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# The Permanente Journal

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**Land of the Remembered**  
24" x 36"  
acrylic on canvas  
Navreet Dhillon, MD

This painting is a tribute to Dr Kamal Charaipotra, the beloved grandfather of Dr Dhillon's niece Kavya. From Dr Dhillon: "Dr Kamal was a much loved and respected pediatrician. My painting is a celebration of his vibrant and charismatic personality. His name, Kamal, meaning lotus flower in Punjabi, is the central bloom in the painting." Dr Dhillon's

painting is also a meditation on Kavya's solace that those who pass become stars in the sky, part of the energy around us, and live on in our memories.

Dr Dhillon is a Primary Care Physician at the Kaiser Permanente San Jose Medical Center in CA. More of Dr Dhillon's work can be seen at: [www.facebook.com/poppymaspearts](http://www.facebook.com/poppymaspearts) and on page 35 of this issue of *The Permanente Journal*.

## 112 CME EVALUATION FORM



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Surgeons write 1.8% of all prescriptions and 9.8% of all opioid prescriptions. Of a total of 180 patients (median age 63 years), 127 did not receive opioids; 53 were prescribed opioids against protocol. The operating surgeon was the only variable independently correlated with protocol adherence. Ambulatory breast surgery patients tolerated a nonopioid pain regimen well. Surgeons' decisions, rather than patient characteristics, primarily drove the choice of pain management in our study.

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Every year, more than 500,000 US Emergency Department visits are associated with cocaine use. In a retrospective analysis, of 1144 consecutive patients with ST-elevation myocardial infarction (STEMI; 2008-2013), 64 patients with suspected STEMI were cocaine positive (CPos) (mean age 53.1, 80% male). True STEMI was diagnosed in 34 patients. Patients with CPos true STEMI were more likely to be uninsured. Among those with suspected STEMI, patients with CPos findings had a higher incidence of false STEMI.

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**CME**

Somalee Banerjee, MD, MPH; Eileen Kim, MD; Melissa M Parker, MS; Lisa K Gilliam, MD, PhD; Rick Dlott, MD; Alyce Adams, PhD

Retrospective cohort study to analyze data from 160,852 patients screened for diabetic peripheral neuropathy (DPN) symptoms from 4/12-3/14. Of patients queried, 50,684 (31.5%) reported symptoms. Patients reporting DPN symptoms experienced a greater increase in new DPN diagnoses and medication use. Women and nonwhite patients were less likely to receive a DPN diagnosis; older patients were more likely. Overall, patients who were older, were Asian, and had lower socioeconomic status were less likely to be treated.

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Seena Safavy, MD; Ramzi B Jabaji, MD; Sharon M Lu, MD; Jeff M Slezak, PhD; Harry A Cosmatos, MD; Stephen G Williams, MD; David S Finley, MD

On retrospective review of patients' medical records (salvage cryoablation 2005-2015), all patients had biopsy-proven local recurrence after radiotherapy. Complete follow-up was obtained for all patients. Seventy-five patients underwent salvage cryotherapy. Mean patient age was 69.3 years. The overall biochemical salvage rate was 50.7% at a median follow-up of 3.9 years. Approximately 50% of the patients achieved biochemical salvage with cryoablation at 5 years. Nadir prostate-specific antigen after salvage was the strongest predictor of biochemical progression-free survival in our cohort.

#### 27 Temporal Changes in Health Care Utilization among Participants of a Medically Supervised Weight Management Program.

Ashok Krishnaswami, MD, MAS; Stephen Sidney, MD, MPH; Michael Sorel, MPH; Wayne Smith, MD; Rohini Ashok, MD

In a retrospective study of 10,693 weight-management program participants across 21 Kaiser Permanente Northern California centers during a 5-year period, at baseline the participants' average age was 51.1 years, and the mean body mass index was 39.7 kg/m<sup>2</sup>. At the end of 4 months, there was a significant decrease in primary care visits, with an increase in ambulatory clinic visits and health care touches (because of increased weight management visits). At the end of 5 years, there was a 25% to 35% decrease from baseline in all 3 health care utilization metrics.

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To better understand differences in how Latinos and non-Latino whites (NLWs) experience cardiovascular disease care, the authors examined self-reported activation, engagement, confidence, and communication comparing Latinos (n = 194) and NLWs (n = 208). Latinos were younger, less educated, and had lower incomes than NLWs, and were significantly less likely to report knowing how to ask good questions about their health and to report positive experiences and confidence with several measures of chronic illness care. Interventions should emphasize question-asking skills.

### 36 Sociodemographic Determinants of Health and Well-Being Among Adults Residing in the Combined Kaiser Permanente Regions.

CME

Matthew C Stiefel, MPA, MS; Nancy P Gordon, ScD; Folasade J Wilson-Anumudu, MPH; Emily L Arsen, MPH

A cross-sectional email-and-phone survey (Winter 2016-2017) with a racial/ethnic group-stratified quota sample (N = 26,304) found 52% in excellent/very good (E/VG) health and 63% were thriving. Blacks were less likely to be in E/VG health than whites, Hispanics, and Asian/Pacific Islanders, but there was little racial/ethnic variation in those who were thriving. Differences in health status and life evaluation are associated very strongly with financial situation and educational attainment, partially explaining racial/ethnic disparities in health and well-being. The lack of strong correlation of health status and life evaluation suggests these are different domains of well-being.

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Tina Sapia, MD; Marie E Faughnan, MD; Jennifer L Schneider, MPH; Lucy M Almers, MPH; Norma Chow, MS LCGC; Scott D Grosse, PhD; Helen Kim, PhD; Jonathan G Zaroff, MD

Hereditary hemorrhagic telangiectasia (HHT) is a rare, genetic, and underdiagnosed disease that causes vascular malformations throughout the body. The "HHT Algorithms" (HHTAs) were applied to the patient population of Kaiser Permanente Northern California. Of 3,065,210 records queried, 163 patients met HHTA criteria. After chart review, the study identified 113 patients with possible undiagnosed HHT. Employing the HHTAs in this community-based population resulted in a modest yield of patients with possible HHT.

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All patients with ulcerative colitis between 2003 and 2017 were admitted for induction therapy. Patients receiving educational hospitalization or treated with infliximab were excluded. A lacto-ovo-semivegetarian diet together with medication prescribed according to ulcerative colitis guidelines was provided during hospitalization. Ninety-two cases were studied (51 initial episodes and 41 relapses). Cases varied in severity (31 mild, 48 moderate, 13 severe). Cumulative relapse rates at 1- and 5-year of follow-up (Kaplan-Meier analysis) were 14% and 27%, respectively, for initial episode cases, and 36% and 53%, respectively, for relapse cases.

### 60 Progel Use is Not Associated with Decreased Incidence of Postoperative Air Leak after Nonanatomic Lung Surgery.

CME

Rebecca C Gologorsky, MD; Amy L Alabaster; Simon K Ashiku, MD; Ashish R Patel, MD; Jeffrey B Velotta, MD

This is a retrospective study of 176 patients (age 18-80 years) who underwent video-assisted thoracoscopic wedge resections between 2014 and 2016. Eighty-four (48%) cases using Progel and 92 (52%) non-Progel cases were included. No difference existed between the Progel and the non-Progel groups in the rate of postoperative air leak. The length of time patients had a chest tube was similar, as was the percentage of patients with a less than 2-day hospitalization.

## ONLINE

Content available at: [www.thepermanentejournal.org](http://www.thepermanentejournal.org)

### Fractional Exhaled Nitric Oxide-Assisted Management of Uncontrolled Persistent Asthma: A Real-World Prospective Observational Study.

Robert Stephen Zeiger, MD, PhD; Michael Schatz, MD, MS; Su-Jau Yang, PhD; Wansu Chen, MS, PhD

This is a prospective observational study in patients aged 12 years and older with uncontrolled persistent asthma identified during a scheduled visit to an Allergy Department. Compared with standard care, Fractional Exhaled Nitric Oxide (FeNO)-assisted care was not associated with reducing the primary composite outcome, nor with a reduction in asthma exacerbations or dispensing of 7 or more short-acting  $\beta_2$ -agonist canisters as separate outcomes. In an atopic subgroup with aeroallergen sensitization, the composite outcome was similar between groups, but the rate of asthma exacerbations was lower with FeNO-assisted treatment.

### Health Status of Young Adults with Insurance Coverage Before and After Affordable Care Act Passage.

Gelliza B Gervacio, MPH; Margo Sidell, ScD, MSPH; Xia Li, MS; Deborah R Young, PhD, MBA; Michael Batech, DrPH; Lei Qian, PhD; Kristi Reynolds, PhD, MPH; Corinna Koebnick, PhD

For this cross-sectional descriptive study, electronic health record information for young adults (age 18-25 years) enrolled in a large Southern California Health Plan in 2008, 2010, or 2015 was obtained (N = 665,686). The number enrolled in the Health Plan increased by 145,000 (65%) with a shift toward low-income young adults. The prevalences of obesity and other health conditions between pre-Affordable Care Act and post-Affordable Care Act periods essentially were unaltered.

### Temporal Trends in Mortality Rates among Kaiser Permanente Southern California Health Plan Enrollees, 2001-2016.

Wansu Chen, PhD; Janis Yao, MS; Zhi Liang, PhD; Fagen Xie, PhD; Don McCarthy, MS; Lee Mingsum, MD, PhD; Kristi Reynolds, PhD; Corinne Koebnick, PhD; Steven Jacobsen, MD, PhD

Trends using data collected at Kaiser Permanente Southern California (KPSC) and those derived through linkage with California State death files were compared with trends in the US and California. The age-adjusted all-cause mortality rate per 100,000 person-years decreased significantly in KPSC, California, and the US. Rates of cancer and heart disease also decreased significantly. No significant difference was found in the trends of race/ethnicity-specific, sex-specific, or race/ethnicity- and sex-specific all-cause mortality rates between KPSC and California or the US.

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Fruit and vegetable prescription programs provide increased access to produce to food-insecure, at-risk populations, yet many lack the educational and social components to support long-term disease prevention. Nine families deemed by clinicians as at risk of chronic disease and food insecurity received weekly \$40 "prescriptions" for produce at partnering farmer's markets. Participants were paired with medical student mentors who delivered weekly nutrition education modules and assisted in produce shopping. Postprogram fruit and vegetable consumption increased, and more patients expressed efforts to include produce in every meal. Student mentors expressed gratitude for one-on-one interaction and felt empowered to learn and deliver nutrition education.

- 70 Ensuring Mentorship of New Physicians in Their First Year: Constructs for New Mentoring Processes.** Wynnyee Tom, MD; Wynnian Tom, MD; Daisy Albarran; Nina Salman, MSHA; Aneema Van Groenou, MD

We aimed to achieve a structured framework for mentor training, evaluation of the mentor-mentee relationship, and development of a bridge for the knowledge gaps and needs of the individual physicians in their departments. The new mentoring process was improved compared with the current mentoring process. Polling of physician mentees after implementation of the checklist showed a 75% completion rate of checklist competencies from January 2017 to April 2018, compared with a baseline of 0%. This process can lead to active participation and meaningful change in competencies among new physicians.

- 73 Promising Methods for Improving Quality Through the Faster Spread of Best Practices.** Michael H Kanter, MD; Patrick T Courneya, MD

- 75 Abstracts from the Kaiser Permanente 2019 National Quality Conference.**

These abstracts reflect the critical importance of a forum for presenting promising quality efforts. Meetings focused on quality improvement, such as those hosted by the Institute for Healthcare Improvement, the American Medical Group Association, and many other organizations, represent a relatively small percentage of all scientific medical meetings. The publication of abstracts from a dedicated quality event such as the Kaiser Permanente National Quality Conference allows those inside and outside of Kaiser Permanente to learn about new and potentially unfamiliar practices that could improve care.

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Acute convulsive seizures are overwhelming events that require immediate attention from clinicians and practitioners, especially when witnessed in a hospital setting. Adequate management of inpatient-witnessed seizures lies in understanding the time-related pathophysiologic stages of the seizure. Although investigating and treating the cause of a seizure has high priority, knowing such dynamics allows clinicians to choose the best treatment options in the best time interval when a seizure occurs in an acute care facility.

## COMMENTARY

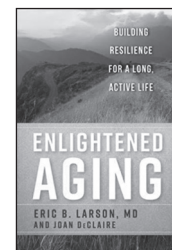
- 105 Disrupting Physician Clinical Practice Peer Review.** Rajesh Swaroop, MD

The goal of physician peer review has been to assess and improve the quality of care by individual physicians. Unfortunately, this enshrined piece of medical practice suffers from deep flaws that hamper the achievement of assessment and improvement. This institution is in serious need of disruption, both for the safety of patients and the wellness of practicing physicians. This commentary describes the inherent flaws of physician practice review and how physicians and health care organizations can address them.

## BOOK REVIEW

- 110 Enlightened Aging: Building Resilience for a Long, Active Life.** Arthur Hayward, MBA, MD

In a departure from most researchers, Larson asks older people how they define successful aging; and he sees their view differs markedly from a more scientific formulation that emphasizes longevity and biomechanical function. Old-old people often describe themselves as doing well, when medical scientists' measurements would indicate they are not.



Stories and poems with illustrations from the upcoming book *100 Little Stories of Big Moments* published by The Permanente Press.

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**William L Toffler, MD**  
Professor Emeritus of Family Medicine, Oregon Health and Sciences University, Portland

# Experience with a Nonopioid Protocol in Ambulatory Breast Surgery: Opioids are Rarely Necessary and Use is Surgeon-Dependent

Kara A Rothenberg, MD<sup>1</sup>; Michelle R Huyser, MD<sup>1</sup>; Joanne K Edquilang, MD<sup>1</sup>; Elizabeth L Cureton, MD<sup>2</sup>; Rita O Kwan, MD, MPH<sup>2</sup>; Peter D Peng, MD<sup>2</sup>; Jonathan D Svahn, MD<sup>2</sup>; Veronica Shim, MD<sup>2</sup>

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## ABSTRACT

**Context:** Surgeons write 1.8% of all prescriptions and 9.8% of all opioid prescriptions. Even small doses prescribed for short-term use can lead to abuse; thus, surgeons are uniquely able to combat the opioid epidemic by changing prescribing practices. As part of a departmentwide quality improvement project, we initiated a nonopioid protocol for all patients undergoing ambulatory breast surgery.

**Objective:** To determine the feasibility of a nonopioid protocol for patients undergoing ambulatory breast surgery and to determine if patient-related factors contribute to surgeon adherence to a nonopioid protocol in ambulatory breast surgery.

**Design:** Retrospective chart review of a prospectively collected database, with  $\chi^2$  analysis and a multiple logistic regression model with the surgeon as the random effect.

**Main Outcome Measure:** Protocol adherence.

**Results:** A total of 180 patients, with a median age of 63 years (range = 18-95 years), were included. Of these, 127 (70.6%) did not receive opioids; in this group there were 2 hematomas (1.6%), and 3 patients required an opioid prescription (2.4%). Fifty-three (29.4%) were prescribed opioids against protocol; in this group, there was 1 hematoma (1.9%). The operating surgeon was the only variable independently correlated with protocol adherence ( $p < 0.0001$ ). Age, race/ethnicity, surgery type, and history of long-term opioid use were not.

**Conclusion:** Ambulatory breast surgery patients tolerated a nonopioid pain regimen well. Surgeons' decisions, rather than patient characteristics, primarily drove the choice of pain management in our study. We believe our protocol can be improved with stricter implementation and education, which must be balanced with practitioner independence.

## INTRODUCTION

Opioid use was associated with approximately 33,000 deaths in the US in 2015.<sup>1</sup> Although opioids are sometimes necessary in the acute postoperative period, there is still a substantial risk of dependency,<sup>2</sup> opioid-induced hyperalgesia,<sup>3</sup> and opioid-related adverse events.<sup>4</sup> Many opioid-related adverse events, such as nausea, vomiting, fatigue, confusion, or constipation, seem benign, but they have been associated with increased length of stay, cost, readmission rates, and inpatient mortality.<sup>3</sup>

Surgeons write only 1.8% of all prescriptions, yet they write 9.8% of all opioid prescriptions.<sup>5</sup> Many of these prescriptions are written for opioid-naïve patients in the immediate postoperative period, which may not always be necessary.<sup>4</sup> Thus, surgeons have a unique opportunity to limit opioid prescriptions in the appropriate settings. Ambulatory surgery, particularly breast surgery, is one of the settings where opioids can be decreased or possibly eliminated.<sup>4,6-8</sup>

To decrease unnecessary opioid prescriptions in our practice, we decided to institute a nonopioid protocol for all ambulatory breast surgeries performed in our practice. The goals of the study were to determine if patients in our practice could have pain adequately managed after ambulatory breast surgery without opioids and to describe our experience with a protocolized discharge plan. Because the protocol was not strictly enforced, we also analyzed those who did not receive the protocol to determine whether patient characteristics were associated with protocol adherence by the surgeon.

## METHODS

The nonopioid protocol began in June 2016, and we reviewed the charts of all ambulatory breast surgery patients from July 2016 to July 2017. Ambulatory breast surgery in our practice was defined as any patient having a lumpectomy with or without sentinel lymph node biopsy (SLN) and/or intraoperative radiation therapy (IORT). Seven surgeons were in our practice, and the data of all 7 surgeons were included, whether or not they chose to follow the nonopioid protocol. No patients, including those with a diagnosis of chronic pain or long-term opioid prescriptions, were excluded. Baseline characteristics of the patients are listed in Table 1.

The protocol suggested counseling regarding pain management expectations as well as prescriptions of acetaminophen and ibuprofen to manage pain; however, there were no strict restrictions or mandates preventing opioid prescriptions. Follow-up included a secure phone call or secure message from our breast care coordinator within 1 to 3 days of surgery and a clinic visit 1 to 2 weeks postoperatively. As with all practices in our integrated health system, all patients received discharge instructions and the phone number for our 24-hour regional call center. If patients called the regional call center or presented to the Emergency Department with pain not responsive to acetaminophen or ibuprofen, they were given an opioid prescription. Also, during postoperative Day 1 follow-up, patients were asked about their pain, and if they requested opioid medications or described moderate to severe pain, a prescription was written.

### Author Affiliations

<sup>1</sup>Department of Surgery, University of California San Francisco-East Bay, Oakland, CA

<sup>2</sup>Department of Surgery, Kaiser Permanente, Oakland, CA

### Corresponding Author

Veronica Shim, MD ([veronica.shim@kp.org](mailto:veronica.shim@kp.org))

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Of the patients who received the protocol, failure was measured by opioids prescribed within 14 days of discharge from the postanesthesia care unit, which was captured by review of secure patient messages, call center logs, follow-up appointment notes, and prescriptions. For patients with long-term opioid prescriptions, failure was measured in the same way; however, refills of the normal prescription by the primary prescriber were not counted. Because the protocol was not strictly enforced, a group of patients were still prescribed opioids, and these patients were further analyzed to improve protocol adherence. Our chart review was performed retrospectively for the purposes of quality improvement; thus, approval from the institutional review board was not required.

We assessed the association of patient- and surgeon-level characteristics with the probability of an opioid prescription using R software (R Foundation),  $\chi^2$  analysis, and a logistic regression model with a random intercept for surgeons.

## RESULTS

We reviewed the charts of 180 consecutive patients. The median age of all 180 patients was 63 years (range = age 18–95 years). Procedures were lumpectomy only (29.4%), lumpectomy with SLN (47.8%), or lumpectomy with SLN and IORT (22.8%). Of the 180 patients, 53 (29.4%) were prescribed postoperative opioids during the study period despite the nonopioid protocol. There were 3 complications, all hematomas requiring that patients be taken back to the operating room. Two of these patients received the nonopioid protocol and 1 did not. Of the 127 patients

(70.6%) who received the nonopioid protocol, 3 (2.4%) were later prescribed opioids because of pain not controlled by the protocol. Results are summarized in Table 2.

Chi-squared analysis showed that the operating surgeon was the only variable independently correlated with protocol adherence ( $p < 0.0001$ ). In our logistic regression with the surgeon as a random effect, neither age, race/ethnicity, surgery type (lumpectomy only, lumpectomy with SLN, or lumpectomy with SLN and IORT), nor history of long-term opioid use was associated with protocol adherence. Interestingly, when surgeons who were more adherent to the protocol strayed from it, further chart review showed that the opioids were often prescribed by a resident physician not familiar with the protocol.

## DISCUSSION

In this study, we evaluated our implementation of a nonopioid policy in ambulatory breast surgery, and the results suggest that opioids can be safely eliminated from the postoperative analgesic regimen of nearly all patients. Perhaps more interestingly, we found that in our practice, postoperative analgesic regimens appear to be driven by the surgeon rather than patient characteristics such as age, race/ethnicity, surgery type, or even a history of chronic pain.

It has already been shown that opioids are overprescribed, but determining an appropriate number to prescribe has been more difficult. Results of a retrospective study of patients who underwent general surgery showed that 70% of prescribed opioids were never taken.<sup>4</sup> These authors' subgroup analysis showed that after partial mastectomy and partial mastectomy with SLN, 85% and 74% of prescribed opioids, respectively, were not taken.<sup>4</sup> Others have shown that opioids may be eliminated completely after ambulatory surgery.<sup>7,8</sup> Findings from a double-blind randomized trial in 2012 showed no difference in pain scores after ambulatory breast surgery between a group of patients receiving acetaminophen with codeine (Tylenol no. 3) or a combination of nonsteroidal anti-inflammatory drugs with acetaminophen (Tylenol).<sup>6</sup>

Despite evidence that opioids can be reduced or eliminated, 99% of surgical patients still receive postoperative opioid prescriptions upon discharge.<sup>9</sup> Physician adherence rates to clinical practice guidelines in general can range anywhere from 20% to 99%.<sup>10–12</sup> The discordance between evidence and prescriber practice has been bridged with success in primary care and acute settings, where education and protocols have decreased the number of opioid prescriptions.<sup>13–15</sup> However, even in the setting of a protocol, our study had only 70.6% adherence. Discussions with our surgeons elicited that those who went against protocol were “assuming it wouldn't work” and that “some patients seemed like they would need them.” Often, the decision to prescribe opioids and the number to prescribe appear to be based on routine, rather than taking the patient and surgical procedure into consideration.<sup>16</sup> Our results are valuable because we have a better understanding about the drivers for these prescriptions, and our results imply that the burden for reducing opioid prescriptions falls on the prescriber. Although protocols may be a way to improve guideline compliance and translate the evidence into

**Table 1. Patient characteristics (N = 180)**

Characteristic	Number (%)
<b>Age, y</b>	
Median	63
Range	18-95
<b>Race/ethnicity</b>	
Asian/Pacific Islander	23 (12.7)
Black/African American	34 (18.9)
Hispanic/Latin American	12 (6.7)
Other/unknown	11 (6.1)
White/Caucasian	100 (55.6)
History of chronic pain	7 (3.9)
<b>Surgery</b>	
Lumpectomy only	53 (29.4)
Lumpectomy + SLN	86 (47.8)
Lumpectomy + SLN + IORT	41 (22.8)
<b>Surgeon</b>	
1	15 (8.3)
2	44 (24.4)
3	8 (4.4)
4	3 (1.7)
5	13 (7.2)
6	81 (45.0)
7	16 (9.0)

IORT = intraoperative radiation therapy; SLN = sentinel lymph node biopsy.

practice, we recognize that practitioner independence, patient autonomy, and other patient-related factors should play a role in prescribing practices as well.

In our study, only 3 (2.4%) of the patients in the nonopioid protocol required opioids, which suggests that not prescribing these medications at all may be effective for most patients who undergo ambulatory breast surgery in our practice. It should be noted that in our integrated health system, patients have access to a 24-hour regional call center that is directly linked to a 24-hour pharmacy to obtain an opioid prescription rather easily and quickly. We would therefore caution other practitioners to confirm that reliable backup methods exist before initiating a nonopioid protocol. If backup methods are less reliable, it may be more reasonable to protocolize the number of opioids prescribed, which can be done using guidelines from the Michigan Surgical Quality Collaborative and the Michigan Opioid Prescribing Engagement Network.<sup>17</sup>

One of our particularly interesting findings was that when our more adherent surgeons strayed from the protocol, further chart

review showed that the opioids were prescribed by a resident not familiar with the protocol. Before the protocol started, it was discussed in the Breast Surgery Department's monthly conference call and in an email to all attending surgeons in the department. Because residents participate in nearly all our cases, this study reminded us that we also need to discuss protocol changes with all stakeholders, including residents. Since our study analysis, we are working to publicize the policy during resident teaching sessions, and we are trying to verbally reinforce the protocol on operative days. Further steps might include creating a discharge order set specifically for ambulatory breast surgery. Another potential step might be to create a pop-up reminder in the electronic health record when opioids are prescribed after ambulatory breast surgery, which requires the prescriber to enter an explanation why opioids are being prescribed.

Our study is limited by a small sample size. Because of the size of our cohort, our study was not powered for statistical significance with our complication rates between the 2 groups (opioids vs no opioids). However, the complication rates in both groups were very low (1.6% in the nonopioid group and 1.9% in the opioid group), and there were no readmissions in either group. Our sample size also limited our analysis of patients with long-term opioid use. Although we found it did not influence prescribing practices, we were unable to determine whether chronic pain or long-term opioid use influenced protocol failure. Other studies have not included patients with chronic pain,<sup>6</sup> and we believe it would be important to include these patients in future larger, prospective studies.

## CONCLUSION

Our study results show that surgeons hold the most influence over the postoperative pain regimen and can likely help reduce the opioid epidemic by eliminating or reducing opioid prescriptions after ambulatory surgery. Protocols may be a way to do this safely without increased harm to the patient. We anticipate future studies with analysis of our protocol effectiveness, particularly as we expand and refine the protocol with respect to evidence and practitioner autonomy. ❖

## Disclosure Statement

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

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Variable	No opioids (n = 127)	Opioids (n = 53)	p value <sup>a</sup>
<b>Age, y</b>			
< 30	3	1	0.346
30-39	2	1	
40-49	13	5	
50-59	34	13	
60-69	41	17	
70-79	27	14	
≥ 80	7	2	
<b>Race/ethnicity</b>			
Asian/Pacific Islander	17	6	0.583
Black/African American	24	10	
Hispanic/Latin American	7	5	
Other/unknown	9	2	
White/Caucasian	70	30	
<b>History of opioid Rx for chronic pain</b>			
Yes	5	2	0.877
No	122	51	
<b>Surgery</b>			
Lumpectomy only	39	14	0.237
Lumpectomy + SLN	55	31	
Lumpectomy + SLN + IORT	33	8	
<b>Surgeon</b>			
1	7	8	NA
2	18	26	
3	0	8	
4	0	3	
5	9	4	
6	80	1	
7	13	3	

<sup>a</sup> p values reflect the logistic model with surgeon as a random effect. IORT = intraoperative radiation therapy; NA = not applicable; Rx = prescription; SLN = sentinel lymph node biopsy.



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## Rest and Pain

Pain the monitor, and Rest the cure, are starting points for contemplation which should ever be present to the mind of the surgeon in reference to his treatment.

— John Hilton, FRCS, FRS, FZS, 1805-1878, British surgeon

# Cocaine Positivity in ST-Elevation Myocardial Infarction: A True or False Association

Ikechukwu Ifedili, MD<sup>1</sup>; Tamunoinemi Bob-Manuel, MD<sup>1</sup>; Siri R Kadire, MD<sup>1</sup>; Britteny Heard, MD<sup>1</sup>; Leah A John, MD<sup>1</sup>; Benjamin Zambetti, MD<sup>1</sup>; Mark R Heckle, MD<sup>1</sup>; Fridtjof Thomas, MD<sup>1</sup>; Showkat Haji, MD<sup>1</sup>; Rami N Khouzam, MD<sup>1</sup>; Guy L Reed, MD<sup>1</sup>; Uzoma N Ibebuogu, MD<sup>1</sup>

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## ABSTRACT

**Introduction:** Every year, more than 500,000 US Emergency Department visits are associated with cocaine use. People who use cocaine tend to have a lower incidence of true ST-elevation myocardial infarction (STEMI).

**Objective:** To identify the factors associated with true STEMI in patients with cocaine-positive (CPos) findings.

**Methods:** We retrospectively analyzed 1144 consecutive patients with STEMI between 2008 and 2013. True STEMI was defined as having a culprit lesion on coronary angiogram. Multivariate and univariate analyses were used to identify risk factors and create a predictive model.

**Results:** A total of 64 patients with suspected STEMI were CPos (mean age  $53.1 \pm 11.2$  years; male = 80%). True STEMI was diagnosed in 34 patients. Patients with CPos true STEMI were more likely to be uninsured than those with false STEMI (61.8% vs 34.5%,  $p = 0.03$ ) and have higher peak troponin levels (21.1 ng/mL vs 2.12 ng/mL,  $p < 0.01$ ) with no difference in mean age between the 2 groups ( $p = 0.24$ ). In multivariate analyses, independent predictors of true STEMI in patients with CPos findings included age older than 65 years (odds ratio [OR] = 19.3, 95% confidence interval [CI] = 1.2-318.3), lack of health insurance (OR = 4.9, 95% CI = 1.2-19.6), and troponin level higher than 0.05 (OR = 24.0, 95% CI = 2.6-216.8) (all  $p < 0.05$ ). A multivariate risk score created with a C-statistic of 82% (95% CI = 71-93) significantly improved the identification of patients with true STEMI.

**Conclusion:** Among those with suspected STEMI, patients with CPos findings had a higher incidence of false STEMI. Older age, lack of health insurance, and troponin levels outside of defined limits were associated with true STEMI in this group.

between patients and physicians, leading to optimal care and avoiding complications associated with unnecessary and invasive coronary angiography. The aims of this study were to identify the frequency and factors associated with true STEMI in patients with CPos findings who present with suspected STEMI and to create a predictive model to help classify those who may be more likely to experience a true positive STEMI.

