = other comorbidities; photo = phototherapy; QOL = quality of life; topical = topical therapy.

Table 2. Percentage of total research stratified by topic and decade

Research topics	1960	1990	2010	Change, 1960 to 1990	Change, 1990 to 2010
Immunology and pathogenesis	47	40	26	+ 488	+ 66
Biologic therapy	0	1	17	NA	+ 2700
Phototherapy	5	10	9	+ 1200	+ 130
Genetics	0	3	8	NA	+ 600
Epidemiology and cost	0	3	8	NA	+ 625
Cardiovascular	0	0	7	0%	NA
Quality of life	5	1	7	0%	+ 2400
Topical therapy	11	23	5	+ 1400	- 37
Other therapy	11	4	4	+ 200	+ 116
Oral therapy	16	11	3	+ 366	- 29
Other comorbidities	0	2	3	NA	+ 200
Infections	0	0	2	NA	NA
Cancer	5	2	1	+ 100	+ 50

NA = not applicable.

of total psoriasis articles in 1960, 1990, and 2010, respectively (Table 2). Publications in immunology and pathogenesis of psoriasis initially grew quickly, rising 488% from 1960 to 1990, and continued to grow steadily, with 66% more articles published in 2010 than in 1990.

Research into phototherapy rose steeply in 1980 (Figure 1), comprising 31% of the articles published that year, 14 times more than the number of articles published in 1960 and 1970 combined. However, interest in phototherapy waned in the following decades, comprising only 9.8%, 8.3%, and 8.8% of total articles published in 1990, 2000, and 2010, respectively.

Some topics have experienced decreased publication. Oral therapy and topical therapy were the second and third most researched topics in 1960, respectively, but were only the eighth and ninth in 2010 (Figure 1). The subjects made up 16% (oral) and 11% (topical) of total articles in 1960 but totaled just 3% and 5% in 2010. This represents a 29% and 37% decrease in the number of articles from 1990.

Biologic therapy publications, however, increased dramatically in recent decades (Figure 1). There were 56 articles (17%) published in 2010, a 7-fold rise in the number of publications compared to 1990 through 2000, when only 8 were published.

Similarly, published research in cardiovascular comorbidities, which was not found in 1960 or 1990, grew tremendously in 2010, comprising 7% of total research (Figure 1). The total number of articles in 2010 (25) was more than what was published for all the previous years combined (5). Research into epidemiology and cost, quality of life, and genetics also experienced a remarkable growth in publications in 2010, with 625%, 2400%, and 600% increases, respectively, over 1990.

Trends in Study Type

Retrospective studies were the most common study type, with 317 original articles (37%), followed by basic science studies (35%) and clinical trials (23%; Table 1). Immunology and pathogenesis of psoriasis was the most common retrospective study topic, with a 25% share. In addition, immunology and pathogenesis of psoriasis accounted for 73% of total basic science research. The most common clinical trials were in topical therapy (32%), followed by

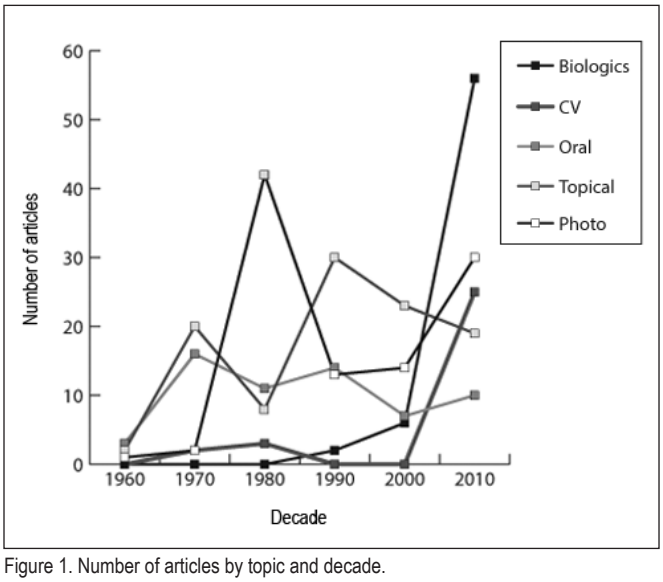

Figure 1. Number of articles by topic and decade.

CV = cardiovascular comorbidities; oral = oral therapy; photo = phototherapy; topical = topical therapy.