## METHODS

We performed a retrospective analysis of 1144 consecutive patients with STEMI as diagnosed in our Emergency Department or an outside referring facility on presentation to the Methodist University Hospital between January 2008 and December 2013. Methodist University Hospital, a large tertiary hospital in downtown Memphis, TN, is the largest primary percutaneous coronary intervention site in the region and receives transfers from numerous outlying facilities. Institutional review board approval was obtained with an informed consent requirement waived. Coronary angiogram results in the cardiac catheterization laboratory were retrieved and analyzed. A positive urine drug screen result determined CPos. True STEMI was defined as having a culprit lesion as detected on coronary angiogram, whereas a false STEMI was defined as an absence of partial or total thrombotic coronary occlusion and/or reduced thrombolysis in myocardial infarction grade flow. Information on patient demographics, risk factors, history, initial vital signs, laboratory data, presenting ECG findings, symptom onset time, procedure times, cardiac catheterization findings, and outcomes were collected. Data were deidentified, extracted by medical residents and research assistants, and verified

## INTRODUCTION

Among the 250,000 patients who arrive at US Emergency Departments each year with ST-elevation myocardial infarction (STEMI), a subpopulation will test positive for cocaine use.<sup>1</sup> The diagnosis of true STEMI in the setting of cocaine positivity can be a challenge because more than 500,000 US Emergency Department visits each year are related to symptoms and complications associated with cocaine use and, in particular, cardiovascular symptoms,<sup>2</sup> which usually necessitate an electrocardiogram

(ECG). A new ECG ST-segment elevation finding in a patient with cardiovascular symptoms, especially chest pain and worsening shortness of breath, usually triggers cardiac catheterization laboratory activation in adherence with current guidelines.<sup>3</sup> However, false activation of the cardiac catheterization laboratory when treating the general population may be as high as 36%.<sup>4</sup> A US prospective observational study revealed a false STEMI rate of 11%,<sup>5</sup> and this value may be higher in the cocaine-use setting considering the prevalence of a true myocardial infarction is 0.7% to 6.0% for chest pain presentations.<sup>2</sup> False findings may occur because various mechanisms can cause chest pain symptoms and cardiovascular complications.<sup>6</sup> A better understanding of the predictors of true STEMI in the cocaine-positive (CPos) population would enable better-informed decisions

### Author Affiliations

<sup>1</sup> University of Tennessee Health Science Center College of Medicine, Memphis, TN

### Corresponding Author

Uzoma N Ibebuogu, MD (uibebugo@uthsc.edu)

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by cardiology fellows and staff cardiologists. Statistical analysis was performed with SPSS version 24 (IBM Corporation, Armonk, NY). A univariate comparison of baseline characteristics was performed using the  $\chi^2$  test. Descriptive measures used were percentages for categorical variables and means  $\pm$  standard deviation for continuous variables. The incidence of false-positive STEMI was calculated as the percentage of all patients diagnosed with STEMI at presentation without a culprit lesion on coronary angiography. We conducted a comparative analysis between patients without (false-positive) and with a culprit lesion as previously described by Nfor et al,<sup>5</sup> and identified risk factors

associated with a true STEMI in patients with CPos findings using the stepwise multivariate logistic regression and created a predictive model using logistic regression coefficients.

## RESULTS

Patients with CPos findings were much younger (age 53.1 vs 59.2 years) and were more likely to be African American, have false STEMI, be uninsured, and have a history that included tobacco and alcohol use; however, these patients on average had fewer coronary artery disease risk factors than patients with negative cocaine findings (Table 1). There was no significant difference in average admission and peak

troponin levels. Among patients who had true STEMI (Table 2), those with CPos findings were younger (age 54.6 vs 58.9 years,  $p = 0.05$ ), more likely to be African American and uninsured and have histories including tobacco and alcohol use. They also were less likely to have multivessel disease on coronary angiography. Table 3 illustrates the differences in patient groups with true vs false STEMI who were CPos (64 patients with CPos findings were identified). One patient who was transferred from an outside facility had symptoms suggesting neurologic problems and did not undergo cardiac catheterization. Among 63 patients with CPos findings who underwent cardiac catheterization, 34 had confirmed (true) STEMI. When compared with CPos patients with false STEMI, those with true STEMI were much more likely to be uninsured, had relatively higher peak troponin levels, and had a lower left ventricle ejection fraction (43.1 vs 54.8,  $p < 0.01$ ). They also required interventions to address coronary lesions in addition to medical management.

Using a stepwise multivariate analysis to eliminate interactions between confounding variables, significant independent predictors of true STEMI in cocaine positivity included age older than 65 years (odds ratio [OR] = 19.3, 95% confidence interval [CI] = 1.2-318.3), self-pay (uninsured) status (OR = 4.9, 95% = CI 1.2-19.6), and troponin level higher than 0.05 (OR = 24.0, 95% CI = 2.6-216.8; Table 4). A multivariate risk score was created using a formula for a population with relatively few events as seen in Pavlou et al<sup>6</sup> and the area under the curve as shown in Figure 1 with a C-statistic of 82% (95% CI = 71-93).

## DISCUSSION

Cardiac catheterization is an invasive procedure associated with known complications.<sup>7</sup> Risk for adverse events remains even as procedure-related complications decline because of better devices, methods, and operator skill. The goal is to maintain a healthy balance between avoiding unnecessary invasive procedures and providing appropriate procedures for patients with true STEMI. Other causes of ST-elevation as determined

**Table 1. Study group baseline characteristics**

Variable	Positive for cocaine use (n = 64) <sup>a</sup>	Negative for cocaine use (n = 1069) <sup>a</sup>	p value $\chi^2$
Age (SD)	53.1 (11.2)	59.2 (12.9)	< 0.01
Sex (men)	51 (79.7)	712 (66.6)	0.03
Length of stay in days (SD)	3.64 (3.9)	4.65 (5.96)	0.18
Death in hospital	1 (1.6)	78 (7.3)	0.12
Race			< 0.01
African American	59 (92.2)	585 (55.0)	
White	5 (7.8)	460 (43.3)	
Married	18 (28.1)	426 (39.5)	0.08
Self-pay (uninsured)	31 (48.4)	221 (20.7)	< 0.01
Diabetes mellitus	12 (19.0)	330 (31.2)	0.04
Hypertension	40 (63.5)	727 (68.6)	0.4
Hyperlipidemia	16 (25.4)	385 (36.4)	0.08
Prior myocardial infarction	12 (19.0)	280 (26.4)	0.19
Family history of CAD	17 (27.0)	424 (41.1)	0.03
CHF	3 (4.8)	100 (9.4)	0.27
CKD	2 (3.2)	61 (5.8)	0.39
ESRD	1 (1.6)	35 (3.3)	0.72
Smoking	55 (87.3)	574 (54.6)	< 0.01
Alcohol use	32 (50.8)	248 (23.6)	< 0.01
Chest pain	59 (92.2)	898 (83.1)	0.06
Hypotension	5 (8.1)	73 (7.1)	0.77
True STEMI	34 (54.0)	721 (70.2)	0.01
IABP	5 (8.2)	121 (11.7)	0.54
Vascular complications	1 (1.6)	24 (2.4)	0.71
Transvenous pacer	1 (1.6)	52 (5.1)	0.36
Ejection fraction by angiography	48.6 (12.7)	46.3 (13.0)	0.24
LVEDP	22.1 (7.6)	23.0 (12.5)	0.56
Admission troponin level	1.84 (5.7)	4.75 (13.8)	0.11
Peak troponin level	12.51 (24.9)	14.36 (25.08)	0.59

<sup>a</sup> Responses are no. (%) unless otherwise indicated.

CAD = coronary artery disease; CHF = congestive heart failure; CKD = chronic kidney disease; ESRD = end-stage renal disease; IABP = intra-aortic balloon pump; LVEDP = left ventricular end-diastolic pressure; SD = standard deviation; STEMI = ST-elevation myocardial infarction.

**Table 2. Demographic differences associated with cocaine positivity in patients with true ST-elevation myocardial infarction**

Variable	Positive for cocaine (n = 34) <sup>a</sup>	Negative for cocaine use (n = 719) <sup>a</sup>	p value $\chi^2$
Age (SD)	54.6 (11.5)	58.9 (12.2)	0.05
Sex (men)	28 (82.4)	494 (68.5)	0.09
Length of stay in days (SD)	4.7 (4.0)	4.8 (5.7)	0.99
Death in hospital	1 (2.9)	35 (4.9)	1
Race			< 0.01
African American	30 (88.2)	370 (51.6)	
White	4 (11.8)	337 (47.0)	
Married	9 (26.5)	282 (39.5)	0.15
Self-pay (uninsured)	21 (61.8)	160 (22.2)	< 0.01
Diabetes mellitus	6 (17.6)	226 (31.4)	0.09
Hypertension	22 (64.7)	478 (66.5)	0.83
Hyperlipidemia	10 (29.4)	268 (37.3)	0.35
Prior myocardial infarction	6 (17.6)	199 (27.7)	0.2
Family history of CAD	12 (35.3)	312 (44.3)	0.3
CHF	2 (5.9)	40 (5.6)	0.71
CKD	0	33 (4.6)	0.39
ESRD	0	13 (1.8)	1
Smoking	31 (91.2)	407 (57.2)	< 0.01
Alcohol use	17 (50.0)	166 (23.3)	< 0.01
Chest pain	32 (94.1)	636 (88.2)	0.29
Hypotension	3 (9.1)	49 (6.8)	0.62
Transferred	11 (32.4)	306 (42.4)	0.24
IABP	3 (9.1)	101 (14.0)	0.72
Intubation	4 (12.1)	57 (8.0)	0.394
CABG	3 (9.1)	70 (9.8)	0.89
Medical management	1 (3.0)	34 (4.8)	0.64
Troponin level at admission (SD)	2.70 (7.2)	5.65 (15.3)	0.29
Troponin level at peak (SD)	21.2 (30.9)	18.43 (27.6)	0.59
HGb (SD)	13.5 (2.2)	13.6 (2.0)	0.91
RDW (SD)	14.9 (2.7)	14.4 (2.4)	0.19
Creatinine level (SD)	1.23 (0.4)	1.24 (1.1)	0.95
LV ejection fraction by ECHO, % (SD)	42.9 (13.6)	45.2 (11.9)	0.4
LV ejection fraction by angiography, % (SD)	43.1 (11.8)	45.4 (11.9)	0.33
LVEDP (SD)	23.2 (7.6)	24.3 (12.7)	0.64
Multivessel disease	16 (47.1)	494 (68.8)	0.01
LBBB	0 (0.0)	24 (3.3)	0.28
ECG pattern			
Anterior	18 (52.9)	249 (34.5)	0.03
Inferior	11 (32.4)	294 (40.8)	0.33
Lateral	1 (2.9)	42 (5.8)	0.48
Culprit lesion			
LAD	18 (52.9)	313 (43.4)	0.27
RCA	13 (38.2)	271 (37.6)	0.94
LCX	2 (5.9)	89 (12.3)	0.26

<sup>a</sup> Responses are no. (%) unless otherwise indicated.

CABG = coronary artery bypass graft; CAD = coronary artery disease; CHF = congestive heart failure; CKD = chronic kidney disease; ECG = electrocardiogram; ECHO = echocardiography; ESRD = end-stage renal disease; HGb = hemoglobin; IABP = intra-aortic balloon pump; LAD = left anterior descending; LBBB = left bundle branch block; LCX = left circumflex; LV = left ventricle; LVEDP = left ventricular end-diastolic pressure; RCA = right coronary artery; RDW = red blood cell distribution width; SD = standard deviation.

on ECG are not associated with myocardial infarction, such as disease processes that necessitate therapy attributable to benign causes such as a normal variant (especially in men) and early repolarization.<sup>8</sup> These factors are present when cardiovascular symptoms arise from potential cocaine use. Patients who test positive for cocaine use usually are men and typically are younger than those with negative cocaine use findings. The benign conditions causing ECG ST-elevation cannot be easily identified if previous ECG results are not available for comparison; this scenario can lead to an unnecessary invasive procedure, especially when patients are admitted to the hospital.<sup>9</sup> Cocaine-associated myocardial infarction usually occurs within 24 hours of cocaine use,<sup>10</sup> so use of a urine test to confirm cocaine positivity might implicate many people for whom cocaine use is not the direct cause of myocardial infarction. Because the benefits of cardiac catheterization usually outweigh the risks, most patients opt to undergo the procedure; however, for the subgroup that is inclined to refuse any invasive procedure, use of a predictive model showing an increased possibility for having true STEMI may serve to encourage them to undergo coronary angiography with possible intervention.

Our study shows that an uninsured patient with positive cocaine and troponin findings who is older than age 65 years is more likely to have a true STEMI. Each factor individually increases the probability of true STEMI, and a combination of these factors further increases the likelihood. We believe that uninsured patients might be sicker at baseline because of poor primary care follow-up, or they may present only when they have symptoms that cannot be managed without a visit to a medical facility. Patients older than age 65 years and those with positive troponin results are more likely to experience an acute coronary event. The prevalence of true STEMI in this population was 70.2% and 54% in the CPos subgroup. Published data from other centers revealed a higher true STEMI rate.<sup>11,12</sup> This finding might be explained because our facility is a large regional center to which patients are referred for cardiac catheterization,

which leads to an increased likelihood of intervention even while ruling out other factors. Our institutional policy that ensures we intervene within the recommended door-to-balloon time and risk-benefit analysis of complications vs death resulting from nonintervention also influence these findings.

A limitation of this study is that use of a urine drug screen as a yardstick for

CPOs does not account for the possibility that cocaine use may have occurred up to 5 days before presentation, which limits our interpretation of this factor as the main cardiovascular complication trigger and false STEMI in our population. CPOs was 5.6%; this prevalence may be unique, which would limit generalization. The risk score must be validated with a different population.

## CONCLUSION

In patients with suspected STEMI, cocaine positivity leads to a higher incidence of false STEMI. A better risk prediction tool is needed to provide a more educated informed consent process before cardiac catheterization. The combination of age older than 65 years, lack of health insurance, and troponin levels outside of defined limits was associated with true STEMI for our patients. ❖

**Table 3. Demographic and medical variables associated with true and false ST-elevation myocardial infarction among patients with positive cocaine findings**

Variable	True STEMI (n = 34) <sup>a</sup>	False STEMI (n = 29) <sup>a</sup>	p value $\chi^2$
Age (SD)	54.6 (11.5)	51.3 (10.8)	0.24
Sex (men)	28 (82.4)	22 (75.9)	0.53
Length of stay in days (SD)	4.7 (4.0)	3.1 (3.6)	0.13
Death in hospital	1 (2.9)	0	1
Race			0.36
African American	30 (88.2)	28 (96.6)	
White	4 (11.8)	1 (3.4)	
Married	9 (26.5)	9 (31.0)	0.78
Self-pay (uninsured)	21 (61.8)	10 (34.5)	0.03
Diabetes mellitus	6 (17.6)	6 (21.4)	0.71
Hypertension	22 (64.7)	18 (64.3)	0.97
Hyperlipidemia	10 (29.4)	6 (21.4)	0.48
Prior myocardial infarction	6 (17.6)	6 (21.4)	0.76
Family history of CAD	12 (35.3)	5 (17.9)	0.16
CHF	2 (5.9)	1 (3.6)	1
CKD	0	2 (7.1)	0.2
ESRD	0	1 (3.6)	0.45
Smoking	31 (91.2)	23 (82.1)	0.29
Alcohol use	17 (50.0)	14 (50.0)	1
Chest pain	32 (94.1)	27 (93.1)	0.87
Hypotension	3 (9.1)	2 (6.9)	1
Transferred	11 (32.4)	8 (27.6)	0.68
IABP	3 (9.1)	2 (7.1)	1
Intubation	4 (12.1)	1 (3.4)	0.36
CABG	3 (9.1)	3 (10.3)	1
Medical management	1 (3.0)	21 (72.4)	< 0.01
Troponin at admission (SD)	2.70 (7.2)	0.89 (3.1)	0.24
Troponin at peak (SD)	21.2 (30.9)	2.12 (5.8)	< 0.01
Hemoglobin (SD)	13.5 (2.2)	13.1 (2.0)	0.47
RDW (SD)	14.9 (2.7)	14.8 (2.3)	0.83
Creatinine level (SD)	1.23 (0.4)	1.82 (2.9)	0.24
LV ejection fraction by ECHO % (SD)	42.9 (13.6)	46.9 (11.1)	0.43
LV ejection fraction by angiography % (SD)	43.1 (11.8)	54.8 (10.9)	< 0.01
LVEDP (SD)	23.2 (7.6)	20.8 (7.6)	0.24

<sup>a</sup> Responses are no. (%) unless otherwise indicated.

CABG = coronary artery bypass graft; CAD = coronary artery disease; CHF = congestive heart failure; CKD = chronic kidney disease; DM = diabetes mellitus; ECHO = echocardiogram; ESRD = end-stage renal disease; IABP = intra-aortic balloon pump; LV = left ventricle; LVEDP = left ventricular end-diastolic pressure; RDW = red blood cell distribution width; SD = standard deviation.

## Disclosure Statement

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**Table 4. Multivariate analysis of troponin level and insurance status**

Significant variables	b (variable)	Exp(b) (95% confidence interval)	Significance
Age > 65 y	2.958	19.261 (1.166-318.261)	0.039
Troponin level > 0.05	3.178	23.959 (2.648-216.804)	0.005
Uninsured	1.595	4.929 (1.240-19.596)	0.024
Constant	-3.375	0.034	0.004

Exp(b) = odds ratio for predictors.

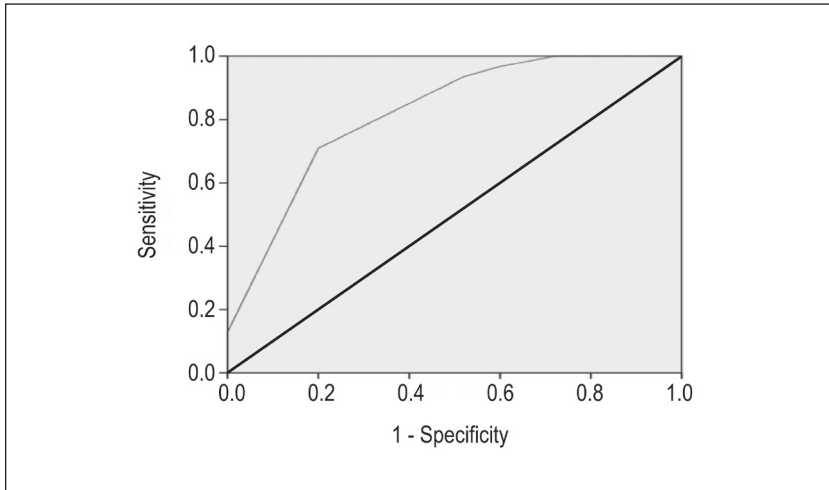


Figure 1. Receiver operating characteristics (ROC) curve showing a C-statistic of 82% (95% confidence interval = 71-93) for true ST-elevation myocardial infarction prediction when factoring in older than age 65 years, lack of health insurance, and troponin value higher than 0.05.

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## Daily Encounters

The method ... which proceeds by means of reason admonishes us to study the nature of the body which one tries to heal and the forces of all the causes which the body encounters daily.

For it is as a result of these that it becomes healthier or sicker than it was before.

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

## ORIGINAL RESEARCH &amp; CONTRIBUTIONS

# Clinical Response to Real-Time Patient-Reported Diabetic Peripheral Neuropathy Symptoms

Somalee Banerjee, MD, MPH<sup>1</sup>; Eileen Kim, MD<sup>2</sup>; Melissa M Parker, MS<sup>3</sup>;  
Lisa K Gilliam, MD, PhD<sup>4,5</sup>; Rick Dlott, MD<sup>6,7</sup>; Alyce Adams, PhD<sup>3</sup>

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## ABSTRACT

**Introduction:** To assess clinician response to real-time patient-reported data about diabetic peripheral neuropathy (DPN) symptoms, we analyzed DPN diagnosis and treatment patterns after administration of a 4-question symptom questionnaire in a large vertically integrated health care system.

**Methods:** Retrospective cohort study to analyze data from 160,852 patients screened for DPN symptoms from April 2012 to March 2014. Electronic medical record data were used to study changes in DPN diagnosis, treatment initiation, and treatment intensification. We used logistic regression to study the association of patient characteristics with the odds of clinical response.

**Results:** Of patients queried, 50,684 (31.5%) reported symptoms. Patients reporting DPN symptoms experienced a greater increase in new DPN diagnoses (16 percentage points;  $p < 0.0001$ ) and medication use (4 percentage points;  $p < 0.0001$ ) compared with those denying symptoms. Among patients reporting symptoms, women and nonwhite patients were less likely to receive a DPN diagnosis, whereas older patients were more likely to receive a DPN diagnosis. Overall, patients who were older, were Asian (hazard ratio = 0.67, 95% confidence interval = 0.63-0.77), and had lower socioeconomic status (hazard ratio = 0.89, 95% confidence interval = 0.80-0.99) were less likely to be treated. However, these racial and socioeconomic differences were not statistically significant for patients with preexisting DPN diagnoses.

**Conclusion:** Patients' real-time reports of DPN symptoms were associated with increased clinical activity. Patient- and clinician-level factors associated with the likelihood of receiving a DPN diagnosis need further study because a formal diagnosis may be associated with more equitable treatment.

## INTRODUCTION

Diabetic peripheral neuropathy (DPN) is the most common complication of both type 1 and type 2 diabetes and affects about 50% of people with longstanding disease.<sup>1</sup> This condition costs the US an estimated \$4 billion to \$15 billion annually in health care costs and lost productivity. The negative impact of DPN on the health care system is likely to increase as the diabetes epidemic grows.<sup>2</sup> The devastating impact of DPN on the quality of life of individual patients with painful and uncomfortable symptoms (eg, pain, tingling, burning sensation, electric shock feeling) is well documented.<sup>1</sup>

Yet, DPN is often underrecognized and undertreated in primary care settings.<sup>3,4</sup> The gold standard for diagnosing DPN, according to the Toronto DPN Expert Group, should be nerve conduction studies; diagnosing DPN by signs and symptoms is not specific or sensitive enough for a definitive diagnosis.<sup>5</sup> However, this labor-intensive

and expensive method is difficult to implement on a large scale. Thus, tools such as patient questionnaires about symptoms have been developed as less intensive methods of identifying patients with possible DPN or related conditions in real time during clinic visits.<sup>6-12</sup>

Little is known about how clinicians respond to the availability of these data in real time, particularly when they are employed on a systemwide scale. In 2012, a brief symptom questionnaire was integrated into the electronic medical record (EMR) in a large integrated health care system to identify uncontrolled symptoms associated with diabetes. This symptom questionnaire was implemented as part of a systemwide effort to improve screening for complications associated with longstanding diabetes to improve care for these complications.

The purpose of this study was to assess the impact of reporting DPN symptoms (eg, pain or paresthesias in the feet) on

subsequent DPN diagnosis and treatment. We hypothesized that the integration into the EMR of patients' self-reported data on their DPN symptoms would be associated with an intensification of DPN recognition and management. Among those patients with symptoms, we further explored individual patient factors associated with the timing of new diagnoses, treatment initiation, and treatment titration.

## METHODS

### Study Design

A retrospective cohort study was conducted to assess implementation of the symptom questionnaire among 234,903 adult patients with diabetes within Kaiser Permanente Northern California (KPNC). KPNC is an integrated, prepaid multispecialty health care system consisting of a hospital system, physician group, and health insurance plan serving more than 4 million members. All clinical data were derived from the EMR of the KPNC medical system.

### Study Population

The study population included patients who were diagnosed with diabetes and identified in the KPNC Diabetes Registry from April 2012 to March 2014 and who were older than age 18 years as of January 2, 2012. Although the type of diabetes is not available in the registry, we estimate that more than 95% of these patients have type 2

### Author Affiliations

<sup>1</sup> Hospitalist-Based Specialty Department, Oakland Medical Center, Oakland, CA

<sup>2</sup> Internal Medicine Department, Oakland Medical Center, Oakland, CA

<sup>3</sup> Division of Research, Oakland, CA

<sup>4</sup> Endocrinology Department, South San Francisco Medical Center, CA

<sup>5</sup> Kaiser Permanente Northern California Regional Diabetes Team, Oakland, CA

<sup>6</sup> Endocrinology Department, Walnut Creek Medical Center, CA

<sup>7</sup> Population Care, Kaiser Permanente Northern California Region, Oakland, CA

### Corresponding Author

Alyce Adams, PhD ([alyce.s.adams@kp.org](mailto:alyce.s.adams@kp.org))

Keywords: diabetes, patient-reported symptoms, peripheral neuropathy, screening, symptom

diabetes in accordance with national prevalence estimates.<sup>13</sup> According to data from the EMR in 2012 to 2014, we excluded patients who had any inpatient or outpatient diagnosis of substance abuse (International Classification of Diseases, Ninth Revision [ICD-9] codes 305.0, 305.2, 305.3, 305.4, 305.5, 305.6, 305.7, 305.8, 305.9, 291, 292, 303, or 304), gestational diabetes (ICD-9 code 648.8), dementia (ICD-9 codes 290.0, 290.1, 290.4, or 331.0), or hospice/palliative care (ICD-9 code V66.7) because these factors may have led to changes in care that were clinically appropriate but not necessarily consistent with guidelines. We further excluded patients who were not enrolled in the medical system for a full 12 months before and after their first screening from the pre-post analyses (described in “Statistical Analysis”) and multivariate models to ensure adequate data capture.

### Comparison Groups

The DPN symptom questionnaire was developed in response to a need to improve the diagnosis and treatment of DPN. It was available in the EMR at KPNC facilities

in April 2012 after medical assistants were trained to use the questionnaire. Medical assistants were instructed to administer the symptom questionnaire to all patients with diabetes while measuring vital signs at the beginning of routine primary care visits. The patient reports were entered into the EMR for the physician to view, and a paper copy was handed to the physician before his/her patient contact. The questionnaire included 4 questions with simple yes or no answers inquiring about symmetrical foot pain and paresthesias to assess DPN symptoms, as well as calf pain, foot sores, and erectile dysfunction, which are also sequelae of poorly controlled diabetes. A questionnaire was flagged in the EMR if any of the questions was answered affirmatively. Previous studies of much longer, validated symptom questionnaires such as the Michigan Neuropathy Screening Instrument have shown high specificity for questions regarding foot pain and paresthesias (92.7%–98.2%), but low sensitivity for DPN (25%–37.6%).<sup>12</sup>

Because one of the primary outcomes of this study was to assess treatment response for neuropathic pain, we focused

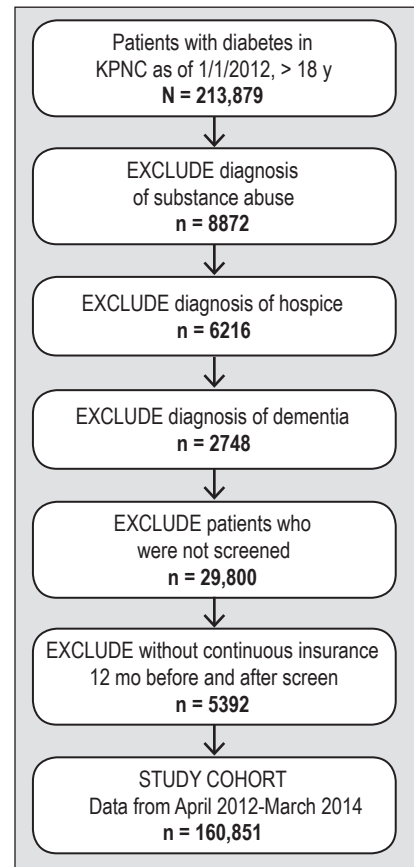


Figure 1. Study design with inclusion and exclusion criteria.

KPNC = Kaiser Permanente Northern California.

on the question assessing neuropathic pain symptoms by taking an affirmative response to the question about the presence of foot numbness, pain, and paresthesias as a “positive” screen. For the main analyses, described in “Statistical Analysis,” we compared changes in health services use before and after the first observed DPN screen for patients who screened “positive” (presence of DPN symptoms) or “negative” (absence of DPN symptoms) for DPN symptoms.

### Outcome Measures

The primary outcomes for this study were 1) clinical documentation of DPN, defined as at least 1 inpatient or 2 outpatient diagnoses for peripheral neuropathy (ICD-9 codes 356.0, 356.9, or 357.2); 2) a new active prescription for at least 1 medication commonly used to treat DPN symptoms at the point of the screening visit or afterward (amitriptyline, nortriptyline, imipramine, desipramine, duloxetine,

### Nondiabetic Neuropathy Diagnoses<sup>a</sup>

265.x Thiamine and niacin deficiency states  
 266.0–266.9 Deficiency of B-complex components  
 277.1 Disorders of porphyrin metabolism  
 277.3 Amyloidosis  
 281.0 Pernicious anemia  
 281.1 Other vitamin B12 deficiency anemia  
 355.1 Meralgia paresthetica  
 355.5 Tarsal tunnel syndrome  
 356.4 Idiopathic progressive polyneuropathy  
 357 Inflammatory and toxic neuropathy  
 357.1 Polyneuropathy in collagen vascular disease  
 357.3 Polyneuropathy in malignant disease  
 357.4 Polyneuropathy in other diseases classified elsewhere  
 357.5 Alcoholic polyneuropathy  
 357.6 Polyneuropathy due to drugs  
 357.7 Polyneuropathy due to other toxic agents  
 357.8x Inflammatory and toxic neuropathy—Other  
 357.9 Inflammatory and toxic neuropathy—Unspecified  
 446.x Polyarteritis nodosa and allied conditions  
 714 Rheumatoid arthritis and other inflammatory polyarthropathies  
 723.0 Spinal stenosis in cervical region  
 724.00 Spinal stenosis in unspecified region  
 724.01 Spinal stenosis in thoracic region  
 724.02 Spinal stenosis, lumbar region, without neurogenic claudication  
 724.03 Spinal stenosis, lumbar region, with neurogenic claudication  
 724.09 Spinal stenosis of other region  
 724.3 Sciatica  
 443.9 Peripheral vascular disease unspecified  
 443.89 Other peripheral vascular disease  
 302.72 Psychogenic dysfunction with inhibited sexual excitement

<sup>a</sup> Diagnostic codes are from International Classification of Diseases, Ninth Revision.



paroxetine, citalopram, pregabalin, venlafaxine, or gabapentin<sup>14</sup>; and 3) intensification of therapy (minimum increase in the daily dose was 10 mg, except for pregabalin and gabapentin for which the minimum dose increase was 25 mg and 100 mg, respectively). For the pre-post analysis (described in “Statistical Analysis”), the DPN diagnosis and medication use were assessed during the 12 months before and after the first observed DPN screen. Treatment intensification was assessed during follow-up

among those with evidence of prior DPN medication use.

Secondary outcomes relating to diabetes management included diagnoses for related pain conditions (a full list of corresponding ICD-9 codes is available in the Sidebar: Nondiabetic Neuropathy Diagnoses); tests; referrals to an endocrinologist, neurologist, and podiatrist; and the mean number of DPN medications prescribed. Baseline characteristics included age, sex, race (black, white, Hispanic, Native American/Alaskan

Native, Pacific Islander/Native Hawaiian, Asian, multiracial), most recent hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>), previous opioid use, non-DPN neuropathy diagnoses, number of physician visits, and visits to the endocrinologist, podiatrist, and neurologist. We also categorized patients into quartiles of the neighborhood deprivation index, which is based on multiple domains of socioeconomic status derived from US Census tract data.<sup>15</sup>

### Statistical Analysis

Contingency tables ( $\chi^2$ ) and differences in means (Student *t*-test) were used to evaluate differences in baseline characteristics across screening status categories and in pre-post analyses comparing health services use before and after symptom reporting. Among the subset of patients reporting symptoms, Cox proportional hazards models were used to assess whether the baseline demographic and clinical characteristics and health services use were associated with the primary outcomes of interest. The index date for these models was the first positive screen. All analyses were performed using statistical software (SAS Version 9.3, SAS Institute, Cary, NC).<sup>16</sup>

## RESULTS

### Characteristics of Screened Population

We identified 196,043 patients who met our inclusion criteria. Of these, 160,851 patients (85%) completed the DPN screen and were equally distributed across the 43 health care facilities in the Northern California Region (Figure 1). Patients who completed the questionnaire in the EMR were similar to those who were not screened in terms of sex, race, and ethnicity. However, patients who did not complete the questionnaire were slightly younger on average (mean age [standard deviation] = 58 [14] years) and were likelier to live in more socioeconomically deprived neighborhoods (55% vs 50% living in less socioeconomically deprived neighborhoods). Of those screened, 50,684 (31.5%) had a positive screen for DPN (Table 1). More than 99% of the population screened had a primary care physician. Among those screened, white patients (n = 25,557; 35.5%) were most likely to have reported DPN symptoms, and Asians were least likely (8129, 24%) to have reported DPN symptoms. With increasing deprivation or poverty per

**Table 1. Baseline characteristics of analytic cohort (N = 160,851) stratified by screening status<sup>a</sup>**

Characteristic	Screen: Do you have tingling, numbness, burning, or pain in your feet? <sup>b</sup>	
	Yes, no. (%): 50,684 (31.5)	No, no. (%): 110,167 (68.5)
Age as of January 1, 2012, mean (SD), y	64.0 (12.0)	61.8 (13.3)
Opioid use in last 90 days	10,426 (42.0)	14,383 (58.0)
Sex		
Women	25,929 (33.3)	51,890 (66.7)
Men	24,755 (29.8)	58,277 (70.2)
Race/ethnicity <sup>c</sup>		
American Indian/Alaska Native	360 (34.5)	684 (65.5)
Asian	8129 (24.0)	25,735 (76.0)
Black	5090 (31.8)	10,934 (68.2)
Hispanic	8276 (29.8)	19,478 (70.2)
Native Hawaiian/Pacific Islander	422 (28.2)	1076 (71.8)
White	25,557 (35.5)	46,444 (64.5)
Multiple race	2358 (34.8)	4414 (65.2)
Most recent HbA <sub>1c</sub> before screen		
< 7% (53 mmol/mol)	18,900 (30.1)	43,948 (69.9)
7%-9% (53-75 mmol/mol)	21,473 (32.2)	45,176 (67.8)
> 9% (75 mmol/mol)	7060 (35.4)	12,870 (64.6)
Neighborhood deprivation index <sup>c</sup>		
First quartile: Least deprived	10,151 (29.7)	24,010 (70.3)
Second quartile	14,141 (31.2)	31,195 (68.8)
Third quartile	14,777 (32.0)	31,377 (68.0)
Fourth quartile: Most deprived	10,880 (33.0)	22,065 (67.0)
Related complications <sup>c</sup>		
Do you have skin sores or open wounds on your feet?		
Yes	5194 (63.2)	3024 (36.8)
No	45,242 (29.8)	106,855 (70.3)
Do you get pain in your calves when you walk?		
Yes	17,783 (60.2)	11,736 (39.8)
No	32,521 (25.0)	97,723 (75.0)
Have you ever had problems with erections due to your diabetes?		
Yes	10,122 (42.5)	13,715 (57.5)
No	8371 (22.4)	29,162 (77.7)

<sup>a</sup> p value < 0.0001 between all groups for all characteristics using the  $\chi^2$  test.

<sup>b</sup> Noted percentage of the patients within each strata of characteristics presented.

<sup>c</sup> Some patients with data unavailable for specified characteristic.

HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>; SD = standard deviation.

Census tract data, there was a small but significant increase in the proportion of positive screens from 10,151 patients (29.7%) of the first quartile of poverty to 10,880 patients (33.0%) of the fourth quartile (most deprived;  $p < 0.0001$ ). Patients with positive screens were more likely to report foot sores ( $n = 5194, 63.2\%$ ) compared with those with a negative screen ( $n = 30,124; 36.8\%$ ;  $p < 0.0001$ ).

**Changes in Health Services Use**

Among patients with a positive screen, the proportion of patients with a DPN diagnosis increased from 30% at baseline to 45% after the screening ( $p < 0.05$ ), whereas those with a negative screen saw an increase in DPN diagnoses of only 10% at baseline to 14% after screening ( $p < 0.05$ ; difference in change after screen between groups = 11 %;  $p < 0.05$ ; Table 2, Figure 2). In the subset of patients without a previous diagnosis, new DPN diagnoses were documented in 22% of patients with a positive screen compared with only 5% in those with a negative screen (difference in change between groups of 16.1%;  $p < 0.05$ ; Figure 2). The proportion using any DPN

medications increased by 8.2 percentage points after a positive screen compared with only 4.2 percentage points after a negative screen (difference in change after screen between groups = 4%;  $p < 0.05$ ; Table 3).

Table 2 shows other changes in health services use stratified by screening status, including diagnoses for nondiabetic neuropathy conditions (difference in change between groups after screen = 9.8%,  $p < 0.05$ ), neurology referrals (difference in change between groups in change after screen = 0.4%,  $p < 0.05$ ), and podiatry referrals (difference in change between groups in change after screen = 2.7%,  $p < 0.05$ ). There was no significant difference in the change in HbA<sub>1c</sub> testing rates by positive vs negative screening status; however, greater than 90% of the population was already receiving HbA<sub>1c</sub> testing.

**Characteristics Associated with a DPN Diagnosis**

The results of the Cox proportional hazards models estimating the likelihood of diagnosis, treatment initiation, and treatment intensification among those with a positive screen are shown in Table 4. Greater than 99% of all the clinical activity occurred

on the day of the screening or soon after the screening. Thus, the predicted odds of clinical activity can be assumed to be the average odds of clinical activity during the year after each screening.<sup>16</sup> Older patients were more likely to receive a DPN diagnosis (45-64 years: hazard ration [HR] = 1.45, 95% confidence interval [CI] = 1.30-1.62; 65-74 years: HR = 1.79, 95% CI = 1.60-2.00; 75 years and older: HR = 1.69, 95% CI = 1.50-1.90). Also more likely to receive a DPN diagnosis were patients with elevated baseline HbA<sub>1c</sub> (7%-9%: HR = 1.24, 95% CI = 1.19-1.31, > 9%: HR = 1.67, 95% CI = 1.56-1.78) and evidence of prior opioid use (HR = 1.18, 95% CI = 1.11-1.25).

Conversely, nonwhite patients were less likely to receive a DPN diagnosis: Black (HR = 0.88, 95% CI = 0.81-0.95), Hispanic (HR = 0.77, 95% CI = 0.72-0.82), Native American (HR = 0.74, 95% CI = 0.55-0.99), Pacific Islander (HR = 0.66, 95% CI = 0.51-0.86), Asian (HR = 0.59, 95% CI = 0.55-0.63), and mixed race (HR = 0.80, 95% CI = 0.72-0.90). In addition, patients with a greater number of primary care physician (PCP) visits were less likely to receive a DPN diagnosis (4-6 visits: HR = 0.86, 95%

Parameter	Positive screen for DPN, no. (%): 50,684 (31.5)		Negative screen for DPN, no. (%): 110,167 (68.5)		p value <sup>a</sup>
	12 mo before	12 mo after	12 mo before	12 mo after	
Number of primary care visits, mean (SD)	5.3 (6.5)	7.5 (7.1)	4.1 (5.4)	6.2 (6.2)	< 0.0001
<b>DPN diagnosis</b>					
Yes	15,080 (29.7)	22,749 (44.9)	10,712 (9.7)	15,630 (14.2)	< 0.0001
No	35,604 (70.3)	27,935 (55.1)	99,455 (90.3)	94,537 (85.8)	
<b>Diagnosis of conditions with similar pain<sup>b</sup></b>					
Yes	16,568 (32.7)	24,396 (48.1)	14,300 (13.0)	20,450 (18.6)	< 0.0001
No	34,116 (67.3)	26,288 (51.9)	95,867 (87.0)	89,717 (81.4)	
<b>HbA<sub>1c</sub> test</b>					
Yes	47,433 (93.6)	48,199 (95.1)	101,996 (92.6)	103,490 (93.9)	0.39
No	3251 (6.4)	2485 (4.9)	8171 (7.4)	6677 (6.1)	
<b>Referral to specialist</b>					
Endocrinologist	995 (2)	1414 (2.8)	1805 (1.6)	2529 (2.3)	0.12
Neurologist	1428 (2.8)	2222 (4.4)	1974 (1.8)	3340 (3.0)	0.01
Podiatrist	3341 (6.6)	5675 (11.2)	4084 (3.7)	6146 (5.6)	< 0.0001
<b>Any DPN drug use</b>					
Yes	9953 (19.6)	14,090 (27.8)	9058 (8.2)	13,637 (12.4)	< 0.0001
No	40,731 (80.4)	36,594 (72.2)	101,109 (91.8)	96,530 (87.6)	

<sup>a</sup> p value from the Cochran Mantel-Haenszel statistic, which tests if the postbaseline measures are equivalent between the positive and negative screen groups, after adjusting for prebaseline measures.

<sup>b</sup> International Classification of Diseases, Ninth Revision, codes for diagnoses with similar symptoms: 265, 266.0-266.9, 277.1, 277.3, 281.0, 281.1, 355.1, 355.5, 356.4, 357, 357.1, 357.3, 357.4, 357.5, 357.6, 357.7, 357.8, 357.9, 446.x, 714, 723.0, 724.00, 724.01, 724.02, 724.03, 724.09, 724.3, 443.9, 443.89.

HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>; SD = standard deviation.

**Table 3. New diagnosis and related drug use relative to baseline over 12 months after screening**

Parameter	Positive screen, no. (%): 50,684 (31.5)	Negative screen, no. (%): 110,167 (68.5)	p value <sup>a</sup>
New treatment started in patients without previous treatment	4137 (10.2)	4579 (4.5)	< 0.0001
New DPN diagnosis (no previous DPN diagnosis)			
Yes	7669 (21.5)	4918 (4.9)	< 0.0001
No	27,935 (78.5)	94,537 (95.1)	
Number of DPN drugs prescribed in patients without previous treatment <sup>b</sup>			
Mean (SD)	0.12 (0.37)	0.14 (0.41)	< 0.0001
Minimum-maximum	0-5	0-5	
Any treatment intensification in patients			
Yes	2293 (23.0)	1660 (18.3)	< 0.0001
No	7660 (77.0)	7398 (81.7)	

<sup>a</sup> p value from the  $\chi^2$  statistic.  
<sup>b</sup> DPN treatment medications are amitriptyline, nortriptyline, imipramine, desipramine, duloxetine, paroxetine, citalopram, pregabalin, venlafaxine, or gabapentin.  
 DPN = diabetic peripheral neuropathy; SD = standard deviation.

CI = 0.81-0.91; 7 or more visits: HR = 0.87, 95% CI = 0.82-0.92).

**Characteristics Associated with Treatment Initiation**

Controlling for clinical and demographic factors, patients more likely to receive treatment after a positive DPN screen were women (HR = 1.33, 95% CI = 1.25-1.42), had an elevated HbA<sub>1c</sub> of greater than 9% (HR = 1.22, 95% CI = 1.11-1.35), reported opioid use (HR = 1.69, 95% CI = 1.57-1.82), had a diagnosis with similar symptoms (HR = 1.35, 95% CI = 1.25-1.45), saw a neurologist (HR = 1.21, 95% CI = 1.01-1.46), and had a higher number of PCP visits (4-6 visits: HR = 1.20, 95% CI = 1.10-1.30; 7 or more visits: HR = 1.32, 95% CI = 1.22-1.43). However, patients of Asian race (HR = 0.67, 95% CI = 0.63-0.77) and those who lived in the least economically deprived neighborhoods (HR = 0.89, 95% CI = 0.80-0.99) were less likely to have treatment initiation after a positive screen.

**Characteristics Associated with Treatment Intensification**

Older patients were less likely to have treatment intensification: Specifically, those between ages 65 and 74 years (HR = 0.66, 95% CI = 0.52-0.83) and age older than 75 years (HR = 0.66, 95% CI = 0.52-0.83). Conversely, patients who were more likely to have treatment intensification after a

positive screen were those with baseline opioid use (HR = 1.26, 95% CI = 1.15-1.37), other diagnoses with similar pain (HR = 1.26, 95% CI = 1.14-1.38), and any visit to a podiatrist (HR = 1.22, 95% CI = 1.07-1.39).

**Treatment Change in Patients with Previous DPN Diagnoses**

Subanalyses performed with the previously described Cox proportional hazards models in patients with a previous DPN diagnosis at the time of screening are presented in Table 5. As in the larger population, patients with prior opioid use (initiation: HR = 1.48, 95% CI = 1.31-1.67; intensification: HR = 1.24, 95% CI: 1.11-1.39) and increased number of PCP visits (> 7 visits: initiation: HR = 1.31, 95% CI = 1.14-1.50; intensification: HR = 1.40, 95% CI = 1.22-1.61) were more likely to have treatment initiation and intensification, respectively. However, among those who received a DPN diagnosis at the time of screening, older age, race, and socioeconomic status were not significantly associated with increased likelihood of new treatment or treatment intensification as it had in the larger population of patients who reported foot pain and paresthesias.

**DISCUSSION**

Among adults with diabetes, reporting DPN symptoms was associated with an increase in the intensity of DPN-related

health care services use. Consistent with our hypothesis, there was an increase in the proportion of patients who received a DPN diagnosis. A positive screen was also associated with an increase in diagnoses for nondiabetic neuropathies. Rates of implementation of the survey were very high throughout the health system. This was likely aided by the integration of this short questionnaire into the EHR workflow of the medical assistants, which simplified its administration. However, the rates of treatment and referrals remained variable. This apparent lack of response may be owing to clinician concerns about the accuracy of the

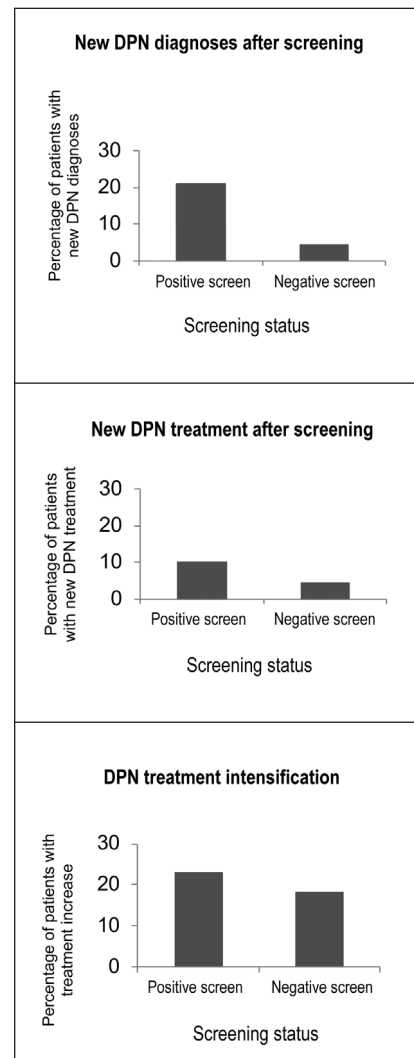


Figure 2. Intensification of DPN management by screening status among diabetic patients screened for DPN symptoms.  
 DPN = diabetic peripheral neuropathy.

screen or the limited efficacy and adverse effects of available DPN treatments. In addition, since our screen question included both numbness and pain, treatment may not have been useful if the patient reported only numbness because the medications would not be effective. The lack of difference in HbA<sub>1c</sub> testing rates between populations with a negative and a positive screen may reflect the already high testing rates. Interestingly, a higher number of primary care visits at baseline was associated with a decreased likelihood of new diagnoses, which may reflect underrecording of DPN diagnoses among patients with complex, competing health care needs. Patients with nondiabetic neuropathy diagnoses

were more likely to have treatment initiation and intensification. This increase in clinical activity could be due to increased reporting of pain from conditions such as sciatica that are frequently more acute and self-limiting. Of note, neurologists may be more comfortable with starting patients on pain medication regimens compared with PCPs. However, intensification of preexisting pain medication regimens may not differ by specialty.

Our findings may, in part, reflect system-level factors that drive clinician response. For example, clinical practice guidelines at KPNC do not recommend nerve conduction studies because results do not change clinical management and could thus contribute

to the low numbers of neurology referrals. Several clinical and demographic factors were associated with an increased likelihood of diagnosis and treatment, including opioid use, age, sex, race/ethnicity, and neighborhood deprivation index. Prior opioid use was associated with increased clinical activity throughout all the subgroup analyses, and this could be because of opioid use acting as an indicator of symptom severity warranting more clinical response or clinical complexity. Older patients were more likely to receive a diagnosis of DPN, but less likely to receive treatment intensification in response to a positive screen. This could reflect physician concerns regarding increased adverse drug events caused by DPN medications.<sup>17-19</sup>

**Table 4. Results of Cox proportional hazards models predicting patient characteristics associated with clinical response among patients with a positive screen over 12 months after screening<sup>a</sup>**

Characteristic (reference)	Likelihood of diagnosis (n = 35,604)		Likelihood of new treatment (n = 40,731)		Likelihood of treatment intensification (n = 9953)	
	Hazard ratio	95% CI	Hazard ratio	95% CI	Hazard ratio	95% CI
Age, y (reference < 45 y)						
45-64	1.45	<b>1.30-1.62</b>	1.13	0.97-1.30	0.84	0.68-1.04
65-74	<b>1.79</b>	<b>1.60-2.00</b>	0.97	0.83-1.14	<b>0.63</b>	<b>0.50-0.78</b>
≥ 75	<b>1.69</b>	<b>1.50-1.90</b>	0.96	0.81-1.13	<b>0.66</b>	<b>0.52-0.83</b>
Sex						
Female (male)	<b>0.88</b>	<b>0.84-0.92</b>	<b>1.33</b>	<b>1.25-1.42</b>	1.05	0.96-1.14
Race (white)						
Black	<b>0.88</b>	<b>0.81-0.95</b>	0.95	0.85-1.06	1.00	0.86-1.16
Hispanic	<b>0.77</b>	0.72-0.82	1.04	0.95-1.14	0.97	0.85-1.10
Native American	<b>0.74</b>	<b>0.55-0.99</b>	0.94	0.64-1.37	1.04	0.68-1.58
Pacific Islander	<b>0.66</b>	<b>0.51-0.86</b>	1.19	0.88-1.63	0.59	0.28-1.24
Asian	<b>0.59</b>	<b>0.55-0.63</b>	<b>0.67</b>	<b>0.63-0.77</b>	0.92	0.77-1.09
Mixed	<b>0.80</b>	<b>0.72-0.90</b>	1.05	0.91-1.22	0.96	0.80-1.15
Neighborhood deprivation index (fourth quartile)						
First quartile (least deprived)	1.03	0.96-1.10	<b>0.89</b>	<b>0.80-0.99</b>	1.00	0.88-1.15
Second quartile	0.10	0.94-1.06	0.96	0.88-1.06	0.97	0.86-1.09
Third quartile	1.01	0.95-1.08	0.97	0.89-1.06	0.96	0.98-1.24
HbA <sub>1c</sub> (< 7% [53 mmol/mol])						
7%-9% (53-75 mmol/mol)	1.24	1.19-1.31	1.05	0.98-1.13	0.93	0.85-1.02
> 9% (75 mmol/mol)	1.67	1.56-1.78	1.22	1.11-1.35	1.05	0.92-1.19
Visits to primary care physician at baseline (< 4)						
4-6	<b>0.86</b>	<b>0.81-0.91</b>	<b>1.20</b>	<b>1.10-1.30</b>	1.10	0.98-1.24
7 or more	<b>0.87</b>	<b>0.82-0.92</b>	<b>1.32</b>	<b>1.22-1.43</b>	1.38	1.24-1.53
Any visit to specialist						
Endocrinologist	1.10	0.92-1.30	0.95	0.75-1.19	1.02	0.81-1.27
Neurologist	0.93	0.78-1.10	<b>1.21</b>	<b>1.01-1.46</b>	1.04	0.88-1.24
Podiatrist	0.95	0.85-1.07	1.11	0.99-1.25	<b>1.22</b>	<b>1.07-1.39</b>
Other						
Opioid use	<b>1.18</b>	<b>1.11-1.25</b>	<b>1.69</b>	<b>1.57-1.82</b>	<b>1.26</b>	<b>1.15-1.37</b>
Nondiabetic neuropathy diagnosis	0.95	0.86-1.03	<b>1.35</b>	<b>1.25-1.45</b>	<b>1.26</b>	<b>1.14-1.38</b>

<sup>a</sup> Bold values denote statistical significance at p value < 0.05. CI = confidence interval; HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>.

**Table 5. Results of Cox proportional hazards models predicting physician 12-month follow-up to patient reports of diabetic peripheral neuropathy (DPN) symptoms in subset of patients with positive screen and previous DPN diagnosis before screen<sup>a</sup>**

Characteristic (reference)	Time to prescription		Time to prescription intensification	
	Hazard Ratio	95% CI	Hazard Ratio	95% CI
Age, y (reference < 45 y)				
45-64	1.03	0.72, 1.49	0.94	0.68, 1.30
65-74	0.98	0.68, 1.42	0.72	0.52, 1.01
75+	0.96	0.66, 1.40	0.78	0.56, 1.09
Sex				
Female (male)	<b>1.27</b>	<b>1.13, 1.42</b>	1.11	0.99, 1.24
Race (white)				
Black	0.87	0.71, 1.05	0.95	0.78, 1.15
Hispanic	1.13	0.96, 1.33	1.08	0.91, 1.27
Native American	1.06	0.57, 1.99	0.87	0.50, 1.51
Pacific Islander	1.62	0.89, 2.95	0.80	0.33, 1.94
Asian	0.84	0.69, 1.02	1.08	0.87, 1.34
Mixed	1.20	0.95, 1.51	1.07	0.86, 1.33
Neighborhood deprivation index (fourth quartile)				
First quartile (least deprived)	0.85	0.72, 1.02	1.02	0.85, 1.21
Second quartile	<b>0.82</b>	<b>0.70, 0.97</b>	0.97	0.83, 1.14
Third quartile	0.92	0.79, 1.07	0.90	0.77, 1.05
HbA <sub>1c</sub> [ $<7\%$ (53 mmol/mol)]				
7-9% (53-75 mmol/mol)	1.04	0.91, 1.18	0.99	0.88, 1.12
$>9\%$ (75 mmol/mol)	1.15	0.96, 1.36	1.05	0.89, 1.25
Visits to primary care physician at baseline				
4-6	<b>1.23</b>	<b>1.06, 1.43</b>	1.08	0.92, 1.27
7 or more	<b>1.31</b>	<b>1.14, 1.50</b>	<b>1.40</b>	<b>1.22, 1.61</b>
Any visit to specialist				
Endocrinologist	1.11	0.82, 1.52	1.12	0.87, 1.45
Neurologist	1.06	0.82, 1.38	1.08	0.89, 1.32
Podiatrist	<b>1.26</b>	<b>1.08, 1.48</b>	<b>1.24</b>	<b>1.08, 1.44</b>
Other				
Opioid use	<b>1.48</b>	<b>1.31, 1.67</b>	<b>1.24</b>	<b>1.11, 1.39</b>
Nondiabetes neuropathy diagnosis	1.13	0.88, 1.46	0.98	0.77, 1.24

<sup>a</sup> Bold values denote statistical significance at  $p$  value  $< 0.05$ . CI = confidence interval; HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>.

Variation by race/ethnicity and sex are not well understood. Asian patients were less likely to receive a DPN diagnosis. However, as suggested by subanalysis of the group of patients with DPN diagnoses, the rates of treatment were equal among the races after receiving a DPN diagnosis. The lack of racial variation in treatment after a positive symptom screen overall suggests that the cause of foot pain in the nonwhite population may point to a non-DPN diagnosis that we did not capture. It is unclear if variation in diagnosis is caused by differences in reporting of symptoms by race/

ethnicity, sex, and socioeconomic status or prevalence of DPN in these populations as described in prior studies.<sup>20</sup>

There are several limitations to this study that warrant discussion. First, this study was conducted in a single health care system and may not reflect general practice in a noncapitated system. However, prior research<sup>21,22</sup> showing undertreatment of DPN in primary care settings and the diversity of our population suggest that our findings may, in fact, be generalizable. In addition, the screen implemented in this setting has not been previously validated and may be

less accurate than other previously validated instruments.<sup>10-12</sup> Furthermore, there is limited incentive for clinicians to record DPN diagnoses in the EMR in this capitated care system that has vertical integration between clinicians and the insurer. Also, even though a variety of ICD-9 codes were used to assess for a DPN diagnosis, it is possible that other ICD-9 codes are used in clinical practice in these various clinics because of differences in practice styles that may not have been included. In addition, we examined indicators of clinician response contained in coded fields and did not include other indications such as physical examinations and communication with patients about symptoms.

Because the intervention was limited to an in-person visit, patients who did not have in-office visits, such as virtual visits, were not privy to the intervention. In addition, there is limited incentive to code DPN in the inpatient setting during acute care episodes. Therefore, it is likely that we have underestimated the number of diagnoses. This study centered around an intervention in the primary care setting, so we did not capture all possible health system interactions such as direct podiatry visits without referral that may have happened outside the primary care visit. However, we did endeavor to capture all actions generated by PCPs, as this was the focus of the screener intervention. In addition, despite our efforts to exclude some subsets of patients from analysis on the basis of the comorbidity, the rates of treatment may not reflect appropriate care for all included patients. We may have overestimated the rates of treatment given that medications used to treat DPN are also used to treat a number of other conditions (eg, depression, seizure disorders).<sup>1</sup> Conversely, we did not count prescriptions that were already prescribed for another condition. Also, because our screening question included both pain and numbness, the change in treatment strategies could be limited because numbness is not treated with the medications we included as part of this study. This study was limited to the first screening of each patient, and further study could be focused on changes in clinical activity after multiple symptom screenings over time.

As mentioned earlier, the proportional hazards assumption for the regression model

used in this study was not met because most of the clinical activity occurred during the screening visit itself. However, because the time-related interactions were not very strong, suppressing these interactions would not lead to additional bias in the model.

Strengths of this analysis included our ability to link patient-reported symptoms with rich electronic health data. To our knowledge, this is one of a few studies that have been able to rigorously assess changes in DPN management in response to patient reports of symptoms.

## CONCLUSION

We found that a single question assessing DPN symptoms from a 4-question screen for diabetic complications was associated with increased rates of DPN diagnoses in the EMR. However, significant changes in treatment and general DPN management were slower to emerge and may have been related to physician concerns about the efficacy and tolerability of treatment, particularly among older patients, and system-level factors related to low use of monofilament testing. Future studies might assess whether interventions combining a brief screener with monofilament testing among patients at highest risk of adverse events might have greater impact on clinical practice. However, such effort would need to consider notable variation in diagnosis rates by race/ethnicity and sex that may reflect differences in patient presentation or clinician interpretation of symptoms. It is interesting to note that, in this health system, the likelihood of treatment after a DPN diagnosis did not vary with race, age, and socioeconomic status. Although this tool was useful for capturing patient-reported information about DPN symptoms in real time, additional decision aids may be required to overcome diagnostic and treatment challenges to ensure that timely treatment occurs. A simple 1-question screen for symptoms can be a triage tool for intensification of clinical services for patients with DPN. ❖

## Disclosure Statement

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

## Author Contributions

Melissa M Parker, MS, contributed to the data collection and statistical analyses and reviewed and edited the manuscript. Somalee Banerjee, MD, MPH, and Alyce Adams, PhD, wrote the manuscript and edited and interpreted the data. Alyce Adams,

PhD, also provided the funding and data. Eileen Kim, MD; Rick Dlott, MD; and Lisa K Gilliam, MD, PhD, reviewed and edited the manuscript.

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**On Keyboards**  
watercolor painting

**Quentin Eichbaum, MD, PhD, MPH, MFA, MMCH, FASCP, FCAP**

Dr Eichbaum reports: "This abstract expressionist watercolor was inspired by the dexterity of musicians in 'Music City' (Nashville, TN). The musician's head is seen behind a complex array of colored keyboards played by his outstretched arms. Medically, the image can also be seen as a metaphor of the physician struggling to keep pace with the 'keyboard' demands of medical data and the electronic medical record."

Dr Eichbaum is a Professor of Pathology, Microbiology, and Immunology at Vanderbilt University Medical Center and a Professor of Medical Education at Vanderbilt University School of Medicine in Nashville, TN. He was born and raised in Africa (Namibia), where the vast, timeless landscapes were at once harshly real and abstract in their sweeping shapes, lines, and colors. This instilled in him a lasting love for watercolor as the medium that could best capture the translucent subtlety of these landscapes and their abstractions. He has studied watercolor with numerous prominent watercolorists in the US and abroad. His works have been sold and exhibited in the US, Europe, and Africa. As a physician, he finds watercolor (a "temperamental medium") a way of surrendering and re-centering himself, and a way of "paying attention" to the world.