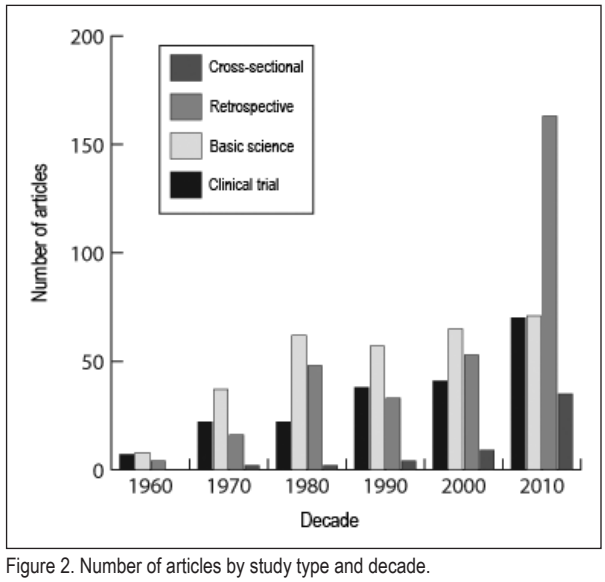

Figure 2. Number of articles by study type and decade.

phototherapy (23%). Quality of life studies made up most of the cross-sectional studies (63%), followed by epidemiology and cost (33%).

Basic science studies were the most published in early decades, comprising 38% to 48% of original studies until 2000 (Figure 2). In 2010, basic science studies comprised only 21% of total research but still produced more articles (n = 71) than in 2000 (n = 65). The number of retrospective studies varied throughout the years but in 2010 experienced a strong rise, with more than 100 more original articles than in year 2000. The number of clinical trials and cross-sectional studies rose steadily through the years, with almost 2-fold and 4-fold increases in the number of articles in 2010 vs 2000. This rise in cross-sectional studies corresponded to the rise in articles related to quality of life, which were almost exclusively time dependent and questionnaire based.

DISCUSSION

For decades, investigators have endeavored to identify the cause of psoriasis and discover better treatments for this condition. This has brought about remarkable discoveries that have altered the way dermatologists view and treat psoriasis. The aim of this retrospective study was to capture the trends in psoriasis research by categorizing original psoriasis-related articles published at the beginning of each decade, starting in 1960.

We found that original psoriasis-related publications grew steadily since 1960 and have experienced a surge in the last decade. These results are encouraging and reflect a robust and thriving research interest in psoriasis. This is likely a result of multiple factors, including increased availability of funding, growing interest from pharmaceutical companies, advancements in technology used in research, an increased number of dermatology and skin biology journals, an increased number of physicians and scientists engaged in research, and an expansion in the type of available treatments.[7]

Our study also demonstrates that research interests have drastically shifted from decade to decade. Although basic science publications in immunology and pathogenesis continue to be the mainstay of psoriasis research, focus on other research topics has evolved. Research in the 1960s and 1970s focused on the available treatments of the disease at the time: topical and oral therapy, which included immunosuppressant agents such as methotrexate.[8] Attention shifted to phototherapy in 1980, which corresponded with the discovery of photochemotherapy (psoralen-ultraviolet A) in the mid-1970s.[9] In 1990, research in phototherapy had dissipated, instead replaced by renewed interest in topical and oral therapy. In particular, studies evaluating cyclosporine and systemic retinoids were frequent.[10-12]

Since 2000, there has been a marked change in the direction of psoriasis research. The emergence of tumor necrosis factor inhibitor therapy for psoriasis occurred during this period, sparking a series of clinical trials that showed remarkable clinical outcomes and changed the way dermatologists manage psoriasis.[13-15] Furthermore, with advancements in DNA technology, publications that analyzed the genetics of psoriasis grew quickly. Last, although the association of psoriasis with cardiovascular disease had been speculated on for some time, the topic received increased attention in recent years.[16] Large clinical trials revealed an increased risk of myocardial infarction and stroke in patients with psoriasis.[17,18] We predict that these high-impact topics will continue to be frequently published in contemporary literature.

We acknowledge certain limitations to the study. We limited our study to the number of articles and did not assess the impact of the articles themselves. Further studies involving citation analysis could be useful. In addition, we drew conclusions about research performed during a decade on the basis of one year of research at the beginning of that decade. The year may not have been representative of that decade because of sampling error. We were limited by our university's subscriptions to peer-reviewed journals, and some articles may not have been accessible. If an article's topic could be categorized under multiple topics, the reviewer chose the best-fit topic. Therefore, our conclusions might have varied if we had categorized these articles differently. Furthermore, the topics and study types were subjectively chosen, thought to best represent broad topics in psoriasis research. Results might have varied if different topics were chosen.

CONCLUSION

The diversity of publications topics in psoriasis research continues to grow at a rapid pace, and recent discoveries have paved the way for future research. Although research topics have changed over the decades, the goal has remained to better understand the disease and its treatment for the benefit of the patient. ❖

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Carpal Tunnel Syndrome in Sarcoidosis: A Case Report of a Rare Neurologic Manifestation

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ABSTRACT

Introduction: Sarcoidosis is a multisystemic inflammatory disease with myriad clinical manifestations. Neurologic involvement in sarcoidosis is uncommon. Peripheral neuropathic presentations include mononeuropathy, mononeuritis multiplex, and generalized sensory, motor, autonomic, and sensorimotor polyneuropathies.

Case Presentation: We report a case of carpal tunnel syndrome caused by sarcoidosis in a 30-year-old woman. Other causes of carpal tunnel syndrome were ruled out. The patient responded well to the standard line of corticosteroid treatment and wrist splinting.

Discussion: Carpal tunnel syndrome caused by sarcoidosis is a rare presentation. The mechanism of neurologic involvement in sarcoidosis is not clear.

INTRODUCTION

Neurologic involvement is reported in 5% to 10% of patients with sarcoidosis.[1] Some authors consider neurosarcoidosis a totally different entity. Most often, a presentation of neurosarcoidosis is multiple fluctuating and remitting cranial nerve palsies. Noncranial neuropathy has been reported in 15% to 40% of cases of neurosarcoidosis.[2] Scott et al[3] reported a case series in which peripheral neuropathy developed in 6% to 18% of patients with neurosarcoidosis.

CASE PRESENTATION

A 30-year-old woman presented with complaints of tingling and numbness in her right hand. On detailed inquiry, the patient also had a history of malaise, anorexia, weight loss, and cough for 1 month. There was no associated muscular weakness of the right hand, fever, or any other systemic involvement. There was no history of tuberculosis. She was a nonsmoker and a nonalcoholic. Results of the physical examination revealed a positive Tinel sign. There was no skin lesion or lymphadenopathy. The systemic findings were normal.

The patient underwent many investigations (Table 1), of which relevant ones included a Mantoux test response of 0 mm at 48 hours and increased angiotensin-converting enzyme levels of 200 U/L. Fasting blood glucose level was 86 mg/dL, and the thyroid function test had a normal result. Nerve conduction studies showed carpal tunnel syndrome of the right hand with involvement of the sensory component without motor deficit. A chest computed tomography scan was obtained and showed right paratracheal and bilateral hilar lymphadenopathy, which was nonnecrotic without any calcification (Figure 1). A parenchymal lesion showed a reticulonodular pattern and suggested a diagnosis of sarcoidosis. Fine-needle aspiration cytology of the mediastinal lymph node showed noncaseating granulomas without any acid-fast bacilli and confirmed the diagnosis of sarcoidosis.

Table 1. Case timeline

Day	Symptoms and treatment
1	Complaints of tingling and numbness in right hand, malaise, anorexia, weight loss, and cough for 1 month Physical examination revealed positive Tinel sign. Systemic findings were normal
3	Mantoux test response was 0 mm at 48 hours and increased angiotensin-converting enzyme level of 200 U/L Blood glucose level and thyroid function test had normal results Nerve conduction studies showed carpal tunnel syndrome of right hand with involvement of sensory component without motor deficit
4	Chest computed tomography scan showed right paratracheal and bilateral hilar lymphadenopathy, which was nonnecrotic without any calcification. Parenchymal lesion showed reticulonodular pattern and suggested sarcoidosis Other causes of carpal tunnel syndrome were ruled out
6	Fine-needle aspiration cytology of mediastinal lymph node showed noncaseating granulomas without any acid-fast bacilli and confirmed the diagnosis of sarcoidosis
7	Treatment started with corticosteroids Carpal tunnel splint was prescribed
21	Symptoms of malaise, cough, anorexia, and weight loss subsided
33	Neuropathic symptoms of tingling and numbness of right hand started subsiding Began tapering corticosteroid
100	Neuropathic symptoms recovered completely
150	Steroid dosage tapering completed and stopped