More of his work can be seen on page 46.

# Salvage Cryoablation for Radiorecurrent Prostate Cancer: Initial Experience at a Regional Health Care System

Seena Safavy, MD<sup>1</sup>; Ramzi B Jabaji, MD<sup>1</sup>; Sharon M Lu, MD<sup>1</sup>; Jeff M Slezak, PhD<sup>2</sup>; Harry A Cosmatos, MD<sup>3</sup>; Stephen G Williams, MD<sup>4</sup>; David S Finley, MD<sup>1</sup>

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## ABSTRACT

**Context:** Local recurrence after radiotherapy for prostate cancer remains challenging to treat effectively. Although oncologic control is highest with salvage prostatectomy, the procedure is associated with substantial morbidity.

**Objective:** To identify factors associated with successful salvage cryoablation for radio-recurrent prostate cancer.

**Design:** We retrospectively reviewed the medical records of patients who underwent salvage cryoablation at our institution between 2005 and 2015. All patients had biopsy-proven local recurrence after radiotherapy. Patients with seminal vesicle invasion or metastases were excluded. Complete follow-up was obtained for all patients.

**Main Outcome Measures:** Primary study endpoint was biochemical progression-free survival based on the Phoenix criteria.

**Results:** Seventy-five patients underwent salvage cryotherapy. Mean patient age was 69.3 years. The overall biochemical salvage rate was 50.7% at a median follow-up of 3.9 years. The following factors were independently associated with successful cryotherapy: Precryotherapy Gleason score of 3 + 3 or 3 + 4, low precryotherapy prostate-specific antigen (PSA), low precryotherapy PSA density, longer time to PSA nadir after radiotherapy, and low postcryotherapy PSA nadir. A postcryotherapy PSA nadir of 0.5 ng/mL or less was associated with a biochemical progression-free survival of 79.7% at 3 years and 64.7% at 5 years, whereas a postcryotherapy PSA nadir above 0.5 was associated with a biochemical progression-free survival of 5.6% at 3 years and 0% at 5 years ( $p < 0.0001$ ).

**Conclusion:** Approximately 50% of the patients achieved biochemical salvage with cryoablation at 5 years. Nadir PSA after salvage was the strongest predictor of biochemical progression-free survival in our cohort.

value above the nadir level with 3 consecutive increases, or a PSA increase of 2 points above the nadir in the absence of 3 consecutive increases.

Metastatic disease was ruled out with computed tomography or magnetic resonance imaging and bone scan. Patients with metastatic disease, a negative prostate biopsy, or biopsy-proven seminal vesicle invasion were excluded from treatment. All procedures were performed at 2 centers by fellowship-trained urologic oncologists. Double freeze-thaw cycles were performed using Galil (Galil Medical, Arden Hills, MN) or Endocare (Cryocare CS, Endocare/Healthtronics Inc, Austin, TX) cryotherapy systems according to the principles previously described by Finley et al.<sup>10</sup> The following variables were culled and analyzed: 1) patient demographics; 2) RT data, including modality (EBRT or brachytherapy), pre-RT PSA, pre-RT biopsy Gleason score and D'Amico risk group, use of ADT, post-RT PSA nadir, time to post-RT PSA nadir; and 3) precryotherapy data, including PSA, PSA doubling time (PSA-DT), precryotherapy Gleason score and D'Amico risk group, prostate volume, ADT use, postcryotherapy PSA nadir, time to postcryotherapy PSA nadir, and time to PSA failure. Statistical analysis was performed using statistical software (SAS/STAT Version 9.2, SAS Institute, Cary, NC).

The primary study endpoint was biochemical progression-free survival (biochemical PFS), based on the Phoenix criteria (PSA nadir + 2). The secondary endpoints included functional outcomes and complications, development of metastases, initiation of hormone therapy, and death. Multivariate analysis with the Kaplan-Meier method and receiver operating curve analysis were used.

## INTRODUCTION

Local recurrence after radiotherapy for prostate cancer remains a challenge to treat effectively. Although oncologic control is highest with salvage prostatectomy, the procedure is associated with substantial morbidity.<sup>1-5</sup> By comparison, both cryoablation and high-intensity focused ultrasonography are options that offer the patient a chance of salvage and that minimize collateral damage.<sup>6-9</sup> In our health care system,

complete follow-up data on this patient cohort were obtained, including use of androgen deprivation therapy (ADT) and serum testosterone levels. Herein, we present our series of cryoablation in the setting of radiorecurrent prostate cancer focusing on factors associated with treatment success.

## METHODS

All patients who underwent salvage cryoablation between October 2005 and July 2015 in our regional health care system were retrospectively reviewed after obtaining institutional review board approval. All patients had biopsy-proven local recurrence after external beam radiotherapy (EBRT) or brachytherapy. Biopsies are typically performed at least 18 to 24 months after radiation therapy (RT). Indications for biopsy included the following: An increase in the prostate-specific antigen (PSA)

### Author Affiliations

<sup>1</sup> Department of Urology, Los Angeles Medical Center, CA

<sup>2</sup> Department of Research & Evaluation, Pasadena, CA

<sup>3</sup> Department of Radiation Oncology, Los Angeles Medical Center, CA

<sup>4</sup> Department of Urology, Riverside Medical Center, CA

### Corresponding Author

Seena Safavy, MD ([seena.safavy@kp.org](mailto:seena.safavy@kp.org))

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**RESULTS**

Seventy-five patients underwent salvage cryotherapy; 70 received whole-gland cryoablation, and 5 underwent hemiablation. Mean patient age was 69.3 years (range = age 54.7–84.6 years). Mean prostate volume was 26.1 mL (range = 9.5–67.0 mL). Fifty-eight patients underwent EBRT, and 16 underwent brachytherapy. The RT modality data were missing for 1 patient (Table 1). The overall biochemical salvage rate was 50.7% (38/75 patients) at a median follow-up of 3.9 years (range = 0.1–9.5 years).

A precryotherapy PSA level of less than 4.0 ng/mL was associated with a 62.0% biochemical PFS at 5 years and 51.7% at 7 years, whereas a precryotherapy PSA level of 7 ng/mL or higher was associated with a 17.2% biochemical PFS at 5 years and a 0% biochemical PFS at 7 years ( $p = 0.033$ , Figure 1). The following factors were associated with successful cryotherapy (Table 2): A precryotherapy Gleason score of 3 + 3 or 3 + 4 ( $p = 0.040$ , Figure 2), precryotherapy PSA (5.1 ng/mL vs 6.9 ng/mL,  $p = 0.009$ ), precryotherapy PSA density ( $0.2 \text{ ng/mL}^2$  vs  $0.3 \text{ ng/mL}^2$ ,  $p = 0.012$ ), time to nadir after RT (25.6 months vs 15 months,  $p = 0.004$ ), and postcryotherapy PSA nadir ( $0.2 \text{ ng/mL}$  vs  $2.7 \text{ ng/mL}$ ,  $p < 0.0001$ ). The PSA-DT was not predictive of failure (20.1 months vs 21.3 months,  $p = 0.954$ ). A postcryotherapy PSA nadir of 0.5 ng/mL or less was

Characteristic	Salvage (n = 38)	Failure (n = 37)	Total (N = 75)	p value
<b>Age at cryotherapy, y</b>				
Mean (SD)	69.0 (6.60)	69.6 (5.34)	69.3 (5.98)	0.8821
Median	69.9	68.9	69.1	
Range	54.7–84.6	55.7–82.7	54.7–84.6	
<b>Prostate volume, mL</b>				
Mean (SD)	26.9 (10.43)	25.2 (10.35)	26.1 (10.35)	0.3790
Median	23.0	23.4	23.0	
Range	12.5–67.0	9.5–53.8	9.5–67.0	
<b>Type of RT, no. (%)</b>				
Brachytherapy	5 (13.2)	11 (29.7)	16 (21.3)	0.1889
EBRT	32 (84.2)	26 (70.3)	58 (77.3)	
Missing	1 (2.6)	0 (0)	1 (1.3)	
<b>RT with ADT, no. (%)</b>				
No	32 (84.2)	24 (64.9)	56 (74.7)	0.0541
Yes	6 (15.8)	13 (35.1)	19 (25.3)	
<b>D'Amico risk at time of cryotherapy, no. (%)</b>				
Missing	1 (2.6)	4 (10.8)	5 (6.7)	0.3725
High	6 (15.8)	10 (27.0)	16 (21.3)	
Intermediate	22 (57.9)	16 (43.2)	38 (50.7)	
Low	9 (23.7)	7 (18.9)	16 (21.3)	

ADT = androgen deprivation therapy; EBRT = external beam radiotherapy; RT = radiation therapy; SD = standard deviation.

associated with a biochemical PFS of 79.7% at 3 years, 64.7% at 5 years, and 50.2% at 7 years. A postcryotherapy PSA nadir above 0.5 was associated with a biochemical PFS of 5.6% at 3 years and 0% at 5 years (Figure 3). Postcryoablation mean time to biochemical failure was 22.9 months (range = 1.1 months – 74.7 months).

Hormone therapy use before and after cryotherapy was fully captured in all patients. Four patients underwent a single dose of leuprolide acetate (Lupron) as neoadjuvant hormone therapy before cryotherapy. All 4 of these patients had castrate levels of testosterone at the time of cryotherapy (range = 12 ng/dL – 33 ng/dL).

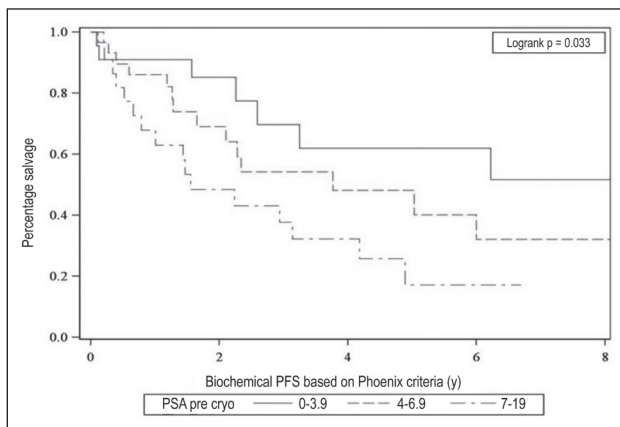


Figure 1. Association of precryotherapy (pre cryo) prostate-specific antigen (PSA) level (ng/mL) with biochemical progression-free survival (PFS), based on the Phoenix criteria (Phoenix\_years on x-axis). A PSA level below 4.0 ng/mL was associated with a 62.0% biochemical PFS at 5 years and 51.7% at 7 years, whereas a precryotherapy PSA level of 7 ng/mL or more was associated with a 17.2% biochemical PFS at 5 years and a 0% biochemical PFS at 7 years.

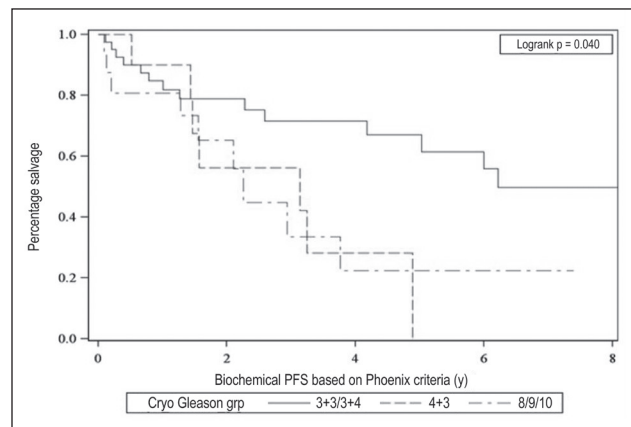


Figure 2. Association of precryotherapy Gleason score with biochemical progression-free survival (Phoenix\_years on x-axis). Gleason score of 3 + 3/3 + 4 was associated with a 67.0% survival at 5 years and a 49.7% survival at 7 years, whereas a Gleason score of 8/9/10 was associated with a 22.4% survival at both 5 and 7 years.

Of the 37 patients in whom cryotherapy failed, 23 subsequently required ADT during our follow-up period (62.2%). Metastases developed in 10 patients (13.3%, 10/75 patients), all of whom were alive at the last follow-up.

Complications included 2 rectal fistulas (2.7%), 5 urethral strictures (6.7%), 19 patients with stress urinary incontinence requiring at least 1 pad per day (25.3%), and 1 death caused by a pulmonary embolism (1.3%). Sixty-nine patients were alive at last follow-up (92%). Among the 6 patients who died, only 1 death was attributed to metastatic prostate cancer (1.3% of 75 patients).

**DISCUSSION**

Radiorecurrent prostate cancer continues to pose a therapeutic challenge to the urologist, requiring a high degree of precision to balance oncologic control with functional outcomes. In this study, we followed a small cohort of patients with robust clinical follow-up to determine their response to salvage therapy. Few studies to date have complete data on androgen deprivation use or serum testosterone levels tied to PSA outcomes. We identified multiple independent predictors of successful salvage after cryoablation consistent with the findings of several other groups.<sup>11,12</sup> Most notably, we found a nadir PSA of 0.5 ng/mL or less after cryotherapy to be a strong predictor of biochemical PFS. In a similar study, Kovac et al<sup>12</sup> demonstrated that the best objective indicator of biochemical PFS in the setting of salvage cryotherapy was a PSA nadir less than 0.4 ng/mL. However, their study did not provide data on metastasis-free and overall survival rates. In our study, we observed a 13% metastasis rate and a 92% overall survival rate. Results of the current study reinforce the notion that postcryotherapy PSA nadir is a significant endpoint that may be used to predict those patients who will ultimately experience cryotherapy failure and will require hormone therapy. Thus, those patients who fail to achieve this nadir value should be monitored more closely after undergoing cryotherapy. Indeed, this also serves as useful information when counseling patients after salvage cryotherapy.

As previously demonstrated, precryotherapy PSA is an important predictor

of successful salvage.<sup>13,14</sup> In our cohort, patients with a precryotherapy PSA below 4.0 ng/mL had a 62.0% biochemical PFS at 5 years and 51.7% biochemical PFS at 7 years. Those with a precryotherapy PSA level of 7 ng/mL or greater had only a 17.2% biochemical PFS at 5 years and a 0% biochemical PFS at 7 years. Similarly, Ng et al<sup>14</sup> reported that patients with a precryotherapy PSA below 4.0 ng/mL had a 5- and 8-year biochemical PFS of 56% and 37%, respectively. Those with a precryotherapy PSA above 9 had a 5- and 8-year biochemical PFS of 14% and 7%, respectively.<sup>14</sup> Thus, salvage cryoablation is most efficacious in patients who present with a low PSA at the time of initial

consultation. This information should be used to encourage radiation oncologists to refer patients early after they observe RT failure, regardless of the definition of failure they choose to follow (ie, American Society for Radiation Oncology, Phoenix, Stuttgart).

In addition to precryotherapy PSA and Gleason score, we found that time to nadir after RT was also a significant predictor of successful salvage cryotherapy (25.6 vs 15 months, *p* = 0.004). In a cohort of 228 men who underwent primary EBRT for T1-T3 prostate cancer, Aref et al<sup>15</sup> also demonstrated that a longer time to nadir after RT was associated with better rates of biochemical disease-free survival.

**Table 2. Factors associated with successful salvage**

Factor	Salvage (n = 38)	Failure (n = 37)	Total (N = 75)	p value <sup>a</sup>
<b>Precryotherapy Gleason score, no. (%)</b>				
Missing	0 (0)	7 (18.9)	7 (9.3)	0.040
3 + 3	9 (23.7)	9 (24.3)	18 (24.0)	
3 + 4	18 (47.4)	5 (13.5)	23 (30.7)	
3 + 5	2 (5.3)	0 (0)	2 (2.7)	
4 + 3	4 (10.5)	7 (18.9)	11 (14.7)	
4 + 4	3 (7.9)	2 (5.4)	5 (6.7)	
4 + 5	1 (2.6)	6 (16.2)	7 (9.3)	
5 + 5	1 (2.6)	1 (2.7)	2 (2.7)	
<b>Precryotherapy PSA, ng/mL</b>				
Mean (SD)	5.1 (2.93)	6.9 (3.65)	6.0 (3.41)	0.009
Median	4.5	6.4	5.5	
Range	0.9-13.7	0.5-18.9	0.5-18.9	
<b>Precryotherapy PSA density, ng/mL<sup>2</sup></b>				
Mean (SD)	0.2 (0.16)	0.3 (0.17)	0.3 (0.17)	0.012
Median	0.2	0.3	0.2	
Q1, Q3	0.1, 0.3	0.2, 0.4	0.1, 0.4	
Range	0-0.7	0-0.7	0-0.7	
<b>Precryotherapy PSA-DT, months</b>				
Mean (SD)	20.1 (13.86)	21.3 (17.07)	20.7 (15.38)	0.954
Median	14.4	16.5	16.3	
Q1, Q3	11.1, 28.2	9.7, 24.4	10.5, 28.2	
Range	(3.8-67.8)	(6.1-83.9)	(3.8-83.9)	
<b>Time to PSA nadir, months</b>				
Mean (SD)	25.6 (19.46)	15.0 (9.55)	20.1 (15.92)	0.004
Median	21.7	11.8	15.6	
Range	1.0-93.6	1.6-43.3	1.0-93.6	
<b>PSA value at postcryotherapy nadir, ng/mL</b>				
Mean (SD)	0.2 (0.19)	2.7 (3.97)	1.4 (3.05)	< 0.0001
Median	0.1	0.8	0.2	
Range	0-1.0	0.1-18.9	0-18.9	

<sup>a</sup> With the exception of precryotherapy PSA doubling time, all factors shown were associated with successful salvage in a statistically significant fashion.

PSA = prostate-specific antigen; PSA-DT = prostate-specific antigen doubling time; Q = quartile; SD = standard deviation.

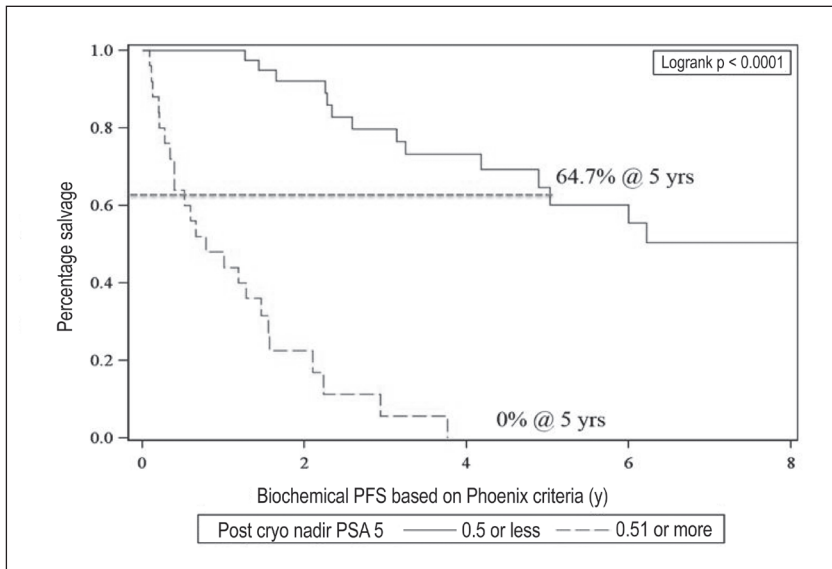


Figure 3. Association of postcryotherapy prostate-specific antigen (PSA) nadir (ng/mL) with biochemical progression-free survival, or PFS (Phoenix\_y on x-axis). A PSA nadir of 0.5 ng/mL or less was associated with a biochemical PFS of 79.7% at 3 years, 64.7% at 5 years, and 50.2% at 7 years. A postcryotherapy PSA nadir above 0.5 was associated with a biochemical PFS of 5.6% at 3 years and 0% at 5 years.

However, they examined this relationship only in the setting of RT and not salvage cryotherapy. The utility of this value in the setting of salvage cryotherapy has not previously been reported in the literature, to our knowledge. Again, we believe that this is very useful information for not only the urologist but also for the referring radiation oncologist when counseling patients who are considering salvage cryotherapy.

The PSA-DT has previously been shown to accurately predict biochemical failure after RT in both the primary and salvage settings.<sup>16,17</sup> Spiess et al<sup>18</sup> demonstrated that a presalvage cryotherapy PSA-DT of 16 months or less was associated with a higher risk of failure ( $p = 0.06$ ). In our cohort, however, PSA-DT was not predictive of failure on the basis of our statistical analyses. However, this is likely owing to the fact that both groups in our study had a relatively long mean PSA-DT (20.1 vs 21.3 months,  $p = 0.95$ ). Thus, no significant conclusions could be drawn from this information.

In a retrospective study consisting of 797 men treated with salvage cryotherapy, Spiess et al<sup>19</sup> reported a biochemical failure rate of 66% with a median follow-up of 3.4 years; biochemical failure was defined as a total serum PSA level above

0.5 ng/mL in this study. Pisters et al<sup>20</sup> reported a 5-year biochemical disease-free rate of 54.5% using the Phoenix definition. In our study, we report a comparable overall salvage rate of 50.7% at a median follow-up of 3.9 years using the Phoenix definition (range = 0.1–9.5 years).

Salvage cryotherapy is associated with inherent morbidity and complications caused by retraumatization of previously damaged tissue. Nevertheless, we believe that it is a relatively safe procedure if performed by a trained specialist. The most devastating complication, rectal fistula, occurred in 2 of our patients (2.7%). The occurrence of this complication is reportedly low in the literature, ranging from 0% to 3.4%.<sup>20–28</sup> In 19 of our patients, urinary incontinence developed after cryotherapy (25.3%), which was defined as needing 1 or more pads daily. A review of the literature indicates a wide range of occurrence of this complication, ranging anywhere from 4.3% to 95%.<sup>20,22–28</sup> Lastly, we had 1 death in our cohort as a result of a perioperative pulmonary embolism. Overall, our results indicate that salvage cryotherapy is an effective treatment option with a low morbidity and mortality rate.

We recognize that our study has several limitations. First and foremost, the

retrospective design of this study comes with its own innate biases. Additional limitations include our relatively short length of follow-up and small sample size. Furthermore, results from our single-institution study may not be generalizable to a greater patient population. We also recognize a lack of data regarding potency in our cohort. Nevertheless, our data were obtained from a fully captured medical record system in a single integrated health care system. Unlike much of the literature regarding cryotherapy that comes from the heterogeneous multi-institutional Cryo On-Line Data Registry, we feel that our data are more robust and consistent. It is important to note that data from the Cryo On-Line Data Registry are variable among different institutions and represent dissimilar operative techniques.<sup>12</sup> In contrast, our entire cohort came from a single health care system using standardized operative techniques. In our review of the relevant literature, we did find another retrospective single-institution study that demonstrated that presalvage PSA and presalvage Gleason score were the best predictors of early recurrence in the setting of salvage cryotherapy.<sup>29</sup>

## CONCLUSION

We identified several statistically significant predictors of success that can be used to guide both the urologist and radiation oncologist in counseling patients before and after salvage cryotherapy. Overall, 50% of the patients achieved biochemical salvage with cryoablation. Multiple independent predictors of success were identified, including low Gleason score, low precryotherapy PSA and PSA density, and longer time to PSA nadir after RT. Importantly, patients who achieved a postcryotherapy PSA nadir of 0.5 ng/mL or less had significantly improved biochemical PFS rates. Nadir PSA after salvage cryotherapy was the strongest predictor of biochemical PFS in our cohort. ♦

## Disclosure Statement

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

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**Little of a Satisfactory Nature**

A schirrhous prostate conveys ... a sense of gristly hardness, and is usually irregularly modulated  
 ... blood frequently escapes with the urine, pain and restlessness become more constant ...  
 Of the treatment, unfortunately, little of a satisfactory nature can be said.

— John Adams, 1806-1877, British surgeon

# Temporal Changes in Health Care Utilization among Participants of a Medically Supervised Weight Management Program

Ashok Krishnaswami, MD, MAS<sup>1</sup>; Stephen Sidney, MD, MPH<sup>2</sup>; Michael Sorel, MPH<sup>2</sup>; Wayne Smith, MD<sup>1</sup>; Rohini Ashok, MD<sup>1</sup>

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## ABSTRACT

**Context:** Obesity is associated with increased incidence of chronic diseases such as type 2 diabetes mellitus, systemic hypertension, and other risk factors for cardiovascular disease. Obesity is also associated with increased use of outpatient clinical services, a metric of health care utilization. However, little is known of temporal changes in health care utilization among obese participants of a medical weight management program.

**Objective:** To assess changes in 3 health care utilization metrics (primary care physician office visits, ambulatory clinic office visits, and health care touches [encounters]) in weight management program participants across 21 Kaiser Permanente Northern California Medical Centers during a 5-year period.

**Design:** Retrospective observational study of 10,693 participants, with a linear-mixed effects model to account for repeated-measures analysis.

**Main Outcome Measures:** Five-year temporal changes in the 3 health care metrics.

**Results:** At baseline, the participants' average age (standard deviation) was 51.1 (12.4) years, and their mean body mass index (standard deviation) was 39.7 (7.2) kg/m<sup>2</sup>. At the end of 4 months, there was a decrease in primary care visits ( $p < 0.001$ ), with an increase in ambulatory clinic visits and health care touches ( $p < 0.001$ ), because of increased weight management visits. At the end of 5 years, there was a 25% to 35% decrease from baseline in all 3 health care utilization metrics ( $p < 0.0001$ ). Although slightly attenuated, these findings were similar in a risk-adjusted model.

**Conclusion:** Our findings may be useful to other integrated health care delivery systems considering initiating a similar weight management program.

older) enrolled in the weight management program between April 1, 2007, and December 31, 2014, that focused on temporal changes in health care utilization during the 5-year period in program participants. The primary outcome for the current study was temporal changes in 3 health care utilization metrics during 5 years compared with baseline, measured up to 1 year before study entry. Specifically, changes in the number of *primary care physician visits* (defined as the number of clinic visits with a department code of Adult and Family Medicine, not a weight management visit), the number of *ambulatory clinic visits* (defined as the number of clinic visits that included subspecialty clinic visits as well as weight management visits), and the number of overall health care touches. *Health care touches* were defined as any of the following: Ambulatory clinic visits, Emergency Department visits, inpatient hospitalizations, inpatient admissions to nonacute care institutions, home health visits, admission to hospice, use of a laboratory facility (as noted by a visit for a blood draw), any Radiology Department visit for radiologic procedures, and telephone encounters. We specifically did not include the use of email encounters because it was beyond the scope of this project.

Statistical analysis was performed using a linear mixed-effects model with unstructured covariance, a random intercept, and a restricted maximum likelihood test option to assess the changes in health care use over the follow-up period, to account for the repeated-measures analysis. The full risk-adjusted model included baseline demographics (age, body mass index, race, median household income) and baseline

## INTRODUCTION

Obesity is associated with an increased incidence of chronic diseases such as type 2 diabetes mellitus, systemic hypertension, and other risk factors for cardiovascular disease. Furthermore, obese patients, compared with healthy-weight individuals, have an approximate 30% increase in outpatient clinical services,<sup>1</sup> a measure of health care utilization. However, health care utilization in obese patients has only recently become recognized as a possible surrogate marker of disability.<sup>2,3</sup> Because of the rising prevalence of obesity and a paucity of data of the effects of weight loss treatment on health care utilization,<sup>4</sup> we sought to study the temporal changes in 3 measures of health care utilization in obese participants of a medically supervised, behaviorally based, weight management program across 21 Kaiser Permanente Northern California (KPNC) Medical Centers.

## METHODS

The details of the program along with a description of the underlying cohort have been extensively described in a previous

article in *The Permanente Journal*.<sup>5</sup> In brief summary, our prior report documented the changes in weight and lipids and addressed predictors of weight loss of 5% or more from baseline at 5 years in 10,693 participants enrolled in a medically supervised weight management program in KPNC. The weight management program consists of 3 phases: A complete meal replacement up to 16 weeks, a transition to regular food between 17 and 29 weeks, and a long-term lifestyle phase between 30 and 82 weeks. We demonstrated that the absolute average weight change (in kilograms) at 5 years was significantly lower from baseline (-6.4 kg,  $p < 0.001$ ), with the accompanying average percentage change in weight also significantly lower from baseline (a decrease of 5.8%). Among participants with 5-year data, weight loss of less than 5.0% occurred in 48.5%, weight loss of 5.0% to 9.9% occurred in 16.3%, and weight loss of 10.0% and greater occurred in 35.2%. There were changes in lipids approximately paralleling the weight changes.

This report is a retrospective, observational study of all 10,693 adults (age 18 years and

## Author Affiliations

<sup>1</sup> San Jose Medical Center, CA

<sup>2</sup> Division of Research, Oakland, CA

## Corresponding Author

Ashok Krishnaswami, MD, MAS ([ashok.krishnaswami@kp.org](mailto:ashok.krishnaswami@kp.org))

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comorbidities (prediabetes, diabetes, hypertension, hyperlipidemia, liver disease, lung disease, myocardial infarction, coronary artery disease [that includes history of prior coronary artery bypass grafting, percutaneous coronary intervention], cerebrovascular accident, atrial fibrillation, sleep apnea, depression). All statistical analyses were performed using Stata Version 15 software (StataCorp, College Station, TX). The study was approved by the KPNC institutional review board.

**RESULTS**

The flow of participants in the study was as follows: Baseline (N = 10,693) and 1-year (N = 10,218), 2-year (N = 8601), 3-year (N = 7941), 4-year (N = 6042), and 5-year follow-up (N = 4261). Patients were included for analysis each year if they reached the first day of that year. At baseline, the average age (standard deviation) was 51.1 (12.4) years, and the mean body mass index (standard deviation) was 39.7 (7.2) kg/m<sup>2</sup> (Table 1). Of participants, 72.0% were white and 72.8% were women.

Baseline health care utilization metrics are also shown in Table 1. Table 2 demonstrates the 5-year unadjusted health care utilization changes. Figure 1 demonstrates the corresponding 5-year health care utilization percentile changes. Although slightly attenuated, these findings were similar in the fully risk-adjusted model (results furnished on request).