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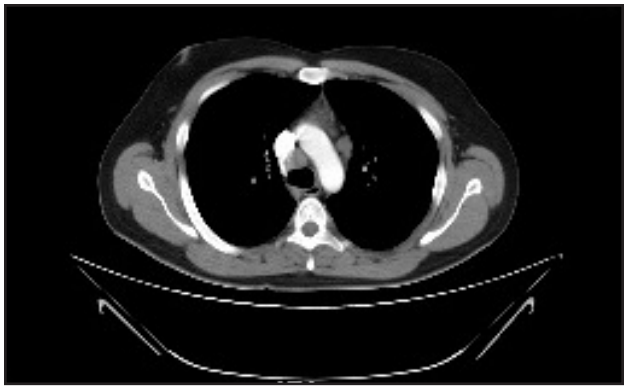

Figure 1. Chest computed tomography scan showing right paratracheal and bilateral hilar nonnecrotic, noncalcific lymphadenopathy.

The patient was treated with corticosteroids, after which her symptoms of malaise, cough, anorexia, and weight loss subsided. Other causes of carpal tunnel syndrome were ruled out. A carpal tunnel splint was prescribed for the patient, after which she recovered.

DISCUSSION

This patient, who presented with neurologic complaints, turned out to have a case of neurosarcoidosis with carpal tunnel syndrome. Other common causes of carpal tunnel syndrome were ruled out on investigations.

The mechanism of neurologic involvement in sarcoidosis is not clear. Granulomatous inflammation of nerve layers, secondarily caused by vasculitic neuropathy, demyelination, panangiitis, compression by sarcoid tissue, or thick edema under perineural tissue are some of the proposed causes of nerve involvement in sarcoidosis.[2] Treatment is mainly corticosteroid based and physical therapy. Our patient responded well to the standard line of treatment.

An association of carpal tunnel syndrome with sarcoidosis is rare, and our case adds to the existing sparse, English-language literature.[2,4-6] The etiopathogenesis of carpal tunnel syndrome in sarcoidosis is not clearly defined. Thinking well beyond commonness may help in detecting the underlying cause of carpal tunnel syndrome, or else the diagnosis might be missed. Specific therapy in such cases may help in alleviating patient suffering and working toward the common goal of better patient care. ❖

Disclosure Statement

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

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Image Diagnosis: Hemorrhagic Bullae in a Primary Varicella Zoster Virus Infection

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CASE REPORT

A 47-year-old man, 20 pack-per-year smoker, and heavy alcohol drinker, with an episode of pulmonary tuberculosis 10 years previously, presented to the Emergency Department with 7 days of cough, mucous sputum, and abdominal pain. Additionally, he presented with 5 days of a pruriginous skin rash that started on the thorax but rapidly disseminated to the entire body, and with 3 days of fever. Physical examination revealed dyspnea, polypnea, fever, dispersed ronchi bilaterally upon chest auscultation, and dispersed papules, pustules, and hemorrhagic vesicular lesions on the skin and oral mucosa (Figures 1 and 2).

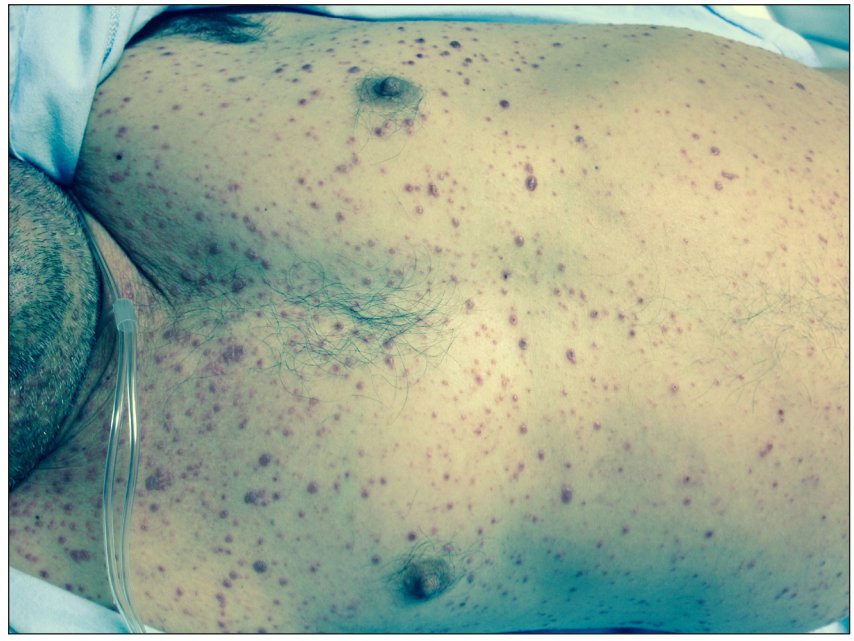

Figure 1. Image of the patient's anterior thorax and upper abdomen. Note the diffuse maculopapular and vesicular lesions with hematic content.