**DISCUSSION**

The current study specifically focused on the temporal changes in health care utilization metrics among obese participants enrolled in a weight management program. It did not address changes in weight, lipids, blood pressure, or either associated costs or a cost-effectiveness analysis. Many of these outcomes have been already addressed.<sup>5</sup> At the end of 4 months, after the acute weight loss period, we found a lower number of primary care physician visits along with an expected increase in all ambulatory clinic visits and health care touches, as a result of the intensive resources dedicated to the weight management participants. However, the main finding of this study was the significant long-term decrease from baseline, between 25% and 35%, in all 3 health care utilization metrics at the end of 5 years.

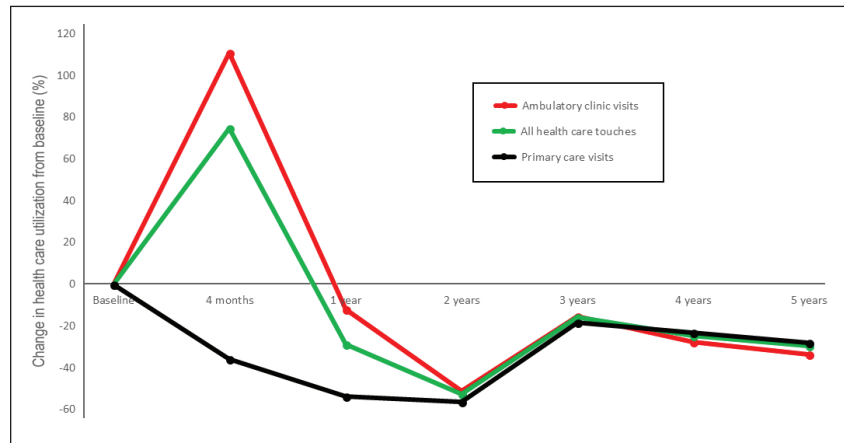


Figure 1. Five-year temporal percentile changes in 3 health care utilization metrics in participants of a medically supervised weight management program across 21 Kaiser Permanente Northern California Medical Centers.

There are limited data available on the effects of weight management programs on health care utilization metrics, with only recent acceptance of health care utilization as a possible surrogate marker of disability.<sup>3</sup> The primary determinants of health care utilization are thought to be related to health status and access to care.<sup>6</sup> However, all study participants had medical insurance and were part of an

integrated health care delivery system. Therefore, we hypothesize that the demonstrated changes in health care utilization were possibly related to changes in objective health status related to improvements in weight, blood pressure, and lipid levels and to subjective improvements in self-perceived health status related to the long-term behavioral portion of the weight management program.<sup>5</sup>

**Table 1. Baseline characteristics and health care utilization metrics of participants of a medically supervised weight management program (N = 10,693) across 21 Kaiser Permanente Northern California Medical Centers**

Variable	Measure
<b>Baseline demographics</b>	
Age, mean (SD), y	51.1 (12.4)
Women, %	72.8
Men, %	27.2
<b>Race, %</b>	
White	72.0
Black/African American	8.3
Latin American (Hispanic)	4.6
Asian/Pacific Islander	6.0
Other	9.1
<b>Clinical characteristics</b>	
Current tobacco use, %	9.2
Body mass index, mean (SD), kg/m <sup>2</sup>	39.7 (7.2)
Neighborhood income, mean (SD), US dollars	66,683 (25,353)
No. baseline comorbidities, median (IQR)	2 (2)
No. baseline medications, median (IQR)	1 (2)
<b>Baseline health care utilization, mean (95% CI)</b>	
Primary care visits	3.9 (3.8-4.0)
Ambulatory clinic visits	14.9 (14.6-15.1)
Health care touches	23.4 (23.0-23.7)

CI = confidence interval; IQR = interquartile range; SD = standard deviation.

Study limitations are related to the observational nature of the study design and a lack of a control group. Although the KPNC population is representative of the surrounding and statewide population,<sup>7</sup> our findings may not be fully generalizable to other weight management programs because program participants had medical insurance and were capable of affording the program fees—a possible selection bias. Although the mechanisms of the change in health care utilization were beyond the scope of this study, the finding from this study of decreased long-term care health care utilization may be pertinent to other integrated and non-integrated health care delivery systems. Further work in this area should assess cost-effectiveness, changes in quality of life, and disability.

## CONCLUSION

In obese participants of a medically supervised, behaviorally based, weight management program in an integrated

health care delivery system in Northern California, there was a substantial decrease in 3 health care utilization metrics (primary care physician office visits, ambulatory clinic office visits, and health care touches) at the end of 5 years. Our findings may be useful to other Kaiser Permanente Regions or other health care delivery systems considering initiation of a similar weight management program. ❖

## Disclosure Statement

This study was supported by a grant from Nestlé HealthCare Nutrition, Inc, Florham Park, NJ. The sponsor did not have access to the primary data; did not participate in data collection, analysis, or interpretation; and did not have a decision to submit the manuscript for publication.

## Authors Contributions

Ashok Krishnaswami, MD, the study supervisor, had full access to the study dataset and takes responsibility for data integrity and analysis accuracy; takes primary responsibility for study concept and design and for data interpretation; performed the statistical analysis; and wrote the initial draft of the manuscript. Rohini Ashok, MD;

Wayne Smith, MD; and Stephen Sidney, MD, MPH, helped conceptualize and design the study and helped interpret the data. Dr Sidney also assisted with data acquisition from Kaiser Permanente databases. Michael Sorel, MPH, assisted with data acquisition and helped interpret the data. All authors read and approved the final manuscript.

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Table 2. Five-year temporal changes in 3 health care utilization metrics in weight management program participants			
Time	Change from baseline	p value	95% confidence interval
Primary care visits			
Baseline	3.9	NA	3.8 to 4.0
4 mo	-1.4	< 0.001	-1.5 to -1.3
1 y	-2.1	< 0.001	-2.2 to -2.0
2 y	-2.2	< 0.001	-2.3 to -2.1
3 y	-0.7	< 0.001	-0.8 to -0.6
4 y	-0.9	< 0.001	-1.0 to -0.8
5 y	-1.1	< 0.001	-1.2 to -0.9
Ambulatory care visits			
Baseline	14.9	NA	14.6 to 15.1
4 mo	+16.5	< 0.001	+16.2 to +16.8
1 y	-1.8	< 0.001	-2.0 to -1.5
2 y	-7.6	< 0.001	-7.9 to -7.3
3 y	-2.3	< 0.001	-2.6 to -1.9
4 y	-4.1	< 0.001	-4.5 to -3.8
5 y	-5.0	< 0.001	-5.4 to -4.7
All health care touches			
Baseline	23.4	NA	23.0 to 23.7
4 mo	+17.5	< 0.001	+17.1 to +17.9
1 y	-6.7	< 0.001	-7.1 to -6.3
2 y	-12.3	< 0.001	-12.7 to -11.9
3 y	-3.7	< 0.001	-4.1 to -3.3
4 y	-5.8	< 0.001	-6.3 to -5.4
5 y	-6.9	< 0.001	-7.4 to -6.3

NA = not applicable.

# Knowing How to Ask Good Questions: Comparing Latinos and Non-Latino Whites Enrolled in a Cardiovascular Disease Prevention Study

Diego X Torres<sup>1</sup>; Wendy Y Lu, MPH<sup>1</sup>; Connie S Uratsu, RN, MS, PHN<sup>1</sup>; Stacy A Sterling, DrPH, MSW<sup>1</sup>; Richard W Grant, MD, MPH<sup>1</sup>

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## ABSTRACT

**Introduction:** Latinos face unique challenges engaging with their health care providers for risk management of cardiovascular disease (CVD).

**Objective:** To better understand differences in how Latinos and non-Latino whites (NLWs) experience CVD care.

**Methods:** We examined self-reported activation, engagement, confidence, and communication comparing Latinos (n = 194) and NLWs (n = 208). Data were taken from baseline survey assessments of participants in the CREATE Wellness Study (NCT02302612), designed to help patients with poorly controlled CVD risk factors more actively engage in their care. The groups were compared using  $\chi^2$  tests and separate logistic regression models adjusting for age, age and income, and age and educational attainment.

**Results:** Latinos in this cohort were younger, were less educated, and had lower incomes than did NLWs. In age-adjusted models, Latinos were significantly less likely to report knowing how to ask good questions about their health (71.1% vs 83.7% for NLW,  $p < 0.01$ ; adjusted odds ratio = 0.49, 95% confidence interval = 0.29-0.83). Further adjustment by educational attainment or income did not attenuate this association. Latinos were also significantly more likely to report positive experiences and confidence with several measures of chronic illness care (adjusted odds ratio range = 1.57-2.01). Further adjustment by educational attainment eliminated these associations.

**Conclusion:** We found notable differences between Latinos and NLWs in their experience of health care. These results provide insights into how CVD risk management programs can be tailored for Latinos. Interventions to improve patient activation and engagement for Latinos with CVD should emphasize question-asking skills.

## INTRODUCTION

Latinos are the largest minority ethnic group in the US and are predicted to comprise up to 30% of the nation's population by the Year 2050.<sup>1</sup> This diverse population experiences unique challenges to engaging in health care, even among those with health insurance. For example, cultural barriers between Latinos and physicians may result in poor communication, which

can consequently lead to poor response to disease prevention interventions.<sup>2</sup>

Cardiovascular disease (CVD) is the leading cause of death among Latinos.<sup>3</sup> Currently, the health care system increasingly relies on disease management programs for chronic conditions such as CVD. Although such efforts are beneficial for some patients, many others still struggle with the management of their chronic illnesses.<sup>4</sup> Research suggests that a more successful approach to chronic disease interventions should include systematic, patient-oriented efforts that increase patients' knowledge, skills, and confidence to manage their condition through proactive participation in their own care.<sup>5</sup> However, limited data exist about knowledge and confidence among Latinos in CVD care programs.

The CREATE Wellness (Changing Results: Engage and Activate to Enhance Wellness) Study ([www.ClinicalTrials.gov](http://www.ClinicalTrials.gov): NCT02302612) is a recently completed clinical trial designed to help patients with poorly controlled CVD risk factors more actively engage in their care. This randomized clinical trial tested a behavioral intervention for Health Plan members with elevated CVD risk factors (high blood pressure, lipids, and/or glycemic levels) and more than 2 years of not meeting care goals. Here, we report the baseline differences between Latinos and Non-Latino whites (NLWs) enrolled in CREATE Wellness. We compared self-reported, validated survey responses related to patient health states, behaviors, activation, and experience to test the hypothesis that Latinos may have unique barriers to engaging in care programs.

## METHODS

### Setting

The CREATE Wellness Study was implemented from February 2014 to October 2017 at 4 medical facilities in Kaiser Permanente Northern California, a nonprofit integrated care delivery system providing care for more than 3.8 million members throughout Northern California, including more than 700,000 Latinos. The distribution of members' demographic and socioeconomic factors is diverse and similar to that of the area population.<sup>6</sup>

### Eligibility and Recruitment

Details of the CREATE Wellness clinical trial design have been published previously.<sup>7</sup> Patient eligibility criteria included membership in a Kaiser Permanente Health Plan, more than 2 years of not meeting care goals for CVD risk management, and ability to provide informed consent in English. Eligible patients received a letter describing the study and a subsequent phone

## Author Affiliations

<sup>1</sup> Division of Research, Oakland, CA

## Corresponding Author

Richard W Grant, MD, MPH ([richard.w.grant@kp.org](mailto:richard.w.grant@kp.org))

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call to schedule an in-person recruitment visit. At this visit, patients independently completed the baseline survey on a desktop computer with a research assistant available to assist as needed.

The Kaiser Permanente institutional review board approved this study. Informed, written consent was obtained from all patients included in the study. All procedures followed were in accordance with the ethical standards of the institutional review board and the Helsinki Declaration of 1975, as revised in 2000.

### Survey Instruments

The baseline survey examined the following domains: Patient confidence, activation, engagement, and satisfaction. Participants' confidence in their ability to communicate with physicians was measured using the Perceived Efficacy in Patient-Physician Interactions (PEPPI) Questionnaire.<sup>8</sup> The extent of participants' activation in their own care was measured using the validated Patient Activation Measure Short Form (PAM-13) instrument.<sup>9</sup> The Effective Consumer Scale (EC-17) explored the attainment of skills, attitudes, and knowledge relating to the self-management of participants' conditions.<sup>10</sup> The Patient Assessment of Chronic Illness Care (PACIC) instrument was used to measure specific actions or qualities of care that participants reported having experienced in the delivery system.<sup>11</sup> In addition, participants answered questions about educational attainment, marital status, yearly household income, and occupational status. All surveys were in English.

### Statistical Analysis

Responses to baseline survey items were dichotomized. The 2 patient groups were compared using  $\chi^2$  tests or *t*-tests as appropriate. We repeated our comparisons using a logistic regression model adjusting for age to account for significant differences between groups. To investigate the potential mediating role of income and educational attainment, we constructed 2 additional models separately adding each of these variables to the

Variable	Latinos (n = 194)	NLW (n = 208)	p value
Age, y (SD)	56.7 (10.0)	62.6 (8.1)	0.01
Women, %	61.9	57.2	0.3
Completed college, %	48.6	74.3	0.01
Married, %	57.7	68.3	0.03
Income ≤ \$50,000/y, %	61.5	38.5	0.01
Currently employed, %	62.4	45.6	0.01

NLW = non-Latino white; SD = standard deviation.

age-adjusted model. Survey outcomes that were significant in the age-adjusted model but no longer significant with the addition of income or educational attainment were considered mediated by these factors.

## RESULTS

### Patient Socioeconomic Status

Survey respondents consisted of 194 Latinos and 208 NLW (Table 1). Latinos in this cohort were significantly younger than NLW (56.7 ± 10.0 years vs 62.6 ± 8.1 years, *p* < 0.01), had less educational attainment (48.6% vs 74.3% completing college, *p* < 0.01), had lower incomes (61.5% vs 38.5% with annual income ≤ \$50,000/y, *p* < 0.01), and were more likely to be currently employed (62.4% vs 45.6%, *p* < 0.01).

### Patient Knowledge and Confidence

Despite demographic differences, we found no significant differences between Latinos and NLW in their confidence in making health care decisions, figuring out solutions to new problems, or explaining their main concern to their physicians (Table 2). However, Latinos were significantly less likely to report knowing how to “ask good questions about their health

**Table 2. Survey results comparing Latinos and non-Latino whites (n = 402)<sup>a</sup>**

Survey domains and questions	Latinos (n = 194)	NLW (n = 208)	p value	Age-aOR (95% CI)
<b>Knowledge and confidence</b>				
I know how to ask good questions about my health and my disease (Usually/Always), %	71.1	83.7	0.01	0.49 (0.29-0.83)
I am confident I can help prevent or reduce problems associated with my health (Agree/Strongly agree), %	96.4	88.0	0.01	4.27 (1.72-10.63)
I feel confident explaining my chief health concern to my doctor (Quite confident/Very confident), %	79.4	86.1	0.07	0.60 (0.35-1.04)
<b>Physician-participant interactions</b>				
I was asked how my chronic condition affects my life (Most of the time/Always), %	50.0	38.9	0.03	1.57 (1.03-2.38)
I was told how my visits with other types of doctors, like an eye doctor or other specialist, helped my treatment (Most of the time/Always), %	49.0	33.6	0.01	1.80 (1.18-2.75)
I was given a written list of things I should do to improve my health (Most of the time/Always), %	59.8	43.3	0.01	2.01 (1.33-3.06)
I was helped to set specific goals to improve my eating or exercise (Most of the time/Always), %	56.2	42.3	0.01	1.81 (1.20-2.75)
I was helped to plan ahead so I could take care of my condition even in hard times (Most of the time/Always), %	50.5	40.9	0.03	1.60 (1.06-2.44)
I was encouraged to go to a specific group or class to help me cope with my chronic condition (Most of the time/Always), %	47.9	35.1	0.02	1.66 (1.09-2.52)
I was encouraged to attend programs in the community that could help me (Most of the time/Always), %	30.9	21.6	0.01	1.81 (1.13-2.91)

<sup>a</sup> Responses were dichotomized (values chosen for analysis shown in parentheses).

aOR = adjusted odds ratio; CI = confidence interval; NLW = non-Latino whites.

or disease” (71.1% vs 83.7% for NLW, age-adjusted odds ratio [age-aOR] = 0.49, 95% confidence interval [CI] = 0.29-0.83,  $p < 0.01$ ). In contrast, Latinos were more likely to report that they were confident in helping to prevent or reduce problems associated with their health (96.4% vs 88.0% for NLW, age-aOR = 4.27, 95% CI = 1.72-10.63,  $p < 0.01$ ).

**Patient Assessment of Chronic Illness Care**

Latinos were significantly more likely to report positive experiences with care of chronic illnesses compared with NLWs (Table 2). For example, Latino participants were more likely to report that their providers encouraged them to go to a specific group or class to help them cope with their conditions (47.9% vs 35.1% for NLW, age-aOR = 1.65, 95% CI = 1.09-2.52,  $p = 0.02$ ), gave them a written list of things they should do to improve their health (59.8% vs 43.3% for NLW, age-aOR = 2.01, 95% CI = 1.33-3.06,  $p < 0.01$ ), and helped them plan ahead so they could take care of their conditions even in hard times (50.5% vs 40.9% for NLW, age-aOR = 1.61, 95% CI = 1.06-2.44,  $p = 0.03$ ).

**Education and Income as Possible Mediators**

We examined the mediating effect of educational attainment and income by adding each variable to our age-adjusted models.

**The ideals of *simpatia* (kindness), *personalismo* (friendliness), and *respeto* (respect) are important concepts in Latino culture that affect interpersonal relationships and perceptions ...**

Neither variable substantively changed the association of Latino race/ethnicity with lower confidence in posing questions to their physician. In contrast, adding educational attainment (but not income) to our age-adjusted model eliminated or attenuated 4 of 7 significant positive associations between being Latino and satisfaction with physician-patient interactions (Table 3).

**DISCUSSION**

Disease management programs to reduce CVD risk are of high priority for the growing population of Latinos in the US. In our study of patients not meeting all goals of CVD care (blood pressure, lipid, and glycemic control) during the preceding 2 years, we found that Latinos were less confident in knowing how to ask good questions about their health compared with NLW, yet they generally reported more positive interactions with their care team. Lack of confidence in asking questions remained significant even after accounting for the potential mediating effect of educational attainment or income level—traditional measures of socioeconomic status.

These findings can be interpreted within a framework that considers the normative values of Latino culture.<sup>12</sup> The ideals

**Table 3. Comparison of Latinos vs non-Latino whites in 3 separate models adjusting for age, age and educational attainment, and age and income (N = 402)<sup>a</sup>**

Survey domains and questions	Age-aOR (95% CI)	Age- and education-aOR (95% CI)	Age- and income-aOR (95% CI)
<b>Knowledge and confidence</b>			
I know how to ask good questions about my health and my disease (Usually/Always), %	0.49 (0.29-0.83)	0.57 (0.34-0.97)	0.53 (0.32-0.89)
I am confident I can help prevent or reduce problems associated with my health (Agree/Strongly agree), %	4.27 (1.72-10.63)	4.92 (1.94-12.49)	4.75 (1.86-12.16)
I feel confident explaining my chief health concern to my doctor (Quite confident/Very confident), %	0.60 (0.35-1.04)	0.61 (0.34-1.07)	0.65 (0.37-1.14)
<b>Physician-participant interactions</b>			
I was asked how my chronic condition affects my life (Most of the time/Always), %	1.57 (1.03-2.38)	1.37 (0.89-2.11)	1.56 (1.02-2.39)
I was told how my visits with other types of doctors, like an eye doctor or other specialist, helped my treatment (Most of the time/Always), %	1.80 (1.18-2.75)	1.6 (1.04-2.5)	1.83 (1.19-2.82)
I was given a written list of things I should do to improve my health (Most of the time/Always), %	2.01 (1.33-3.06)	1.72 (1.11-2.66)	2.12 (1.38-3.27)
I was helped to set specific goals to improve my eating or exercise (Most of the time/Always), %	1.81 (1.20-2.75)	1.45 (0.94-2.24)	1.79 (1.17-2.73)
I was helped to plan ahead so I could take care of my condition even in hard times (Most of the time/Always), %	1.60 (1.06-2.44)	1.40 (0.91-2.17)	1.63 (1.07-2.51)
I was encouraged to go to a specific group or class to help me cope with my chronic condition (Most of the time/Always), %	1.66 (1.09-2.52)	1.40 (0.90-2.17)	1.75 (1.13-2.69)
I was encouraged to attend programs in the community that could help me (Most of the time/Always), %	1.81 (1.13-2.91)	1.65 (1.01-2.71)	1.85 (1.14-3.00)

<sup>a</sup> Variables were dichotomized and values chosen for analysis shown in parentheses. aOR = adjusted odds ratio; CI = confidence interval.

of *simpatia* (kindness), *personalismo* (friendliness), and *respeto* (respect) are important concepts in Latino culture that affect interpersonal relationships and perceptions<sup>13</sup> and should thus be recognized and built on in clinical settings.<sup>14</sup> Our results specifically underscore how the concept of *respeto*, defined as the importance of respecting and deferring to those in a position of authority, can influence efforts to help Latino patients engage with their health care team, even after accounting for educational attainment and income level. Prior qualitative research by our group supports these findings, with patients explaining deference to physician authority and expertise as “it’s the doctor’s job to know what to ask.”<sup>15</sup>

Prior research findings have demonstrated the impact of cultural differences between Latinos and NLW on 3 core domains of health care that are relevant to CVD risk reduction. For example, Latinos have been shown to have lower adherence to medications for chronic conditions owing to culturally mediated concerns about treatment<sup>16–18</sup> and adverse effects. Similarly, researchers have found that behavioral change strategies related to diet and exercise are more effective when tailored to the needs and beliefs of the Latino population.<sup>19,20</sup> Other work has focused on modifying educational interventions for both Spanish- and English-speaking Latinos.<sup>21–24</sup> Fundamental to all these efforts to influence how Latino patients engage in care is the necessity of effective communication between physicians and patients, which has been shown to be challenging for Latinos in the US.<sup>25</sup>

A key component of physician-patient communication is the ability of patients to articulate concerns, reservations, and lack of understanding through questions.<sup>26</sup> To date, teaching patients the skill of asking questions in the context of medical care has been studied only in a small pilot.<sup>27,28</sup> This work demonstrated that teaching the question-asking skill improved patient activation, which is thought to be in the causal pathway toward better communication and ultimately more effective health care.<sup>29,30</sup> Reluctance to ask questions, especially for patients not meeting CVD management goals, provides a critical and potentially ameliorable barrier to more effective health care for Latinos.

Several limitations of our study should be taken into consideration. Our study cohort consisted of insured patients consenting to participate in a clinical trial of behavioral change, and thus the participants may not be representative of the overall population. However, the finding that question-asking remains an important barrier even among Latinos in this more motivated group suggests that the problem could be even worse among the uninsured and those less willing to participate in research. Another limitation of our study is that all participants spoke English and were willing to answer questions on a desktop computer (with the help of a research assistant), which reduces the generalizability of our findings to Spanish monolingual or low-English proficiency Latinos, who may have additional challenges. Nonetheless, the rich data from our panel of validated

survey instruments provide new insights into the needs of Latino patients who are otherwise motivated to improve their health. Finally, social desirability bias may have influenced how participants responded to the survey questions.

**Prior qualitative research by our group supports these findings, with patients explaining deference to physician authority and expertise as “it’s the doctor’s job to know what to ask.”**

## CONCLUSION

Our results provide a potential target for future interventions tailored specifically to Latino patients. Although our findings reflect the complexity of developing culturally tailored management strategies, they also provide a foundation that can be built on in future interventions. Implementing techniques to increase patients’ confidence in their communication abilities around question-asking may help address some of the challenges that Latinos face because of culturally mediated health disparities. ❖

## Disclosure Statement

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

## Authors’ Contributions

*Diego X Torres performed data analysis and wrote the manuscript; Wendy Y Lu, MPH, performed data analysis; Connie S Uratsu, RN, MS, PHN, performed data analysis and edited the manuscript; Stacy A Sterling, DrPH, MSW, contributed to the study design and edited the manuscript; and Richard W Grant, MD, MPH, obtained funding, conceived and designed data analysis, and edited the manuscript.*

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## Able

The patient is neither a disease to be discussed, nor a showcase of pathologic interest, nor a dispassionate bystander. He is a sick person in the alien environment of the hospital, disturbed by his illness and involved in it at least as much as the doctors. He is anxious to know what is happening, entitled to find out, and generally able to make helpful contributions to all aspects of his clinical management.

— Alvan R Feinstein, MD, 1925-2001, clinician, researcher, epidemiologist;  
regarded as one of the fathers of epidemiology



**The Promise of Spring**

24" x 24"

oil paint on canvas

**Navreet Dhillon, MD**

Dr Dhillon describes this painting as "a reflection of hope and optimism during trying times."  
It was painted with a palette knife.

Dr Dhillon has been a Primary Care Physician at the Kaiser Permanente San Jose Medical Center in California since 2004. A self-taught artist, she finds inspiration in her two children, nature, and in the Sikh philosophy of "Chardi Kala," which roughly translates to "eternal optimism." Dr Dhillon donates all proceeds from her art. Most recently, she had a fundraiser for Cecelia's Closet, a local nonprofit that helps low income families and children. Her work is available at: [www.facebook.com/poppypjasperarts](http://www.facebook.com/poppypjasperarts).

More of her art can be seen on the cover.

## ORIGINAL RESEARCH &amp; CONTRIBUTIONS

# Sociodemographic Determinants of Health and Well-Being Among Adults Residing in the Combined Kaiser Permanente Regions

Matthew C Stiefel, MPA, MS<sup>1,2</sup>; Nancy P Gordon, ScD<sup>1,3</sup>; Folasade J Wilson-Anumudu, MPH<sup>1</sup>; Emily L Arsen, MPH<sup>1,4</sup>

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## ABSTRACT

**Context:** Kaiser Permanente commissioned a health and well-being (HWB) survey of adult members and nonmembers in its 8 Regions.

**Objective:** To estimate the prevalence of HWB indicators and evaluate differences in prevalence of excellent/very good (E/VG) health and thriving overall in life (thriving) by race/ethnicity, age group, sex, education, and financial situation.

**Design:** Cross-sectional survey conducted by email and phone during Winter 2016-2017 with a racial/ethnic group-stratified quota sample. Participants (N = 26,304) provided sociodemographic characteristics and ratings for 6 HWB indicators. Using population-weighted data, we estimated the prevalence of HWB indicators and used logistic regression models to test for differences in E/VG health and thriving by sociodemographic factors.

**Main Outcome Measures:** Overall health and overall life evaluation.

**Results:** Of adults, 52% were in E/VG health and 63% were thriving. Blacks were less likely to be in E/VG health than whites, Hispanics, and Asian/Pacific Islanders, but there was little racial/ethnic variation in those who were thriving. E/VG health and thriving varied significantly by level of education and financial situation. Across all racial/ethnic groups, large differences in percentages were observed in E/VG health and thriving between the lowest and highest levels of education and financial situation but little racial/ethnic variation within education and financial situation strata.

**Conclusion:** Differences in health status and life evaluation are associated very strongly with financial situation and educational attainment, and these social determinants partially explain racial/ethnic disparities in HWB. The lack of strong correlation of health status and life evaluation suggests these are different domains of well-being.

## INTRODUCTION

The Kaiser Permanente (KP) mission is to provide high-quality, affordable health care services and to improve the health of its members and the communities it serves. The organizational vision asserts KP's commitment to total health, which is grounded in a shared belief that total health extends beyond freedom from physical affliction to incorporate mind, body, and spirit. In support of KP's strategy, the Member and Community Health and Well-Being Survey (HWBS) was conducted during Winter 2016-2017 as a

baseline assessment of member and community health and well-being (HWB) in the geographic areas covered by the 8 KP Regions.

The HWBS is adapted from an instrument developed by the measurement team for the 100 Million Healthier Lives (100 Million Healthier Lives) initiative, led by the Director of the KP Care Management Institute Center for Population Health and supported by the Institute for Healthcare Improvement.<sup>1</sup> The 100 Million Healthier Lives measurement team was charged with defining and measuring "healthier lives." After extensive review of the literature and consultation with experts, the team adapted the World Health Organization's definition of *health* ("a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity"<sup>2</sup>) to include the dimension of spiritual well-being. Following Evans and Stoddart,<sup>3</sup> who postulated that health is a component

of the broader construct of well-being rather than equivalent to it, overall well-being was conceptualized as comprising physical and mental health and social and spiritual well-being.<sup>1</sup> Through a literature review, the team identified measures that had been validated in multiple populations and developed a brief assessment questionnaire to operationalize the HWB constructs. A version of the resulting questionnaire was used for the HWBS. A slightly different version of the questionnaire is also being used by the Veterans Administration and communities around the country as part of the 100 Million Healthier Lives campaign.

In this article, we 1) describe the HWBS and report survey results from more than 26,000 members and nonmembers across the 8 KP Regions; 2) provide evidence that overall health status and evaluation of overall life are different domains of well-being; 3) examine how the indicators of excellent/very good (E/VG) health and thriving in life (thriving) differ by age group, sex, race/ethnicity, educational attainment, and perceived financial situation; and 4) demonstrate that racial/ethnic differences in educational attainment and financial situation partially explain population-level racial/ethnic differences in well-being.

## METHODS

### Study Sample

The final survey respondent sample included 26,304 English-speaking adult members and nonmembers aged 18 years and older residing in one of the KP geographic Regions (Colorado, Georgia, Hawaii, Mid-Atlantic States, Northern California, Northwest, Southern California, and Washington). A quota-driven sampling scheme was used to collect information from approximately 3200 people in each Region, including a target of at least 400 members and 400 nonmembers from each of 4 racial/ethnic

### Author Affiliations

<sup>1</sup> Care Management Institute, Oakland, CA

<sup>2</sup> Institute for Healthcare Improvement, Oakland, CA

<sup>3</sup> Kaiser Permanente Northern California Division of Research, Oakland

<sup>4</sup> Mount Sinai Hospital, New York, NY

### Corresponding Author

Matthew C Stiefel, MPA, MS (matt.stiefel@kp.org)

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groups (white, black, Hispanic, Asian/Pacific Islander). The Kaiser Foundation Research Institute's National Compliance Officer determined that this study was not human subjects research and was exempted from review by KP's institutional review board.

### Data Collection

The HWBS was administered by an independent vendor who was contracted to provide a de-identified dataset for analysis. The vendor received a database of names, email addresses, phone numbers, and race/ethnicity for a Region-stratified random sample of 294,072 KP members, with proxy identifiers substituted for medical record numbers. Group Health Cooperative (Group Health), which was not yet officially part of KP at the time of the survey, provided a separate dataset of 30,000 members containing the same information. Inclusion criteria included: 1) registration on the KP or Group Health member portal, 2) at least 18 years of age, and 3) English as the primary language. The vendor recruited nonmember respondents primarily from commercial online panels representative of the population. In addition to the age and English-language criteria, nonmember respondents were required to have health insurance.

The survey was conducted from December 2016 to March 2017. Members were sent an email by the vendor indicating that KP or Group Health had engaged the vendor to conduct the survey in support of its mission to improve the health of its members and communities and that their responses would be kept strictly confidential by the vendor and not shared with KP or Group Health in a way that could identify them. A subsample of 10% of members from each racial/ethnic group in each Region was contacted to complete the survey via phone interview to enable assessment of response mode bias. Nonmembers were sent a similar email that did not identify KP or Group Health as the survey sponsor. When regional race/ethnicity quotas for nonmember respondents were not achieved through online panels, the vendor used random-digit dialing phone sampling to attempt to meet quotas via

phone interview. Nonmembers participating as part of an online research panel received a modest financial incentive for completing an online or telephone survey on the basis of their contractual arrangements with the panel vendor. Members and those contacted by phone received no financial incentive. For the online survey, up to 8 email blasts were sent to the online member and nonmember panels. For phone surveys, up to 6 calls were attempted before seeking another participant. Once the racial/ethnic group quota for a survey sample cell (eg, KP, blacks) was met, recruitment for that cell ended.

Most (82.2%) of the surveys were completed online, with significantly lower online completion by nonmembers. The response rate was slightly higher for the online survey than for the phone survey. The overall response rate using the 2 data collection modes and after excluding ineligible respondents was approximately 25%.

### Measures

The survey was designed to take approximately 5 minutes to complete online and less than 10 minutes to complete as a phone interview. The questionnaire included questions about sociodemographic characteristics and 9 validated items measuring different dimensions of HWB (Appendix A, available from: [www.thepermanentejournal.org/files/2019/18-091-App.pdf](http://www.thepermanentejournal.org/files/2019/18-091-App.pdf)).

#### Sociodemographic Characteristics

Respondents were asked to provide information about age, gender (male, female, transgender, other), Hispanic ethnicity (yes/no), what best described their race (white, black, Asian/Pacific Islander, or other, with multiple options allowed), and the highest level of education completed. Age was categorized as 18 to 44 years (younger adults), 45 to 64 years (middle-aged adults), and 65 years and older (older adults). The vendor assigned respondents to 1 of 4 racial/ethnic groups on the basis of their response to race/ethnicity questions. Those who indicated Hispanic ethnicity were classified as Hispanic irrespective of racial identity. Respondents were classified as Asian/Pacific Islander if they identified themselves as Asian/Pacific Islander but

not as Hispanic, as black if they identified themselves as black but not as Hispanic or Asian/Pacific Islander, and as white if they identified themselves only as white. Education was categorized as less than high school graduate (11th grade or lower), high school graduate (12th grade or general equivalency diploma [GED]), some college (1-3 years of college or technical school), or college graduate (bachelor's degree or  $\geq 4$  years of college). Because of the small number in the less than high school graduate category, the bottom 2 categories were combined into high school graduate or lower in the analysis. When age or sex data were missing or sex was other than male or female, values were imputed so that the correct weighting factor could be assigned. However, because there were not enough transgender people to identify separately in the analysis, analyses by sex were restricted to self-reported male and female.

#### Health and Well-Being Indicators: Overall Life Evaluation

Two similar items were used to create the Cantril Self-Anchoring Striving Scale used in the Gallup-Healthways (now Gallup-Sharecare) Well-Being Index.<sup>4</sup> Individuals were asked to separately rate their current life and their anticipated life in 5 years on a ladder scale from 0 to 10, with 0 representing the worst possible life and 10 representing the best possible life. Following Gallup's algorithm,<sup>5</sup> respondents who rated their current life as 7 or higher and their anticipated life as 8 or higher were classified as thriving. Those who rated both their current and anticipated life in the 0 to 4 range were classified as suffering. Those who did not fall into either category were classified as struggling. We calculated mean scores for each racial/ethnic group for current, anticipated, and overall life evaluation. We also calculated mean scores for a measure of optimism (difference between an individual's ratings of anticipated and current life).

#### Physical and Mental Health

Four items comprising the Health-Related Quality of Life-4 (HRQoL-4) assessment used in federal health surveys such as the Behavioral Risk Factor Surveillance System<sup>6</sup> were included to assess health. A single item assessed overall

health on a scale of excellent, very good, good, fair, or poor, and responses were categorized as E/VG, good, or fair/poor. Additional items asked about the number of days in the past 30 days that the participant’s physical health and mental health were not good and that usual activity was limited because of poor physical or mental/emotional health.

**Social Well-being**

Social well-being was conceptualized as having 2 components: Perceived financial situation and social support. Financial situation was assessed with the Cantril’s ladder scale item (worst and best possible financial situation) used by Porter and Garman.<sup>7</sup> We categorized respondents as thriving financially for ratings of 7 to 10, struggling financially for ratings of 5 to 6, and suffering financially for ratings of 0 to 4. Social support was assessed using a 5-point scale assessing how often respondents received the social and emotional support they need,<sup>8</sup> with “usually” or “always” classified as high support, “sometimes” as fair support, and “never” or “rarely” as low support.

**Spiritual Well-being**

Participants were asked how strongly they agreed or disagreed with the statement “I lead a purposeful and meaningful life.”<sup>9</sup> They were classified as high on spiritual well-being if they indicated “agree” or “strongly agree,” moderate if they indicated “somewhat agree” or “neither agree or disagree,” and low if they disagreed.

**Weighting of Survey Data to the Population**

Respondents’ data were assigned Region-specific population weighting factors to reflect the age, sex, and racial/ethnic composition of the population to which we wanted to generalize the results. Region-specific population weighting factors for members were derived from the number of members in the 2 sex groups, 3 age groups, and 4 racial/ethnic groups in each Region. Weighting factors for nonmembers in each Region were derived from 2010 US Census Bureau data about the numbers of adults in the same sex, age, and racial/ethnic groups in the geographic catchment area for that Region after excluding KP members. Thus, in Regions, the combined weighted

member and nonmember respondent samples reflected the demographic composition of adults in the total Region on the basis of census data. Further assessment indicated that the weighted respondent samples closely approximated the true number and age, sex, and racial/ethnic distribution of members and nonmembers in each Region, on the basis of internal and census data.

**Data Analysis**

Data were analyzed using SAS statistical software Version 9.3 (SAS Institute Inc, Cary, NC)<sup>10</sup> procedures for data obtained from complex survey designs. All analyses were conducted with weighted data. Sociodemographic and HWB characteristics of the study population were

summarized with descriptive statistics. Correlation analysis was used to assess the association of the overall health status and overall life evaluation indicators, with strength of association characterized as weak ( $r < 0.39$ ), moderate ( $r = 0.40-0.59$ ), or strong ( $r < 0.60$ ).<sup>11</sup>

Differences in sociodemographic characteristics by race/ethnicity were assessed using logistic regression models and Wald  $\chi^2$  tests, and racial/ethnic differences in mean life evaluation and optimism were assessed by linear regression and  $t$ -tests. Differences in the lower and upper categories of overall health and overall life evaluation by sociodemographic factors were assessed using logistic regression with Wald  $\chi^2$  tests. Multivariable logistic regression models tested for racial/ethnic

**Table 1. Characteristics of study sample<sup>a</sup>**

Characteristics	All, N <sup>b</sup> (wtd %)	White, no. (wtd %)	Black, no. (wtd %)	Hispanic, no. (wtd %)	Asian/Pacific Islander, no. (wtd %)
<b>Age, y</b>					
18-44	10,189 (49.3)	2460 (39.2)	1842 (48.9) <sup>c</sup>	3208 (65.0) <sup>c</sup>	2679 (52.6) <sup>c</sup>
45-64	8827 (33.4)	3119 (35.9)	1902 (35.7)	1733 (27.9)	2073 (34.2)
≥ 65	7288 (17.3)	3648 (24.8)	1219 (15.4) <sup>c</sup>	969 (7.1) <sup>c</sup>	1452 (13.2) <sup>c</sup>
<b>Sex</b>					
Men	10,254 (48.8)	3928 (54.4)	1667 (40.0) <sup>c</sup>	2120 (42.3) <sup>c</sup>	2539 (51.2)
Women	15,805 (50.3)	5235 (45.6)	3249 (58.8)	3714 (56.7)	3607 (48.2)
Transgender	113 (0.7)	33 (0.7)	26 (1.0)	30 (0.8)	24 (0.5)
Other	54 (0.2)	17 (0.1)	11 (0.2)	18 (0.2)	8 (0.1)
<b>Race/ethnicity</b>					
White	9227 (48.0)	9227 (—)	—	—	—
Black	4963 (10.8)	—	4963 (—)	—	—
Hispanic	5910 (28.4)	—	—	5910 (—)	—
Asian/Pacific Islander	6204 (12.9)	—	—	—	6204 (—)
<b>Education</b>					
< HS graduate	876 (3.5)	178 (2.1)	170 (3.7) <sup>d</sup>	359 (6.7) <sup>c</sup>	169 (2.0)
HS graduate	3572 (13.6)	1113 (10.9)	760 (17.3)	1139 (19.6)	560 (7.0)
Some college	7986 (30.1)	2675 (27.8)	1872 (35.4)	2047 (37.1)	1392 (18.8)
≥ 4 years of college or college graduate	13,661 (52.8)	5214 (59.2)	2125 (43.6) <sup>c</sup>	2303 (36.6) <sup>c</sup>	4019 (72.2) <sup>c</sup>
<b>Financial situation</b>					
Suffering	3711 (15.6)	1221 (14.6)	863 (18.9) <sup>c</sup>	893 (17.5) <sup>d</sup>	734 (12.7)
Struggling	6449 (23.0)	2065 (21.6)	1302 (25.7)	1533 (23.3)	1549 (25.2)
Thriving	16,144 (61.4)	5941 (63.8)	2798 (55.3) <sup>c</sup>	3484 (59.1) <sup>d</sup>	3921 (62.0)

<sup>a</sup> Data are weighted to the study population. Comparisons of blacks, Hispanics, and Asian/Pacific Islanders with whites were made on the following characteristics: Percentages of younger adults and older adults, men, less than HS graduate and college graduate, and suffering and thriving financially.

<sup>b</sup> Total N = 26,304, but 78 people were missing data for sex and 203 were missing data for education.

<sup>c</sup> Differs from reference group at  $p < 0.001$ .

<sup>d</sup> Differs from reference group at  $p < 0.01$ .

HS = high school; wtd = weighted.



differences in E/VG health and thriving after controlling first for age group and sex (Model 1), then for age group, sex, education, and financial situation (Model 2). Reference groups used in all statistical comparisons were age 18 to 44 years, men, white, college graduate, and thriving financially. All logistic regression models excluded respondents missing sex and/or education data ( $\leq 1.41\%$  of weighted sample). Logistic regression model fit was assessed using C statistics; values of 0.70 or higher and more than 0.80 respectively indicate good and strong model fit.<sup>12</sup> Age- and sex-standardized comparisons of racial/ethnic groups were done using the Proc Surveyreg procedure (SAS software version 9.3, SAS Institute Inc, Cary, NC) recommended by the Centers for Disease Control and Prevention.<sup>13</sup> This procedure standardized the weighted estimates for each racial/ethnic group to the same 2010 census age group and sex distribution of adults aged 20 years or older; a second step assessed the statistical significance of differences between racial/ethnic groups and between different strata within racial/ethnic groups.

**RESULTS**

**Characteristics of Study Sample**

Table 1 shows that 50.8% of the study participants were women and 49.3% were aged 18 to 44 years (younger adults), 33.4% aged 45 to 64 (middle-aged), and 17.3% aged 65 and older. The racial/ethnic distribution was 48.0% white, 10.8% black, 28.4% Hispanic, and 12.9% Asian/Pacific Islander (Asian/Pacific Islander). More than half (52.8%) were college graduates, and 61.4% were thriving financially. Whites were more likely than blacks, Hispanics, and Asian/Pacific Islanders to be older adults ( $p < 0.001$ ). Blacks and Hispanics were less likely and Asian/Pacific Islanders were more likely than whites to be college graduates ( $p < 0.001$  for both). Blacks ( $p < 0.001$ ) and Hispanics ( $p < 0.01$ ) were less likely than whites to be thriving financially and more likely to be suffering financially.

Just over half (52%) of adults assessed their health as E/VG and 35% as good (Figure 1). Sixty-three percent reported they were thriving, 35% were struggling, and 2% were suffering. The distributions

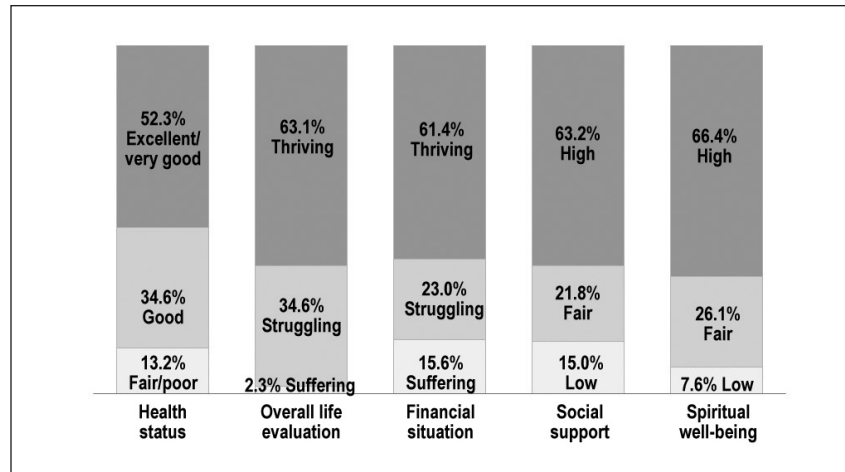


Figure 1. Population distribution of 5 health and well-being indicators

**Table 2. Rating of health and life evaluation by sociodemographic factors, weighted percentage (95% margin of error)<sup>a</sup>**

Factors	Health			Overall life evaluation		
	Fair/poor	Good	Excellent/very good	Suffering	Struggling	Thriving
All	13.2 (0.7)	34.6 (1.0)	52.6 (1.1)	2.3 (0.3)	34.6 (1.0)	63.1 (1.0)
<b>Age, y</b>						
18-44	10.1 (0.9)	32.9 (1.4)	57.0 (1.5)	1.4 (0.3)	33.2 (1.4)	65.4 (1.4)
45-64	15.9 (1.4) <sup>b</sup>	35.9 (1.9)	48.1 (2.0) <sup>b</sup>	3.2 (0.7) <sup>b</sup>	35.1 (1.9)	61.7 (1.9) <sup>c</sup>
≥ 65	16.7 (1.9) <sup>b</sup>	36.7 (2.7)	46.6 (2.8) <sup>b</sup>	3.2 (0.9) <sup>b</sup>	37.7 (2.6)	59.1 (2.7) <sup>b</sup>
<b>Sex<sup>d</sup></b>						
Men	11.8 (1.1)	33.2 (1.6)	55.0 (1.7)	2.3 (0.5)	32.9 (1.6)	64.8 (1.6)
Women	14.2 (1.0)	35.7 (1.3)	50.1 (1.4) <sup>b</sup>	2.2 (0.4)	36.0 (1.3)	61.8 (1.3) <sup>c</sup>
<b>Race/ethnicity</b>						
White	12.5 (1.0)	32.0 (1.5)	55.5 (1.5)	2.8 (0.5)	34.8 (1.5)	62.4 (1.5)
Black	15.7 (1.5) <sup>b</sup>	39.8 (2.2)	44.5 (2.2) <sup>b</sup>	1.6 (0.5) <sup>c</sup>	35.0 (2.1)	63.3 (2.1)
Hispanic	14.3 (1.7)	35.5 (2.4)	50.2 (2.5) <sup>b</sup>	1.9 (0.7) <sup>e</sup>	33.6 (2.4)	64.5 (2.4)
Asian/Pacific Islander	11.1 (1.2)	37.6 (2.0)	51.3 (2.0) <sup>b</sup>	1.9 (0.5) <sup>e</sup>	36.0 (1.9)	62.1 (2.0)
<b>Education</b>						
High school graduate or less	21.3 (2.1) <sup>b</sup>	42.3 (2.7)	36.4 (2.6) <sup>b</sup>	3.8 (1.0) <sup>b</sup>	41.8 (2.7)	54.4 (2.7) <sup>b</sup>
Some college	16.5 (1.5) <sup>b</sup>	38.3 (2.0)	45.3 (2.0) <sup>b</sup>	2.9 (0.7) <sup>b</sup>	39.6 (2.0)	57.4 (2.0) <sup>b</sup>
≥ 4 years college or college graduate	8.7 (0.8)	29.9 (1.3)	61.4 (1.4)	1.5 (0.3)	29.4 (1.4)	69.1 (1.4)
<b>Financial situation</b>						
Suffering	33.8 (2.6) <sup>b</sup>	39.7 (2.7)	26.4 (2.4) <sup>b</sup>	11.9 (1.8) <sup>b</sup>	69.9 (2.6)	19.2 (2.2) <sup>b</sup>
Struggling	18.1 (1.7) <sup>b</sup>	42.7 (2.1)	39.2 (2.1) <sup>b</sup>	1.2 (0.5) <sup>b</sup>	57.1 (2.1)	41.8 (2.1) <sup>b</sup>
Thriving	6.1 (0.7)	30.2 (1.3)	63.7 (1.4)	0.3 (0.2)	17.5 (1.1)	82.2 (1.1)

<sup>a</sup> Data are weighted to the study population. Differences in percentages of adults who were in excellent/very good health, fair/poor health, suffering in life, and thriving in life were tested for age group (reference group: 18-44 y), sex (reference group: Men), race/ethnicity (reference group: White), education (reference group: College graduate), and financial situation (reference group: thriving).

<sup>b</sup> Differs from reference group at  $p < 0.001$ .

<sup>c</sup> Differs from reference group at  $p < 0.01$ .

<sup>d</sup> Because there were not enough transgender people to identify separately in the analysis, analyses by sex were restricted to men and women.

<sup>e</sup> Differs from reference group at  $p < 0.05$ .

across categories for both the financial situation and social support indicators were similar, with approximately 60% in the highest category and 15% in the lowest category. The distribution across categories of spiritual well-being was slightly wider, with 66% in the highest category, 26% in the middle category, and approximately 8% in the lowest category. Seventy-five percent of adults rated their current life in the 7 to 10 range, 18% as 5 or 6, and 7% in the 0 to 4 range (data not shown); 72% rated their anticipated life in the 8 to 10 range; 23%, in the 5 to 7 range; and 5%, in the 0 to 4 range (data not shown).

**Health Status and Life Evaluation by Sociodemographic Factors**

Reported health status varied by age, race/ethnicity, financial situation, and educational level. Younger adults were more likely than middle-aged and older adults to report E/VG health and less likely to

report fair/poor health ( $p < 0.001$ , Table 2). Blacks, Hispanics, and Asian/Pacific Islanders were less likely than whites to report E/VG health ( $p < 0.001$ ), and whites were less likely than blacks to report fair/poor health ( $p < 0.001$ ). The proportion of adults reporting E/VG health increased with financial situation and educational level, a relationship that appeared more pronounced for the former.

Across all age, sex, racial/ethnic groups, and educational levels, less than 4% of adults were suffering, and approximately 35% and 60%, respectively, were struggling and thriving. Younger adults were more likely than middle-aged and older adults to be thriving and less likely to be suffering ( $p < 0.001$ ). Men were more likely than women to be thriving ( $p < 0.01$ ), but suffering did not vary by sex. No significant differences in thriving by race/ethnicity were observed. Differences in thriving across levels of financial situation

were larger than those observed for E/VG health. There was no difference in thriving between respondents at the 2 lowest levels of education and only a modest difference between respondents at those levels and college graduates.

**Sociodemographic Factors as Predictors of Excellent/Very Good Health and Thriving**

Table 3 shows the results of the logistic regression models evaluating the independent contributions of sociodemographic factors to predicting E/VG health and thriving. Each outcome was first separately modeled using age, sex, and race ethnicity (Model 1) before adding education and financial situation (Model 2). For both E/VG health and thriving, relationships between age group, sex, and race/ethnicity observed in bivariate analyses did not change after simultaneously controlling for these factors; C statistics were moderate at 0.57 for E/VG health and 0.53 for thriving. Respondents without a college degree were less likely than college graduates to have E/VG health and be thriving. Similarly, those who were suffering or struggling financially were less likely than those who were thriving financially to have E/VG health and be thriving in life. Adding education and financial situation to the E/VG health model reduced or eliminated differences related to age group and sex, reduced differences for blacks and Asian/Pacific Islanders compared with whites, and increased the difference between Hispanics and whites. Adding education and financial situation to the thriving model reduced the age group difference, reversed the sex difference, and made differences between blacks and Asian/Pacific Islanders and whites statistically significant ( $p < 0.01$  and  $p < 0.05$ , respectively). C statistics for Model 2 were 0.69 for E/VG health and 0.78 for thriving. In an additional analysis, adding financial situation alone to Model 1 for E/VG health and thriving resulted in C statistics that approximated those of Model 2 for each, whereas adding education alone resulted in little improvement over the first models (data not shown).

Figure 2 shows age and sex-standardized prevalence estimates of E/VG health

**Table 3. Multivariable logistic regression models of excellent/very good health and thriving overall in life, odds ratios (95% confidence intervals)**

Factors	Excellent/very good health		Thriving overall in life	
	Model 1	Model 2	Model 1	Model 2
<b>Age, y</b>				
18-44	Reference	Reference	Reference	Reference
45-64	0.65 (0.59-0.72) <sup>a</sup>	0.59 (0.53-0.66) <sup>a</sup>	0.84 (0.75-0.93) <sup>a</sup>	0.70 (0.61-0.79) <sup>a</sup>
≥ 65	0.59 (0.51-0.67) <sup>a</sup>	0.48 (0.41-0.55) <sup>a</sup>	0.75 (0.66-0.86) <sup>a</sup>	0.46 (0.39-0.54) <sup>a</sup>
<b>Sex<sup>b</sup></b>				
Men	Reference	Reference	Reference	Reference
Women	0.82 (0.75-0.89) <sup>a</sup>	0.96 (0.87-1.06)	0.86 (0.78-0.94) <sup>c</sup>	1.14 (1.02-1.27) <sup>d</sup>
<b>Race/ethnicity</b>				
White	Reference	Reference	Reference	Reference
Black	0.69 (0.62-0.77) <sup>a</sup>	0.77 (0.68-0.86) <sup>a</sup>	0.99 (0.88-1.11)	1.19 (1.04-1.37) <sup>d</sup>
Hispanic	0.77 (0.68-0.87) <sup>a</sup>	0.87 (0.77-0.99) <sup>d</sup>	1.03 (0.90-1.16)	1.13 (0.97-1.32)
Asian/Pacific Islander	0.81 (0.73-0.90) <sup>a</sup>	0.73 (0.65-0.82) <sup>a</sup>	0.90 (0.80-1.00)	0.84 (0.74-0.96) <sup>c</sup>
<b>Education</b>				
≥ 4 years of college or college graduate	—	Reference	—	Reference
Some college	—	0.63 (0.57-0.71) <sup>a</sup>	—	0.84 (0.74-0.96) <sup>c</sup>
High school graduate or less	—	0.43 (0.38-0.50) <sup>a</sup>	—	0.73 (0.63-0.85) <sup>a</sup>
<b>Financial situation</b>				
Thriving	—	Reference	—	Reference
Struggling	—	0.36 (0.33-0.41) <sup>a</sup>	—	0.14 (0.13-0.16) <sup>a</sup>
Suffering	—	0.22 (0.19-0.25) <sup>a</sup>	—	0.05 (0.04-0.05) <sup>a</sup>

<sup>a</sup>  $p < 0.001$ .  
<sup>b</sup> Because there were not enough transgender people to identify separately in the analysis, analyses by sex were restricted to men and women.  
<sup>c</sup>  $p < 0.01$ .  
<sup>d</sup>  $p < 0.05$ .

and thriving for racial/ethnic groups, stratified by education and financial situation. E/VG health varied by race/ethnicity only for respondents with at least some college. Among respondents with at least some college, blacks were significantly less likely than whites to have E/VG health and be thriving (35.8% vs 48.6% and 55.0% vs 65.0%, respectively;  $p < 0.001$  for both). Asian/Pacific Islanders who were college graduates were significantly less likely than whites to have E/VG health (54.7% vs 65.0%,  $p < 0.001$ ). No racial/ethnic group differences in E/VG health were observed among those who were suffering financially. However, blacks, Hispanics, and Asian/Pacific Islanders who were struggling or thriving financially were significantly less likely than whites to report E/VG health (30.8%, 35.7%, and 37.0% vs 43.2%, and 57.8%, 62.5%, and 59.8% vs 68.2%, respectively;  $p < 0.05$  for all).

Among college graduates, blacks and whites did not differ on thriving. However, among those with no postsecondary education, blacks were more likely than whites to be thriving (59.2% vs 50.8%,  $p < 0.01$ ), as were blacks with some college (59.0% vs 53.2%,  $p < 0.05$ ). Hispanics with some college were more likely than whites to be thriving (66.0% vs 53.2%,  $p < 0.001$ ). Asian/Pacific Islanders who were college graduates were less likely than whites to be thriving (65.5% vs 69.8%,  $p < 0.01$ ). Blacks were more likely than whites to be thriving in life at the levels of financially suffering (22.7% vs 16.5%,  $p < 0.05$ ) and financially thriving (86.0% vs 81.9%,  $p < 0.01$ ). Asian/Pacific Islanders who were struggling financially were less likely than whites to be thriving (34.5% vs 40.4%,  $p < 0.01$ ). Hispanics and whites did not differ on the thriving by financial situation.

For all racial/ethnic groups, E/VG health and thriving prevalence varied substantially by level of education and financial situation (Figure 2). In comparison to college graduates, the prevalence of E/VG health among those with a high school education or less was approximately 30 percentage points lower for whites and 17, 26, and 22 percentage points lower for blacks, Hispanics, and Asian/Pacific Islanders, respectively. Disparities in the prevalence of E/VG health by financial

situation were even greater. The difference in prevalence of E/VG health between those thriving financially and those suffering financially was approximately 40 percentage points for whites and Hispanics, 34 percentage points for blacks, and 27 percentage points for Asian/Pacific Islanders. Differences within racial/ethnic groups in prevalence of thriving between those with a high school education or less and college graduates ranged from 11 percentage points among blacks to 19 percentage points among whites. In contrast, differences within racial/ethnic groups in prevalence of thriving between those who were financially suffering and financially thriving ranged from 50 to 64 percentage points.

We also compared racial/ethnic groups on mean ratings of current and anticipated life and optimism about the future using

age- and sex-standardized data (Table 4). All groups had similar mean ratings for current life. However, the mean rating for anticipated life was higher for blacks and Hispanics than for whites and Asian/Pacific Islanders. Optimism among blacks was greater than among whites, Hispanics, and Asian/Pacific Islanders, and optimism among Hispanics was also greater than among whites and Asian/Pacific Islanders.

Finally, we examined the relationship between overall health and overall life evaluation measures. They were not strongly correlated ( $r = 0.38$ ), suggesting that they represent different dimensions of overall well-being. We also studied the effect of entering health status and overall life evaluation into the full sociodemographic logistic regression models (Model 2). Compared with adults in E/VG health,

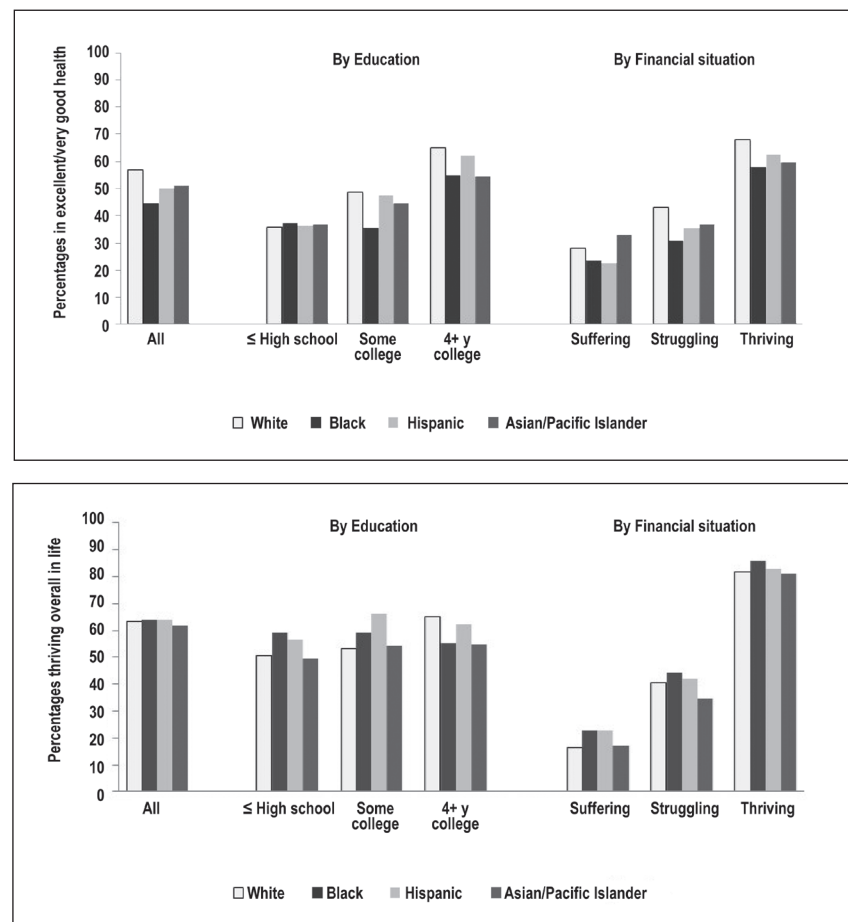


Figure 2. Prevalence of excellent/very good health and thriving in life by race/ethnicity, stratified by education and financial situation

those in good health (odds ratio = 0.43, 95% confidence interval = 0.38-0.48) or fair/poor health (odds ratio = 0.22, 95% confidence interval = 0.18-0.26) were less likely to be thriving. Similarly, compared with adults who were thriving, those who were suffering or struggling were less likely (odds ratio = 0.37, 95% confidence interval = 0.33-0.41) to be in E/VG health. However, model fit did not improve in either case (Table 5).