A thoracic computed tomography scan showed peribronchovascular parenchymatous densities with areas of ground-glass opacity, suggesting an infectious process with endobronchial dissemination (Figure 3). Fiberoptic bronchoscopy showed scattered ulcerated and vesicular lesions in the airway lining. Blood tests showed cytolytic hepatitis and rhabdomyolysis. Despite treatment with acyclovir, ceftriaxone, and azithromycin, the patient deteriorated rapidly and exhibited severe acute respiratory distress syndrome, with a PaO2/FiO2 ratio of 95 mmHg. At this point our patient was transferred to the intensive care unit to be started on mechanical ventilation, hemodialysis for acute kidney injury, norepinephrine cardiovascular support for septic shock, and extracorporeal membrane oxygenation, which he continued for 20 days. The sepsis workup from admission was sterile for bacteria, fungi, and mycobacteria; serology studies for hepatitis B virus, hepatitis C virus, and human immunodeficiency virus were negative; and no relevant immunosuppression factors could be identified. Serologic tests were positive for varicella zoster virus (VZV)-specific immunoglobulin G and immunoglobulin M, determined by enzyme-linked immunosorbent assay and enzyme-linked fibrinolytic assay. The serum was also positive for VZV deoxyribonucleic acid, determined by polymerase chain reaction. Because our patient had no known history of chickenpox, and had never been vaccinated for VZV, we made the diagnosis of primary VZV infection. By day 35 after admission, our patient had improved sufficiently and was transfered to the medical ward.

DISCUSSION

Chickenpox is usually a benign disease, but in immunocompromised individuals it can lead to clinical complications with significant morbidity and mortality.[1] VZV infection causes primarily chickenpox, which is characterized by a typically disseminated skin rash.[2] Lung infection because of VZV is uncommon, and it usually occurs two to seven days after the appearance of skin rash. The initial cutaneous lesions of varicella often involve the scalp, face, and/or trunk and are pruritic, erythematous macules. The maculopapular phase of infection evolves to a vesicular phase, during which fluid-filled vesicles

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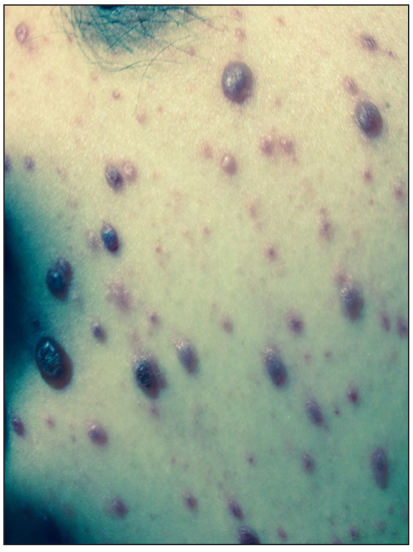

Figure 2. Magnified image of the patient's upper abdomen, showing the dispersed skin lesions in greater detail. Note the small maculopapular erythematous lesions and large vesicles with hemorrhagic content.

appear in existing or new erythematous lesions, leading to the typical "dewdrop on a rose petal"[3] appearance. In the case we report here, the skin lesions were not the typical dewdrop on a rose petal appearance because of the hemorrhagic content of the vesicles. Hemorrhagic vesicles in chickenpox are very unusual and are generally associated with severe immunodeficiency.[4,5]

This was a case of VZV pneumonia in a young adult patient with an unusual skin rash and acute respiratory distress syndrome, which has a high severity even for this age group. Our patient had no known history of contact with infected persons or evidence of congenital or acquired immunodeficiency beyond what was caused by chronic alcohol and tobacco abuse. Some components of tobacco smoke are known to suppress important pathways of the innate respiratory immune system.[6] Clinical studies have also shown that the incidence of acute respiratory distress syndrome is much higher in patients with a known history of alcohol abuse.[7] This case highlights the impact these two habits can have as immunosuppressant factors.[8,9] Primary infection by VZV in adults and immunocompromised individuals may have a more severe presentation and serious complications. Prompt and accurate diagnosis is essential to prevent life-threatening sequelae. ❖

Disclosure Statement

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

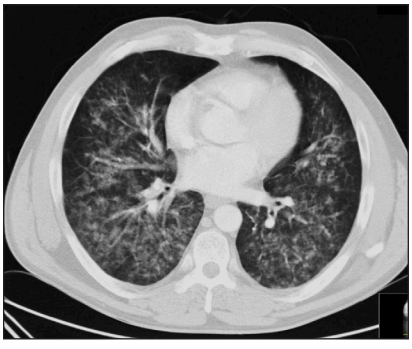

Figure 3. Computed tomography scan of the patient's thorax showing peribronchovascular parenchymatous densities with areas of ground-glass opacity.