**DISCUSSION**

In a survey of a geographically and racially/ethnically diverse population of US adults in the 8 Regions served by KP, we found that most adults were doing well on indicators of HWB. Approximately half the population reported E/VG health, and more than 60% were thriving, thought their financial situation was good, usually got enough social and emotional support, and felt their life was purposeful and meaningful.

We benchmarked our survey results for health status against state-level data from the 2016 Behavioral Risk Factor Surveillance Survey (BRFSS)<sup>14</sup> and benchmarked overall life evaluation against state-level data from the 2016 Gallup-Sharecare Well-Being Survey (GSWBS),<sup>15</sup> restricting our analyses of national survey data to adults in the states where KP Regions are located. A similar percentage of adults were in E/VG health in the HWBS and the BRFSS. The percentage of adults who were thriving in the HWBS was higher than in the GSWBS (63% vs 56%); both surveys reported a similarly low percentage of adults who were suffering.

The relationships of sociodemographic characteristics to overall health in the HWBS were similar to those found in the BRFSS; younger adults were more likely to report E/VG health than were middle-aged and older adults, with no significant differences between the 2 latter groups. Adults with some college or a college degree were significantly more likely than adults with less education to be in E/VG health, although the percentage of adults in the HWBS with some college who rated their health as E/VG was lower than in the BRFSS. Our financial situation measure differs from the BRFSS household income measure, but we

**Table 4. Mean ratings of current life, anticipated life in 5 years, and optimism, by race/ethnicity, mean (95% confidence interval)<sup>a</sup>**

Race/ethnicity	Current life	Anticipated life	Optimism about future
All	7.43 (7.39-7.47)	8.04 (8.00-8.08)	+ 0.61 (0.58-0.64)
White	7.45 (7.39-7.51) <sup>b</sup>	7.96 (7.91-8.02) <sup>c</sup>	+ 0.51 (0.47-0.56) <sup>c</sup>
Black	7.34 (7.26-7.43) <sup>d</sup>	8.33 (8.25-8.41) <sup>e</sup>	+ 0.99 (0.91-1.06) <sup>e</sup>
Hispanic	7.47 (7.37-7.58)	8.16 (8.06-8.26) <sup>c,e</sup>	+ 0.69 (0.61-0.77) <sup>c,e</sup>
Asian/Pacific Islander	7.37 (7.29-7.44)	7.86 (7.79-7.93) <sup>c</sup>	+ 0.49 (0.44-0.55) <sup>c</sup>

<sup>a</sup> All means are based on weighted data that were age- and sex-standardized to the 2010 US adult population.

<sup>b</sup> Differs from blacks at p < 0.05.

<sup>c</sup> Differs from blacks at p < 0.001.

<sup>d</sup> Differs from whites at p < 0.05.

<sup>e</sup> Differs from whites at p < 0.001.

+ = overall, the group anticipated that their life would be better in the future.

**Table 5. Model 2 for excellent/very good health without and with health status and for thriving without and with overall life evaluation, odds ratio (95% confidence interval)**

Characteristic	Excellent/very good health		Thriving overall in life	
	Model 2 <sup>a</sup>	With overall life evaluation	Model 2 <sup>a</sup>	With health status
<b>Age, y</b>				
18-44	Reference	Reference	Reference	Reference
45-64	0.60 (0.53-0.66) <sup>b</sup>	0.62 (0.56-0.69) <sup>b</sup>	0.70 (0.61-0.79) <sup>b</sup>	0.80 (0.70-0.91) <sup>b</sup>
≥ 65	0.47 (0.41-0.54) <sup>b</sup>	0.53 (0.46-0.61) <sup>b</sup>	0.46 (0.40-0.54) <sup>b</sup>	0.55 (0.47-0.65) <sup>b</sup>
<b>Sex<sup>c</sup></b>				
Men	Reference	Reference	Reference	Reference
Women	0.96 (0.88-1.06)	0.93 (0.85-1.03)	1.14 (1.02-1.27) <sup>d</sup>	1.15 (1.03-1.29) <sup>d</sup>
<b>Race/ethnicity</b>				
White	Reference	Reference	Reference	Reference
Black	0.70 (0.63-0.79) <sup>b</sup>	0.73 (0.65-0.83) <sup>b</sup>	1.30 (1.14-1.49) <sup>b</sup>	1.30 (1.13-1.50) <sup>b</sup>
Hispanic	0.82 (0.72-0.94) <sup>b</sup>	0.85 (0.74-0.97) <sup>d</sup>	1.16 (0.98-1.37)	1.19 (1.01-1.41) <sup>d</sup>
Asian/Pacific Islander	0.70 (0.62-0.78) <sup>b</sup>	0.74 (0.66-0.84) <sup>b</sup>	0.87 (0.77-0.99) <sup>d</sup>	0.89 (0.78-1.02)
<b>Education</b>				
≥ 4 years of college or college graduate	Reference	Reference	Reference	Reference
Some college	0.63 (0.57-0.71) <sup>b</sup>	0.64 (0.57-0.72) <sup>b</sup>	0.84 (0.74-0.96) <sup>c</sup>	0.94 (0.82-1.08)
High school graduate or less	0.43 (0.38-0.50) <sup>b</sup>	0.44 (0.39-0.51) <sup>b</sup>	0.73 (0.63-0.85) <sup>b</sup>	0.91 (0.77-1.07)
<b>Financial situation</b>				
Thriving	Reference	Reference	Reference	Reference
Struggling	0.36 (0.33-0.41) <sup>b</sup>	0.53 (0.47-0.60) <sup>b</sup>	0.14 (0.13-0.16) <sup>b</sup>	0.17 (0.15-0.19) <sup>b</sup>
Suffering	0.22 (0.19-0.25) <sup>b</sup>	0.39 (0.34-0.46) <sup>b</sup>	0.05 (0.04-0.05) <sup>b</sup>	0.06 (0.05-0.07) <sup>b</sup>
<b>Overall life evaluation</b>				
Thriving	—	Reference	—	—
Struggling/suffering	—	0.37 (0.33-0.41) <sup>b</sup>	—	—
<b>Overall health</b>				
Excellent/very good	—	—	—	Reference
Good	—	—	—	0.43 (0.38-0.48) <sup>b</sup>
Fair/poor	—	—	—	0.22 (0.18-0.26) <sup>b</sup>
Model C statistic	0.68	0.73	0.78	0.81

<sup>a</sup> As reported in Table 3.

<sup>b</sup> p < 0.001.

<sup>c</sup> Because there were not enough transgender people to identify separately in the analysis, analyses by sex were restricted to men and women.

<sup>d</sup> p < 0.05.

<sup>e</sup> p < 0.01.

observed a similar pattern of an increasing percentage of respondents reporting E/VG health as perceived financial situation improved. As in the 2014 GSWBS, the prevalence of thriving in the HWBS was negatively associated with age and positively associated with financial situation.<sup>16</sup> Although we were unable to find published GSWBS statistics showing the relationship of educational attainment to thriving at the individual level, the Gallup World Poll shows a positive association at the country level.<sup>17</sup>

In terms of racial/ethnic group differences in overall health and overall life evaluation, the percentages of whites, blacks, and Asian/Pacific Islanders in E/VG health and fair/poor health closely approximated those in the BRFSS, and both surveys found substantial disparities between whites and blacks at the upper and lower levels of health status. However, compared with the BRFSS, Hispanics in the HWBS were more likely to be in E/VG health (50.2% vs 37.4%) and less likely to be in fair/poor health (14.3% vs 26.2%). This resulted in a relatively small disparity in the HWBS between Hispanics and whites regarding E/VG health and no disparity in fair/poor health, whereas white-Hispanic disparities in the BRFSS on both health measures were larger than those between whites and blacks.

In the HWBS, we found no significant racial/ethnic differences in the percentage of adults who were thriving. Although the percentage of Asian/Pacific Islanders who were thriving in the HWBS was the same as that reported by the GSWBS for the national sample, the percentages of whites, blacks, and Hispanics who were thriving were significantly higher in the HWBS than in the GSWBS (62%-64% vs 53%-56%).<sup>18</sup>

As in the GSWBS, we found that at the group level, blacks and Hispanics rated their anticipated life situation significantly higher than did whites and Asian/Pacific Islanders. Blacks and Hispanics also exhibited significantly greater optimism about the future than did whites and Asian/Pacific Islanders, with optimism among blacks being significantly greater than among whites, Hispanics, and Asian/Pacific Islanders, even though the average rating on the current life item

in the HWBS was higher than that in the GSWBS.<sup>19</sup> According to Gallup, during the 8 years of Barack Obama's presidency, blacks consistently exhibited higher levels of optimism about the future than did the other 3 racial/ethnic groups.<sup>19</sup> However, the discrepancy between mean ratings of

of education and the lowest and highest levels of financial situation were much larger than the disparities between racial/ethnic groups of similar education and financial situation. Similar findings have been reported for income.<sup>33,34</sup> These results suggest that education and financial situa-

**... during the 8 years of Barack Obama's presidency, blacks consistently exhibited higher levels of optimism about the future than did the other 3 racial/ethnic groups ... these positive expectations ... may contribute to resiliency in the face of poor financial situation, discrimination, and harassment.**

anticipated life and current life in surveys conducted 5 years later is much larger for blacks than for the other racial/ethnic groups, suggesting that these positive expectations were generally not met. It has been suggested that this optimism, manifested more by blacks and Hispanics than by whites and Asian/Pacific Islanders, may contribute to resiliency in the face of poor financial situation, discrimination, and harassment.<sup>20,21</sup>

The positive associations of health status with education<sup>22-26</sup> and income<sup>27-29</sup> and negative association of health status with financial resource strain<sup>30,31</sup> are well documented. This led the Institute of Medicine (now the National Academy of Medicine) to identify both educational attainment and financial resource strain as important social determinants of health.<sup>32</sup> We found that disparities across educational levels were greater for E/VG health than for thriving, whereas disparities across levels of financial situation were greater for thriving than for E/VG health. Furthermore, for both these outcomes, disparities between the lowest and highest levels of financial situation were greater than disparities between the lowest and highest levels of education.

We also found that racial/ethnic group disparities in the prevalence of E/VG health and thriving within levels of educational and financial situation were relatively small, although stratification did not eliminate differences between whites and blacks on health status. However, in all racial/ethnic groups, disparities in the prevalence of E/VG health and thriving between the lowest and highest levels

tion partially explain the population-level racial/ethnic disparities in HWB.

Education and financial situation were both significant independent predictors of E/VG health and thriving in our multivariate models. However, financial situation appeared to be a stronger predictor than education for both outcomes; it accounted for most of the added precision resulting from incorporating financial situation and education into models that included age, sex, and race/ethnicity. This does not mean that education is a less important factor than financial situation. It has been hypothesized that higher educational attainment exerts both a direct effect on health status by increasing health-promoting behaviors and reducing exposure to occupational risks and an indirect effect through its association with higher income level. Compared with people with low levels of educational attainment, those with high levels of educational attainment are more likely to have sufficient financial resources to purchase healthy foods, live in low-deprivation neighborhoods, have good access to health care, and experience lower financial strain, all of which contribute to better health.<sup>25,35</sup>

In our survey, we chose to ask about financial situation rather than asking about income. There is less evidence about the relationship of subjective assessment of financial situation to health status and life evaluation than there is for income. Perceived financial situation (also called financial well-being and financial satisfaction) differs from more traditional measures of household income or salary in that it incorporates subjective evaluation

of demands on available income, financial aspirations, and sense of financial security, which can vary by age and social reference group. Perceived financial situation also differs from financial resource strain in that, like income, it is viewed as a continuum rather than focused only on the ability to pay for necessities. Higher levels of income or financial satisfaction have been shown to be associated with high life satisfaction<sup>36-39</sup> and life evaluation.<sup>16</sup> Using Gallup World Poll data, Ng and Diener<sup>40</sup> found that, in many countries, financial satisfaction was a stronger predictor of positive life evaluation than income.

There is also some evidence that asking about financial situation rather than income provides a better indication of financial strain.<sup>30,31</sup> Tucker-Seeley et al<sup>31</sup> suggest that a person's perception of his/her financial situation may be a more robust predictor of self-rated health. We think that this likely extends to predicting overall life evaluation as well. Tucker-Seeley also has suggested that individuals at all income levels are going to be more comfortable and truthful responding to a question about their financial situation rather than being asked about their household income.<sup>41</sup>

Although the Gallup World Poll found a positive association between higher educational attainment and life satisfaction at the country level,<sup>42</sup> this relationship may be influenced by age, pre-adult socioeconomic status, and the job market at the time of college graduation. For instance, for younger and middle-aged adults from lower and middle socioeconomic status households, acquiring a college degree may lead to the type of job, income, and social status they aspired to while growing up. In contrast, those who began life in a higher socioeconomic status household or graduated into a depressed job market may experience an occupational and financial situation worse than they had expected, leading to less satisfaction with their life situation. Reported satisfaction may be related to comparison of outcomes to aspirations.<sup>43</sup>

Finally, our results suggest that organizations and governments interested in assessing the total health of populations

should be measuring multiple domains of HWB, not just health status. The 100 Million Lives initiative is using a version of this instrument as a standard measure of HWB across participating communities and has developed a version of the questionnaire for use with adolescents. In addition, well-being is increasingly being used as an important outcome measure for governments and large systems.<sup>44</sup>

The strengths of our study include a large, racially/ethnically, and geographically diverse, population-weighted study sample and the use of validated well-being variables. However, several limitations deserve mention. As with many quota-driven and random-digit dial surveys, our response rate was relatively low. The survey was conducted primarily online with members who were registered to use KP's patient portal and with commercial online panels of nonmembers; even after weighting to regional age, sex, and race/ethnicity composition based on census data, the respondent sample may not be representative of the study population on other characteristics, such as education and income. This may partially explain differences in estimates of E/VG health and thriving for racial/ethnic groups in the HWBS, compared with the benchmark surveys. For example, compared with BRFSS data for states where KP Regions are located, all racial/ethnic groups in the HWBS had significantly higher percentages of college graduates. Because high educational attainment and thriving financially were both associated with greater likelihood of E/VG health and thriving, the greater similarity of blacks and Hispanics to whites and Asians on these social determinants likely accounts for the smaller racial/ethnic disparities we found on the HWB indicators than have been found in other studies.

## CONCLUSION

This study demonstrates that the brief HWB survey instrument can provide useful data to assess community HWB at a population level, and potentially at the individual patient level as well. Similar instruments have been developed

to assess and monitor similar aspects of HWB constructs.<sup>45-47</sup> Findings from this study demonstrate that differences in overall health status and overall life evaluation are associated very strongly with financial well-being and with educational attainment, and these social determinants partially explain racial/ethnic disparities in HWB at the population level. Findings also suggest that life evaluation and health status are distinct dimensions of well-being. Future research will focus on the use of HWBS data to compare the HWB of members and nonmembers in the 8 KP Regions and to examine the association of social support and spiritual well-being with health status and overall life evaluation. We are also in the process of developing and validating a summary well-being index score that incorporates individuals' evaluation of their health, life situation, financial situation, social support, and spiritual well-being. ❖

## Disclosure Statement

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

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**Together**  
watercolor painting

**Quentin Eichbaum, MD, PhD, MPH, MFA, MMCH, FASCP, FCAP**

From Dr Eichbaum: "This representational abstract watercolor—of houses with joining paths surrounded by complex contraptions—may be seen as a metaphor of walking with a partner through life's complexities; or, in medicine, of walking alongside a patient through illness."

Dr Eichbaum is a Professor of Pathology, Microbiology, and Immunology at Vanderbilt University Medical Center and a Professor of Medical Education at Vanderbilt University School of Medicine in Nashville, TN.

He was born and raised in Africa (Namibia), where the vast, timeless landscapes were at once harshly real and abstract in their sweeping shapes, lines, and colors. This instilled in him a lasting love for watercolor as the medium that could best capture the translucent subtlety of these landscapes and their abstractions.

He has studied watercolor with numerous prominent watercolorists in the US and abroad. His works have been sold and exhibited in the US, Europe, and Africa. As a physician, he finds watercolor (a "temperamental medium") a way of surrendering and re-centering himself, and a way of "paying attention" to the world.

More of his work can be seen on page 21.



# Assessing the Hereditary Hemorrhagic Telangiectasia Algorithms in a Community-Based Patient Population

Tina Saparia, MD<sup>1</sup>; Marie E Faughnan, MD<sup>2</sup>; Jennifer L Schneider, MPH<sup>3</sup>; Lucy M Almers, MPH<sup>3</sup>; Norma Chow, MS LCGC<sup>4</sup>; Scott D Grosse, PhD<sup>5</sup>; Helen Kim, PhD<sup>6</sup>; Jonathan G Zaroff, MD<sup>3</sup>

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## ABSTRACT

**Introduction:** Hereditary hemorrhagic telangiectasia (HHT) is a rare, genetic, and underdiagnosed disease that causes vascular malformations throughout the body. Two specific combinations of International Classification of Diseases, Ninth Revision–Clinical Modification diagnosis codes, the “HHT Algorithms” (HHTAs), were developed previously from a derivation cohort to help identify undiagnosed HHT cases.

**Objectives:** To test these 2 algorithms, and a third, newly designed HHTA, in an independent population with available clinical records and thus identify people who might have undiagnosed HHT.

**Methods:** The HHTAs were applied to the patient population of Kaiser Permanente Northern California. The HHTAs produced 3 groups (A, B, and C) using different combinations of diagnosis codes reflecting clinical manifestations of HHT. First, the number of Kaiser Permanente Northern California patients with each code was determined by database programming. Next, detailed chart review was performed, and patients with a Curaçao score of 2 or higher were considered to have possible HHT.

**Results:** Of 3,065,210 records queried, 163 patients met HHTA criteria. After chart review, the study identified 113 patients with possible undiagnosed HHT (Group A: n = 3, Group B: n = 3, Group C: n = 107).

**Conclusion:** Employing the HHTAs in this community-based population resulted in a modest yield of patients with possible HHT. Further research is required to assess the utility of the HHTAs in identifying patients with actual HHT.

## INTRODUCTION

Hereditary hemorrhagic telangiectasia (HHT) is an inherited disorder of blood vasculature, with an estimated prevalence of 1 in 5000 to 1 in 10,000 people worldwide. It is a highly penetrant disorder that causes diverse manifestations, including epistaxis (most commonly)<sup>1</sup>; telangiectasias caused by dilation of superficial capillaries usually in the nasal, oral, or gastric mucosa or the dermis of the hands or face; and arteriovenous malformations (AVMs) found in the lungs, brain, or liver, whose rupture can cause life-threatening complications, such as stroke and brain abscess.<sup>2</sup> Chronic gastrointestinal bleeding may result in the development of iron-deficiency anemia with advancing age. HHT may go unrecognized and untreated for decades and can cause premature death.<sup>3-5</sup> Among patients presenting before age 60 years, mortality is twice that expected in the general population and is directly attributed to severe manifestations of HHT such as gastrointestinal bleeding, cerebral hemorrhage, and pulmonary hemorrhage and/or hypoxemic respiratory failure caused by

pulmonary AVMs.<sup>6</sup> HHT is underdiagnosed because physicians can fail to connect HHT’s diverse manifestations as part of an underlying syndrome.

Previously, 2 specific combinations of International Classification of Diseases, Ninth Revision–Clinical Modification (ICD-9-CM) codes, the “HHT Algorithms” (HHTA Group A and Group B), were developed from an administrative database derivation cohort to help identify potential undiagnosed HHT cases.<sup>7</sup> The purpose of the present study was to test those 2 HHTAs in an independent population with available clinical records and thus identify people who might have undiagnosed HHT. In addition, a third HHTA (Group C) was designed for this study in an attempt to increase the sensitivity for detecting HHT. If data-mining using the HHTA in a clinical population could be established to be effective in identifying patients with undiagnosed HHT, it would likely represent a cost-effective strategy to prevent premature morbidity and mortality.

## METHODS

We conducted a cross-sectional study of the Kaiser Permanente (KP) Northern California (KPNC) population, an integrated health services delivery organization. Containing approximately 4 million persons, KPNC’s membership has demographics that closely approximate those of the underlying census population of Northern California.<sup>8</sup> Eligible subjects were all living adult (aged 21 years or older) members who were continuously enrolled in KPNC between January 2010 and May 2012 (allowing gaps of 6 months or less). In addition, the electronic medical record had to include the presence of at least 1 of the combinations of ICD-9-CM codes in the HHTAs listed in Table 1. Members with an ICD-9-CM diagnosis code for HHT (448.0) present in administrative data from January 2008 onward were excluded from this study.

In the first phase of this study, a KPNC database programmer/analyst queried the KPNC research databases to determine how

### Author Affiliations

<sup>1</sup> Redwood City Medical Center, CA

<sup>2</sup> University of Toronto, Ontario, Canada

<sup>3</sup> Division of Research, Oakland, CA

<sup>4</sup> San Francisco Medical Center, CA

<sup>5</sup> US Centers for Disease Control and Prevention, Atlanta, GA

<sup>6</sup> University of California, San Francisco Center for Cerebrovascular Research

### Corresponding Author

Jonathan G Zaroff, MD ([jonathan.g.zaroff@kp.org](mailto:jonathan.g.zaroff@kp.org))

Keywords: arteriovenous malformations, brain abscess, hereditary hemorrhagic telangiectasia, population science, rare disease surveillance

HHTA Group	Clinical findings	ICD-9-CM coding
A	Pulmonary AVM <i>and</i> at least 1 of the following: Epistaxis, brain AVM, peripheral AVM, or gastrointestinal angiodysplasia	[747.3 or 417.0] <i>and</i> [784.7, 747.81, 747.6, 537.82, 537.83, 569.84, or 569.85]
B	Brain AVM <i>and</i> gastrointestinal angiodysplasia	747.81 <i>and</i> [537.82, 537.83, 569.84, or 569.85]
C	Epistaxis ( $\geq 2$ encounters) <i>and</i> at least 1 of the following: Gastrointestinal angiodysplasia, peripheral AVM, or other unspecified capillary diseases	784.7 <i>and</i> [537.82, 537.83, 569.84, 569.85, 747.6, or 448.9]

AVM = arteriovenous malformation; HHTA = hereditary hemorrhagic telangiectasia algorithm; ICD-9-CM = International Classification of Diseases, Ninth Revision-Clinical Modification.

many KPNC members met the study inclusion criteria, according to the different HHTA groups.

In the second phase of the study, we performed a detailed review of all members' charts identified in Phase 1. During this process, the investigators (TS, JGZ) reviewed electronic medical records to verify each individual ICD-9-CM code in the HHTA identified for each member. Physician review (TS, JGZ) of clinical notes, encounters, imaging, and laboratory results was completed for subjects with verified codes. Data were collected from the medical records using an electronic case report form that included demographic data and the presence or absence of the following diagnostic Curaçao criteria for HHT: Epistaxis (at least 2 encounters < 7 days apart), telangiectasias (multiple, mucocutaneous), visceral AVM or gastrointestinal telangiectasias, and family history of HHT.<sup>2,9</sup> The Curaçao score was calculated, and the clinical diagnosis of HHT was considered possible when 2 or more of the criteria were present. A lack of information (eg, detailed family history) resulted in that criterion being considered absent. To ensure quality of chart review, all charts were reviewed by 2 physicians (TS, JGZ). When questions arose, those physicians consulted with another group of physician specialists with expertise in the diagnosis and management of HHT.

The statistical analysis for this study was descriptive. We reported the prevalence of each of the 3 HHTA (and each component ICD-9-CM code) in the KPNC population (per 10,000 people), stratified according to the age of the members at the time of our analysis. Finally, we reported the proportions of chart-reviewed cases with possible HHT for each HHTA category.

The Kaiser Foundation Research Institute's institutional review board (IRB) approved this study with a waiver of consent. When joining KP, most members give permission for database research to be done using their health information. The IRB thus approved the data-mining aims but would not approve patient contact with prospective testing for manifestations of HHT without research funding available to pay for the testing, which was beyond the budgetary scope of the present study. For patient safety, the IRB did approve communication from the study investigators to each subject's primary care practitioner about the data-mining results so that they could order HHT testing if clinically appropriate, but the results of clinically indicated testing could not be reviewed for research purposes as part of this research study. The study investigators and the IRB agreed that the potential benefit of preventing rare but dangerous complications in subjects with previously undiagnosed HHT outweighed any discomfort or anxiety the patients might experience by knowing the information was obtained from a data-mining study.

**Table 2. Prevalence of hereditary hemorrhagic telangiectasia algorithm groups by age distribution**

Group	N	Prevalence per 10,000			
		Total	Age $\leq 35$ y	Age 36-50 y	Age $> 50$ y
Known HHT	129	0.421	0.246	0.414	0.792
Algorithm A	11	0.039	0.095	0	0.053
Algorithm B	9	0.029	0.000	0.015	0.071
Algorithm C	143	0.467	0.057	0.153	1.156

HHT = hereditary hemorrhagic telangiectasia.

## RESULTS

The database program queried the charts of 3,065,210 adult KPNC members and identified 129 persons with an existing diagnosis (ICD-9-CM Code 448.0) of HHT (prevalence = 0.42/10,000), all of whom were excluded from the HHTA analysis.

The number of KPNC members meeting criteria for each of the HHTA is shown in Table 2 for the total and age-stratified populations. For HHTA Group C, there was a notable rise in population prevalence associated with increasing age. The mean age (standard deviation) for Group A was 61 (25) years, for Group B it was 65 (17) years, and for Group C it was 72 (15) years.

The distribution of the specific ICD-9-CM code combinations leading to inclusion into the 3 different HHTA groups is shown in Table 3. Using the HHTAs, we identified 11 KPNC members who met Group A criteria, 9 members who met Group B criteria, and 143 members who met Group C criteria (1 of whom was also identified by the Group B program). Most Group C cases ( $n = 99$ ) had ICD-9-CM codes for epistaxis and "Other capillary diseases (unspecified)."

For the second (chart review) phase of the study, all patients meeting programmatic criteria for HHTA Groups A through C were chart reviewed. Chart review discovered 1 member, identified by both HHTA Group B and Group C, with known HHT that did not have ICD-9-CM code 448.0 in the patient's record, and that patient was excluded from the analysis. One individual met criteria for both Groups B and C, so the total chart review sample size was 162 members. These members had a mean age of 68 years (median = 71 years, range = 28-93 years). The distribution of self-identified race/ethnicity was as follows (> 1 response allowed): 48%, white; 22%, Latino; 13%, Asian; 13%, multiracial; 7%, African American; and 19%, unknown. A family history of HHT, brain AVM, or pulmonary AVM was not identified in any of the records that were reviewed.

The chart review results according to HHTA group are shown in Table 4. Programmatic false-positives were common. For example, it was discovered that the HHTA Group A program, which was previously published, had erroneously included ICD-9-CM code 747.3X (allowing both 747.31 and 747.32) instead of just 747.32.<sup>7</sup> Thus, 4 cases with code 747.31 (pulmonary artery coarctation and atresia) were accidentally included in HHTA Group A. The chart review evaluation of Group B revealed a high programmatic false-positive rate, generally because of cerebral aneurysms or other types of cerebral vascular abnormalities being miscoded (hospital coder error) as brain AVM. Programmatic false-positives owing to other confounding disease processes causing the finding of interest were also common. For example, the program identified several people who had hepatic cirrhosis as the cause of pulmonary AVMs, skin abnormalities, and vascular abnormalities of the gastrointestinal tract. After exclusion of these patients, a total of 113 patients met our definition of possible HHT with a Curaçao score of 2 or greater. The primary care practitioners for these members were notified so that the patients could be referred for appropriate clinical evaluation.

**Table 3. Distribution of ICD-9-CM code combinations in each hereditary hemorrhagic telangiectasia algorithm group**

Group	ICD-9-CM codes	Diagnoses	N
A (n = 11)	(747.3 or 417.0) + 784.7	Pulm AVM + epistaxis	8
	(747.3 or 417.0) + 747.81	Pulm AVM + brain AVM	2
	(747.3 or 417.0) + 537.82	Pulm AVM + GIAng	1
B (n = 9)	747.81 + 537.82	Brain AVM + upper GIAng	4
	747.81 + 569.84	Brain AVM + GIAng	5
C (n = 143)	784.7 + 537.82	Epistaxis + upper GIAng	17
	784.7 + 537.83	Epistaxis + upper GIAng w/ hemorrhage	3
	784.7 + 569.84	Epistaxis + GIAng	17
	784.7 + 569.85	Epistaxis + GIAng w/ hemorrhage	7
	784.7 + 448.9	Epistaxis + other capillary diseases	99

AVM = arteriovenous malformation; GIAng = gastrointestinal angiodysplasia; ICD-9-CM = International Classification of Diseases, Ninth Revision-Clinical Modification; Pulm = pulmonary; w/ = with.

**Table 4. Chart review outcomes according to hereditary hemorrhagic telangiectasia algorithm group**

Outcome	HHTA Group		
	A	B	C
Total charts reviewed	11	9	143
False-positives	8	6	36
Possible HHT (Curaçao score $\leq$ 2)	3	3	107
Pulmonary AVM	3	0	0
Brain AVM	0	3	3
Spinal AVM	0	0	4
Hepatic AVM	0	0	4

AVM = arteriovenous malformation; HHT = hereditary hemorrhagic telangiectasia; HHTA = hereditary hemorrhagic telangiectasia algorithm.

## DISCUSSION

This study's database program found a diagnosed HHT prevalence of 0.42 per 10,000, or approximately 1 per 24,000, in the adult KPNC population who satisfied the study's membership criterion. This result is substantially lower than the likely true prevalence of HHT (1 in 5000 to 1 in 8000).<sup>6,10-13</sup> It is virtually identical, though, to that found among adults in the published analysis of nationwide IBM MarketScan claims data (IBM Corp, Armonk, NY).<sup>7</sup> Thus, it is very likely that there are numerous KPNC members with undiagnosed HHT, just as in the general US population with health insurance. The objective of this study was to attempt to close that gap by identifying KPNC members likely to have HHT on the basis of signs and symptoms of HHT recorded in medical records.