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Key to Success

The power of making a correct diagnosis is the key to all success in the treatment of skin disease; without this faculty, the physician can never be a thorough dermatologist, and therapeutics at once cease to hold their proper position, and become empirical.

— Louis A Duhring, MD, 1845-1913, American physician and professor of dermatology

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Section A.

Article 1. (page 11) Safe and Effective Implementation of Telestroke in a US Community Hospital Setting

The use of telemedicine may be an important tool for the evaluation of treatment of potential stroke patients. All of the below are ways in which telemedicine improves stroke care delivery except:

☐ a. identification of patients potentially eligible for endovascular intervention
☐ b. eliminating the bedside physician from the decision-making process
☐ c. aiding in thrombolytic decisions
☐ d. aiding in triage decisions

Implementation of telestroke led to:

☐ a. increased rate of intracranial hemorrhage
☐ b. increased patient transfers
☐ c. increased rate of tissue plasminogen activator administration
☐ d. significant physician dissatisfaction

Article 2. (page 27) Standardizing Management of Adults with Delirium Hospitalized on Medical-Surgical Units

Posthospitalization, patients who are diagnosed with delirium have higher rates of:

☐ a. mortality
☐ b. patient satisfaction
☐ c. hip fractures
☐ d. opiate abuse

The medication guidelines that were developed as part of this pilot recommend use of which of the following for treatment of delirium unrelated to alcohol withdrawal?

☐ a. anticholinergics
☐ b. sedatives and hypnotics
☐ c. lorazepam
☐ d. haloperidol

Article 3. (page 74) Anal Health Care Basics

When a patient has an anal complaint such as pain and bleeding, you should:

☐ a. assume it is hemorrhoids and advise use of Preparation H
☐ b. tell him/her it happens and will resolve on its own
☐ c. perform an anoscopy, and then prescribe steroid-based treatments
☐ d. perform external examination and a digital rectal exam if possible, and then treat correctly if the diagnosis is clear or refer to a specialist if there is any question regarding the diagnosis

Steroid-based treatments for anal problems such as hemorrhoids:

☐ a. have been shown to decrease hemorrhoidal bleeding
☐ b. should be avoided because they have not been shown to help
☐ c. almost always relieve anal pain
☐ d. should be prescribed for any anal complaint

Article 4. (page 97) Amniotic Fluid Embolism: Using the Medical Staff Process to Facilitate Streamlined Care

Which of the following signs or symptoms occurs in less than half of the cases of amniotic fluid embolism?

☐ a. pulmonary edema or acute respiratory distress syndrome
☐ b. fetal distress
☐ c. hypotension
☐ d. seizures
☐ e. cardiopulmonary arrest

Each of the following are indications for the institution of extracorporeal membrane oxygenation except:

☐ a. acute respiratory distress syndrome
☐ b. hypocarbic respiratory failure
☐ c. excessively high plateau airway pressure on ventilator
☐ d. severe hypoxemia despite positive end-expiratory pressure of 15cm - 20cm H_2O
☐ e. severe hypoxemia < 50

Section B.

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

Key
5 = highly likely
4 = likely
3 = unsure
2 = unlikely
1 = highly unlikely
0 = I already did this

	Objective 1 Integrate learned knowledge and increase competence/ confidence to support improvement and change in specific practices, behaviors, and performance.	**Objective 2** Lead in further developing "Patient-Centered Care" activities by acquiring new skills and methods to overcome barriers, improve physician/patient relationships, better identify diagnosis and treatment of clinical conditions, as well as, efficiently stratify health needs of varying patient populations.	**Objective 3** Implement changes and apply updates in services and practice/policy guidelines, incorporate systems and quality improvements, and effectively utilize evidence-based medicine to produce better patient outcomes.
Article 1	5 4 3 2 1 0	5 4 3 2 1 0	5 4 3 2 1 0
Article 2	5 4 3 2 1 0	5 4 3 2 1 0	5 4 3 2 1 0
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Section C.

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

_____

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_____

Section D. (Please print)

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Date _____