The chart review evaluation unearthed a variety of issues leading to false-positive programmatic designation into the HHTA groups, including an erroneous ICD-9-CM code in the program, hospital miscodes, and the confounding presence of hepatic cirrhosis, which may result in pulmonary AVM formation and gastrointestinal bleeding. Future studies of the HHTAs might thus consider adding an ICD-9-CM code for hepatic cirrhosis as a programmatic exclusion criterion.

The chart review evaluation of Group C patients revealed a lower (25%) false-positive programming rate than for Groups A and B patients, although the majority (69%) of cases without miscodes had abnormalities limited to less-specific HHT findings, such as skin telangiectasias, epistaxis, and/or gastrointestinal angiodysplasia. Thus, it is unlikely that a large proportion of the Group C cases actually have undiagnosed HHT, despite having a Curaçao score of 2 (in most cases) or greater by chart review.

This study has several important limitations, mostly related to its retrospective design. First, not all patients with known HHT or the component findings of the HHTAs have the appropriate ICD-9-CM code linked into their medical records, because of coding errors. Second, family history is generally underdocumented in KPNC medical records, limiting the chance of finding a family history of HHT, brain AVM, or pulmonary AVM by retrospective chart review. Third, epistaxis and gastrointestinal angiodysplasia are not specific to HHT and likely become more commonly coded in the charts of older patients who have accrued many office visits during their years of KPNC membership. Thus, HHTA Group C may be more likely to identify elderly patients without HHT than patients who truly have HHT.

Finally, the clinical evaluations to determine whether the patients identified in this research study actually have HHT are ongoing, and the findings of those evaluations are beyond the scope and IRB approval of this retrospective research study. As stated earlier, there was no IRB approval for direct patient contact by the study investigators to encourage patients to get further testing or to complete surveys. In other words, the present study was designed to test the HHTAs to the level of retrospective chart review without patient contact. A future study will be required to describe the results of clinical testing and outcomes in this population.

## CONCLUSION

The HHTAs identified a modest number of patients with possible HHT in this community-based retrospective cohort study. The HHTAs also identified patients who clearly did not have HHT but did have hospital coding errors leading to cohort inclusion or confounding conditions mimicking the effects of HHT, such as hepatic cirrhosis. Further examination of the HHT algorithms using a prospective study design allowing for patient contact, a detailed family history, and HHT-specific testing would likely be informative. ❖

## Disclosure Statement

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

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## Compliance with Ethics Guidelines

*No human subjects research was involved in this study by any of the authors. The Kaiser Foundation Research Institute's institutional review board approved this study with a waiver of consent.*

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## No True Hemophilia

He ... had his first nose bleeds at the age of 12 years, and throughout his youth ... .  
 Since the age of 35 the hemorrhages have become very frequent, always in the form of epistaxis ... . He has had two teeth pulled without having had notable consequent hemorrhages. This is, therefore, no true hemophilia ... .  
 Small purple spots ... are true cutaneous hemangiomas ... . This anatomic disposition is not limited to the skin; it extends also to the mucous membranes.

— Henri-Jules-Louis-Marie Rendu, 1844-1902, French physician

# Relapse Prevention by Plant-Based Diet Incorporated into Induction Therapy for Ulcerative Colitis: A Single-Group Trial

Mitsuro Chiba, MD, PhD<sup>1</sup>; Kunio Nakane, MD, PhD<sup>2</sup>; Tsuyotoshi Tsuji, MD, PhD<sup>3</sup>; Satoko Tsuda, MD<sup>4</sup>; Hajime Ishii, MD, PhD<sup>4</sup>; Hideo Ohno, MD<sup>4</sup>; Kenta Watanabe, MD<sup>4</sup>; Yu Obara, MD<sup>4</sup>; Masafumi Komatsu, MD, PhD<sup>4</sup>; Takeshi Sugawara, MD<sup>5</sup>

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## ABSTRACT

**Context:** No known previous study has focused on plant-based diet (PBD) to prevent relapse of ulcerative colitis (UC) except our previous educational hospitalization study.

**Objective:** To describe the relapse rate in a large case series of UC after incorporation of PBD into induction therapy.

**Design:** All patients with UC between 2003 and 2017 were admitted for induction therapy. Patients receiving educational hospitalization or treated with infliximab were excluded. A lacto-ovo-semivegetarian diet (PBD) together with medication prescribed according to UC guidelines was provided during hospitalization.

**Main Outcome Measures:** The primary endpoint was relapse during follow-up. The secondary endpoint was change over time in the plant-based diet score (PBDS), which evaluated adherence to the PBD.

**Results:** Ninety-two cases were studied, of which 51 were initial episodes and 41 were relapses. Cases varied in severity (31 mild, 48 moderate, 13 severe) and extent (15 proctitis, 22 left-sided colitis, 55 extensive colitis). More severe cases existed among the relapse cases than among the initial episode cases. Cumulative relapse rates at 1- and 5-year follow-up (Kaplan-Meier analysis) were 14% and 27%, respectively, for the initial episode cases, and 36% and 53%, respectively, for relapse cases. At long-term follow-up (6 years 4 months), PBDS was significantly higher than baseline PBDS ( $p < 0.0001$ ).

**Conclusion:** Relapse rates in UC after induction therapy with PBD were far lower than those previously reported with conventional therapy. Adherence to PBD was significantly higher than baseline even at 6-year follow-up. We conclude PBD is effective for preventing UC relapse.

(Study identification no.: UMIN000019061; Registration: [www.umin.ac.jp](http://www.umin.ac.jp))

hospitalization.<sup>10</sup> Cumulative relapse rates for initial episode cases were 4% and 17% at 1 and 5 years, respectively, which were, again, better outcomes than those reported elsewhere. However, the clinical focus in this study was narrow. The subjects were those with mild disease or in remission who did not need immediate treatment. In the present study, our aim was to clarify whether treatment incorporating PBD during hospitalization was effective in prevention of relapse in ordinary patients with UC.

Biologics have revolutionized treatment of various conditions including IBD. In Japan, infliximab, the first biologic introduced for IBD, became available for treatment of UC in 2012. The guidelines for UC limit the use of infliximab or adalimumab to patients who are unresponsive to conventional therapy such as glucocorticoids.<sup>11</sup> Considering the occurrence of corticosteroid dependence or surgical intervention at 1 year in nearly 50% of patients with UC treated with glucocorticoids,<sup>12</sup> we changed the first choice of medication for cases with moderately severe (moderate) and severe UC from prednisolone (glucocorticoid) to infliximab in 2012. Comparison of our outcomes with those reported previously is possible under the same strategy. Therefore, cases with moderate and severe UC after 2012 were not included in this study.

## INTRODUCTION

Ulcerative colitis (UC) and Crohn disease have a common etiopathogenesis and features, and they fall under the collective term *inflammatory bowel disease* (IBD).<sup>1</sup> Epidemiologic findings in Western countries show that since the start of the 21st century, the incidence of IBD has not accelerated at the same rate observed at the end of the 20th century but rather is more stable.<sup>2</sup> It is natural, however, that the prevalence is increasing in Western countries. The incidence of IBD is rapidly increasing in newly industrialized countries in Asia, including Japan, South Korea, and China, and in Central and South America. There is a great concern for the increasing number of patients with IBD globally.<sup>2</sup>

Despite the recognition of westernization of lifestyle as a major driver of the

growing incidence of IBD,<sup>3,4</sup> no countermeasures such as lifestyle changes have been recommended, except that patients with Crohn disease should not smoke.<sup>5</sup> Among various environmental risk factors, we concluded that the most ubiquitous environmental risk factor was westernized diet.<sup>6</sup> Namely, we regard IBD as a lifestyle disease caused mainly by our omnivorous (Western) diet.<sup>7-10</sup> We have designed a plant-based diet (PBD) to counter the westernized diet, and we have been providing PBD to all patients with IBD since 2003.<sup>8</sup> We have achieved better outcomes than those reported in both the active stage and quiescent stage in Crohn disease.<sup>7,9</sup> We suspect these outcomes are owing to the replacement of a westernized diet with a PBD. In a previous study, we reported relapse prevention in UC by PBD through educational

## Author Affiliations

<sup>1</sup> Inflammatory Bowel Disease Section, Akita City Hospital, Japan

<sup>2</sup> Gastroenterology Division, Akita City Hospital, Japan

<sup>3</sup> Gastrointestinal Endoscopy Section, Akita City Hospital, Japan

<sup>4</sup> Akita City Hospital, Japan

<sup>5</sup> Nakadori General Hospital, Akita, Japan

## Corresponding Author

Mitsuro Chiba, MD, PhD (mchiba@m2.gyao.ne.jp)

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IBD typically affects children, teens, young adults, and adults in their prime. It has an impact on physical and psychological well-being, education and/or work, quality of life, and socioeconomic status.<sup>13</sup> Prevention of relapse is a critical step to halting impairment caused by the disease. Our goal is the prevention of relapse during the follow-up period. We hypothesized that treatment incorporating PBD will decrease the relapse rate of UC.

## METHODS

### Design and Settings

We designed a single-group trial, which was conducted in Akita in northern Japan. Both Nakadori General Hospital and Akita City Hospital are tertiary care hospitals in Akita. The first author (MC) worked for the former between 2003 and 2012 and has been working for the latter since 2013. This study was approved by the ethical committees of Nakadori General Hospital and Akita City Hospital (Protocol no. 19-2003 and no. 15-2015). Written informed consent was obtained from all patients.

### Patients

All patients with UC who needed immediate treatment between April 2003 and October 2017 were advised to be admitted for induction therapy. Patients were excluded if they had any of the following: 1) educational hospitalization,<sup>10</sup> recommended because of mild disease or remission that did not need immediate treatment; 2) infliximab and PBD as first-line (IPF) therapy<sup>9</sup> as of August 2012, when infliximab became available for treatment of UC in Japan (patients with moderate to severe UC were treated with prednisolone during the prebiologic era); and 3) proctocolectomy after the hospitalization caused by either severe disease refractory to prednisolone or mild disease intractable to medical treatments. The severity was judged according to the criteria of Truelove and Witts.<sup>14</sup>

### Treatment During Hospitalization

Medication was initiated according to UC guidelines.<sup>11</sup> The exception was some mild cases. The need for medication was judged on the basis of evaluation of patient

history, endoscopic findings, laboratory findings, and circumstances. As a result, medication was not provided in a subset of mild cases.

In this study, the PBD provided during hospitalization was a lacto-ovo-semivegetarian diet that was described previously.<sup>7</sup> The PBD (about 30 kcal/kg of standard body weight) included fish once a week and meat once every 2 weeks. During hospitalization, food other than the meal service was discouraged. The plant-based diet score (PBDS), which evaluated adherence to the PBD, was 35 during hospitalization.<sup>8</sup>

The same program provided during educational hospitalization for UC<sup>10</sup> was provided during hospitalization. Namely, the program included lifestyle diseases, healthy lifestyle habits,<sup>15</sup> pathogenesis of IBD, and information on the PBD. During hospitalization, patients were provided with answers to any questions they had. A registered dietitian also visited the patients and talked to them about the PBD and helped them get used to it.

Blood samples for measurement of C-reactive protein; erythrocyte sedimentation rate; complete blood cell counts; total protein, albumin,  $\alpha_2$ -globulin, transaminase, cholesterol, and cholinesterase levels; and so on were taken weekly to assess the clinical course. *Remission* was defined as a disappearance of bloody stool.<sup>14</sup> Patients who achieved or almost achieved remission were discharged. Morphologic improvement was confirmed either by colonoscopy or double contrast-enhanced barium enema study.<sup>7</sup>

At the end of the hospitalization, a qualified dietitian gave dietary guidance for 30 to 40 minutes to the patient and the person who prepared the patient's meals.<sup>7</sup> Patients were advised to continue with the PBD after discharge.

### Follow-Up Studies

Follow-up was continued as long as possible. The interval between visits to the Outpatient Department after discharge varied depending on the stability of the patient's condition. For a patient who was in unstable remission, the interval was 4 to 6 weeks. For a patient who was in stable remission, the interval was 8 weeks. For a patient who was in remission for more

than a few years without medication, the interval was 3 to 6 months. Patients were occasionally encouraged to adhere to the PBD without being asked about patient adherence to the PBD. When patients gained body weight above a standard body weight, they were advised to maintain the standard body weight. Patients were occasionally provided with information on lifestyle or IBD; for example, a summary sheet of an IBD lecture held biannually at Akita City Hospital.

### Food-Frequency Questionnaire and Plant-Based Diet Score

A questionnaire of dietary habits and lifestyle behaviors before onset or relapse of the disease was obtained immediately after admission. On the basis of the questionnaire, a table was drawn that summarized the patient's current and future recommended lifestyle and dietary habits.<sup>7,10</sup> This table was given to the patient during hospitalization and was used by the dietitian when giving dietary guidance. The questionnaire was repeated during short-term ( $\leq 2$  years) or long-term ( $> 2$  years) follow-up.

A PBDS was calculated from the questionnaire. The method for how the PBDS was calculated has been described previously.<sup>8</sup> In brief summary, 8 items considered to be preventive factors for IBD (vegetables, fruits, pulses [beans, soybeans, peas, etc], potatoes, rice, miso soup, green tea, and plain yogurt) contributed to a positive score (PBDS+), whereas 8 items considered to be IBD risk factors (meat, minced or processed meat, cheese/butter/margarine, sweets, soft drinks, alcohol, bread, and fish) contributed to a negative score (PBDS-). Scores of 5, 3, and 1 were given according to the frequency of consumption: Every day, 3 to 5 times per week, and 1 to 2 times per week, respectively. The PBDS was calculated as the sum of the positive and negative scores, and it ranged between -40 and +40. A higher PBDS indicated greater adherence to the PBD.<sup>8</sup>

### Assessment of Efficacy

The primary endpoint was relapse during the follow-up period. Relapse was defined as a flare-up that required more aggressive medical treatment.<sup>16-19</sup> Reappearance of

streak blood, a small volume of blood, or bloody stool was not counted as relapse if the blood disappeared or was controlled with previous medication and/or modification of the diet or a lifestyle behavior.

The secondary endpoint was change over time in PBDS. Short- ( $\leq 2$  years after discharge) and long-term ( $> 2$  years) chronological change in the PBDS were studied.

### Safety Evaluations

Safety assessments included vital signs, patient symptoms, findings during daily practitioner rounds, weekly laboratory data, and physical examination findings.

Table 1. Demographics of 92 patients				
Characteristic	Total	Initial episode cases	Relapse cases	p value <sup>a</sup>
Male, no. (%)	45 (49)	25	20	0.9818
Female, no. (%)	47 (51)	26	21	
Age, y				
Range	11-81	11-80	14-81	
Mean (SD)	39 (19)	39 (19)	40 (18)	0.5876
Median (IQR)	36 (23-54)	35 (22-56)	36 (26-52)	
Extent of ulcerative colitis, <sup>20</sup> no. (%)				0.9267
Proctitis	15 (16)	9	6	
Left-sided colitis	22 (24)	12	10	
Extensive colitis	55 (60)	30	25	
Severity <sup>14,20</sup>				0.0346
Mild	31 (34)	18	13	
Moderate	48 (52)	30	18	
Severe	13 (14)	3	10	
Disease duration, mo				
Range	1-296	1-24	1-296	
Mean (SD)	35 (63)	3 (4)	75 (78)	< 0.0001
Median (IQR)	4 (1-35)	1 (1-4)	46 (8-127)	
Case referral status, no. (%)				0.5575
Referred	53 (58)	28	25	
Nonreferred	39 (42)	23	16	
Smoking status, no. (%)				0.8190
Current smoker	17 (18)	9	8	
Nonsmoker	75 (82)	42	33	
Medication during hospitalization, no. (%)				0.0033
None	11 (12)	6	5	
A: Local (suppository, enema)	9 (10)	7	2	
B: 5-aminosalicylic acids, oral	27 (29)	21	6	
C: A and B	15 (16)	8	7	
Immunomodulator	30 (33)	9	21	
Prednisolone alone or with any combination of A, B, C, and tacrolimus	22	8	14	
Prednisolone and azathioprine and any combination of A, B, C, and CAP	6	1	5	
Azathioprine and B or C	2	0	2	
Corticosteroid dependent	5 (5)	1	4	0.0950
Previous proctocolectomy	0 (0)	0	0	
Hospitalization, d				
Range	7-125	13-125	7-121	
Mean (SD)	37 (27)	34 (25)	42 (29)	0.1142
Median (IQR)	29 (22-45)	25 (20-39)	32 (23-50)	
Follow-up period after discharge				
Mean (SD)	5 y 11 mo (4 y 3 mo)	5 y 2 mo (3 y 9 mo)	6 y 10 mo (4 y 7 mo)	0.0935
Median (IQR)	5 y 1 mo (2 y 2 mo-9 y 3 mo)	4 y 1 mo (2 y 1 mo-8 y 1 mo)	6 y 4 mo (2 y 8 mo-11 y 3 mo)	

<sup>a</sup> Comparison between initial attack cases and relapse cases ( $\chi^2$  test). CAP = cytopheresis; IQR = interquartile range; SD = standard deviation.

**Statistical Analysis**

Demographic parameters are expressed as mean and standard deviation (SD) and/or median (interquartile range), as appropriate. The frequency of categorical variables between initial episode cases and relapse cases was assessed using the  $\chi^2$  test. Chronologic changes in PBDS+, PBDS-, and PBDS in identical patients were compared using the paired *t*-test or Wilcoxon test. Kaplan-Meier survival analysis was used to calculate the cumulative proportion of patients who had a relapse. Comparison of cumulative relapse rates between initial episode cases and relapse cases was tested using the log rank test. All directional tests were 2-tailed. A *p* value  $\leq 0.05$  was considered statistically significant. Statistical analyses were performed using JMP 8 software (SAS Institute Inc, Cary, NC, USA).

**RESULTS**

**Patients**

A total of 179 patients with UC were admitted (Figure 1). Sixty-four cases of educational hospitalization were excluded. Ten surgical colectomy cases were excluded, of which 9 cases were relapses and 1 was an initial episode. Sixteen cases of IPF therapy were also excluded, but 3 of these cases overlapped with excluded colectomy cases (duplicates). Therefore, 92 cases were ultimately included in this study (Figure 1).

Demographic characteristics of the 92 patients are presented in Table 1. Of the 92 cases, 51 cases were initial episodes and 41 cases were relapses. The male-to-female ratio was 1:1 in both groups. The median age of the initial episode cases was 35 years, and the median age of the relapse cases was 36 years. Extensive colitis<sup>20</sup> was the most frequent extent with more than half of cases, followed by left-sided colitis and proctitis in both groups. Although moderate cases were most frequent and severe cases the least frequent in both groups, there were more severe cases among the relapse cases than among initial episode cases (*p* = 0.0346, Table 1). The difference between the mean disease duration for the initial episode cases (3 months) compared with that for the relapse cases (75 months) was statistically significant (*p* < 0.0001, Table 1).

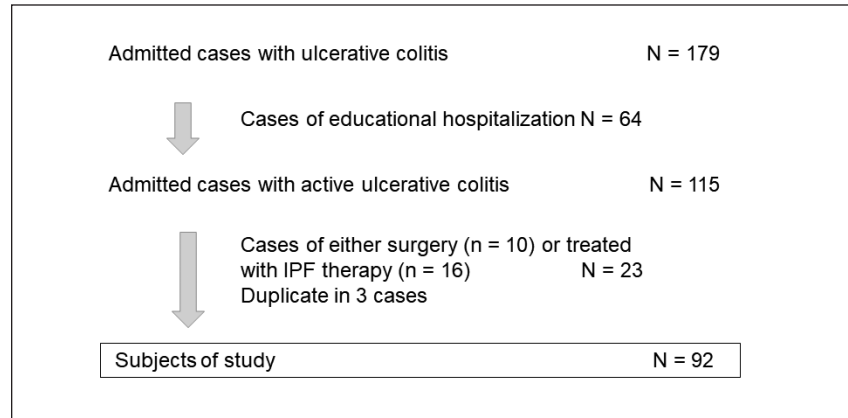


Figure 1. Enrollment of inpatients with ulcerative colitis. Cases of educational hospitalization were either mild in severity or in the quiescent phase (remission), and they did not need immediate treatment.<sup>10</sup> Admitted cases with active ulcerative colitis needed immediate treatment. Infliximab and a plant-based diet as first-line (IPF) therapy replaced glucocorticoid therapy for induction in severe or moderate cases since August 2012.

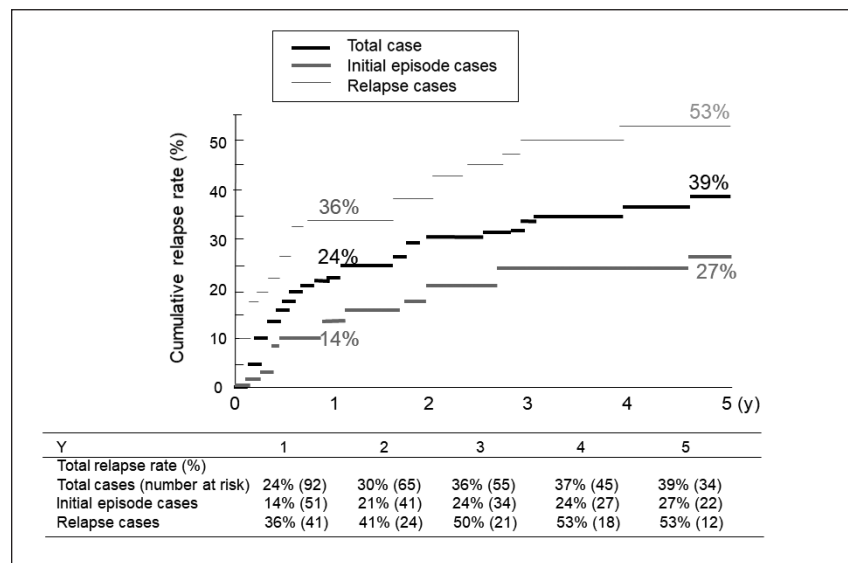


Figure 2. Cumulative relapse rates during follow-up after discharge for patients with ulcerative colitis. Log rank test between initial episode cases and relapse cases found *p* = 0.0318.

Medication was not provided during the hospitalization in 11 cases (12%). They were mild cases, except for 2 moderate cases. Adverse events caused by 5-aminosalicylic acid prescribed by referring physicians exacerbated 2 patients' diarrhea, and withdrawal of the drug therapy resulted in remission. Immunomodulators (systemic prednisolone and/or azathioprine) were used in 9 (18%) of 51 initial episode cases, whereas they were used in 51% of relapse cases (21 of 41 cases, Table 1).

Periods of hospitalization were shorter for initial episode cases (median = 25

days) than those for relapse cases (32 days). Median hospital days in non-medication cases (*n* = 11) was 15.0 days (interquartile range = 13-19 days). All 92 patients achieved remission or near-remission by the time of discharge. Of 10 patients excluded from this study because of colectomy, 1 patient was experiencing an initial episode of UC. The colectomy rate for initial episode cases during the first hospitalization was 1.9% (1/52). The median follow-up period for initial episode cases and relapse cases was 4 years 1 month and 6 years 4 months, respectively (Table 1).



## Efficacy

**Primary Endpoint: Relapse Rate:** The overall cumulative relapse rates at 1, 2, 3, 4, and 5 years of follow-up were 24%, 30%, 36%, 37%, and 39%, respectively. The cumulative relapse rates were 14%, 21%, 24%, 24%, and 27%, for each of those follow-up years, for the initial episode cases and 36%, 41%, 50%, 53%, and 53%, respectively, for the relapse cases (Figure 2). The relapse cases showed significantly higher relapse rates than the initial episode cases ( $p = 0.0318$ ). The mean time to relapse was 7 years 2 months for the initial episode cases and 4 years 3 months for the relapse cases.

**Secondary Endpoints:** Four patients were mistakenly not asked to respond to the food-frequency questionnaire. Therefore, baseline PBDS was determined on the basis of 88 patients. The mean (SD) baseline PBDS+, PBDS-, and PBDS were 23.2 (8.1), 11.9 (6.2), and 10.9 (9.3), respectively (Table 2). For 41 patients, at the median follow-up period of 1 year, respective scores were 33.0 (5.6), 3.7 (3.8), and 29.3 (7.6). These 3 values were significantly better than those at baseline ( $p < 0.0001$ , Table 2). In the other 41 patients, at the median follow-up period of 6 years 5 months, the respective scores were 26.9 (7.6), 7.5 (4.9), and 19.4 (9.0). These 3 values were significantly better than those at baseline:  $p = 0.0171$  for PBD score+ and  $p < 0.0001$  for PBD score- and PBD score (Table 2).

## Safety

All patients ate the PBD, and none experienced a serious adverse effect that could be suspected of being caused by a PBD.

## DISCUSSION

The cumulative relapse rates at 1 and 5 years in the initial episode cases after induction therapy incorporating PBD were 14% and 27%, respectively. The PBDS was significantly higher than baseline even at 6-year follow-up. The relapse rates were lower than those previously reported with conventional therapy in Europe. This difference is consistent with our hypothesis that this PBD prevents relapse of UC.

Relapsing and remitting are characteristic in the most patients with UC except for about 10% of patients with initial attack only.<sup>21</sup> Approximately 20% of patients will undergo colectomy within 10 years, and 30% within 25 years. Relapse is most frequent in the first year of diagnosis, followed by the second year after diagnosis. Thereafter, disease activity decreases over time.<sup>17,21,22</sup> The disease course in the preceding period is significantly correlated to the subsequent disease course.<sup>21</sup> Therefore, the relapse rate is influenced by the period of remission and disease duration of the patients before entry to a study; a longer remission period translates to a lower relapse rate. Consequently, the relapse rate is

best studied not by using patients with established UC that has been plaguing them for months to years but by studying patients who present with their first episode of UC.

Studies of relapse rates in inception UC cases are surprisingly scarce, but their available cumulative relapse rates are listed in Table 3.<sup>16,18,23-25</sup> The dates (1970-2011) of these reports are from before the era of biologic use. The treatment guidelines for the induction and maintenance of remission of initial presentations of UC remained unchanged. The cumulative relapse rate at 1 year was reported to be around 50% (44%-51%) in Norway, Netherlands, and Denmark.<sup>16,23,24</sup> The European Collaborative Study Group of Inflammatory Bowel Disease (EC-IBD) reported it to be 28%.<sup>18</sup> Our 14% cumulative relapse rate is far better than those reported.

If the number of severe cases decreases after colectomy during the induction phase, it might explain the low relapse rate in the follow-up period. Our colectomy rate during the induction phase was 1.9% (1/52). It was 0.6% (4/630) in a report from Romberg-Camps et al<sup>23</sup> and 1.1% (8/710) in a report from Burisch et al.<sup>26</sup> Therefore, it is unlikely that the colectomy rate influenced the relapse rate in the present study.

Some clinical and environmental factors are known to be associated with relapse; young age at diagnosis is associated and

**Table 2. Chronologic change in plant-based diet (PBD) score**

Timeframe	n	Follow-up (mo)		PBD score+		p value	PBD score-		p value	PBD score (sum)		p value
		Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		Mean (SD)	Median (IQR)		Mean (SD)	Median (IQR)	
Baseline	88	—	—	23.2 (8.1)	24.0 (17.0-28.8)		11.9 (6.2)	12.0 (8.0-16.8)		10.9 (9.3)	12.0 (4.0-17.0)	
<b>Follow-up<sup>a</sup></b>												
Short term	41	14.8 (7.6)	12.0 (10.5-24.0)	33.0 (5.6)	33.0 (28.0-38.0)	< 0.0001 <sup>b</sup>	3.7 (3.8)	3.0 (0.5-6.0)	< 0.0001 <sup>b</sup>	29.3 (7.6)	31.0 (24.0-36.0)	< 0.0001 <sup>b</sup>
Baseline	41			23.9 (7.6)	26.0 (17.5-29.0)		11.9 (5.2)	12.0 (9.0-16.5)		12.0 (8.7)	12.0 (0-15.0)	
Long term	41	80.4 (36.6)	76.5 (43.8-110.8)	26.9 (7.6)	26.0 (21.0-33.5)	0.0171 <sup>b</sup>	7.5 (4.9)	7.0 (3.5-10.0)	< 0.0001 <sup>b</sup>	19.4 (9.0)	20.0 (12.5-25.5)	< 0.0001 <sup>b</sup>
Baseline	41			24.7 (7.0)	25.0 (21.0-28.5)		13.0 (5.2)	12.0 (9.0-17.0)		11.7 (8.8)	13.0 (6.0-17.0)	

<sup>a</sup> Patients with short-term PBD score (n = 41) and those with long-term PBD score (n = 41) were different: 24 patients overlap.

<sup>b</sup> p value obtained with paired t-test or Wilcoxon test.

IQR = interquartile range; SD = standard deviation.

smoking is inversely associated with relapse.<sup>27</sup> These factors are shown in Table 3, and it is unlikely that they explain our favorable outcomes.

Mucosal healing has been recently recommended as the goal of IBD treatment.<sup>28</sup> Patients with mucosal healing have better prognosis than those without mucosal healing in regard to relapse rate, admission rate, and colectomy rate. However, mucosal healing is achieved in only about one-third (88 of 298) of treated patients with UC.<sup>29</sup> In addition, the mucosal healing rate increases along with a longer clinical remission: 30%, 45.9%, and 62.9% for clinical remission less than 1 year, 1 to 3 years, and more than 3 years, respectively.<sup>30</sup> Mucosal healing was not discussed in other reports of inceptive cases.<sup>16,18,23-25</sup>

The large difference between most practices worldwide and our practice lies in our greater propensity to hospitalize initial cases of UC. The current international guideline recommends hospitalization only for severe cases.<sup>11</sup> Mild or moderate cases are treated on an outpatient basis. Our cases, even mild cases, were treated on an inpatient basis. In most of the patients, there was no hesitation about admission because they were aware of the abnormality and wanted to be treated. Hospitalization provides an excellent opportunity to implement and teach PBD. This difference in practice could explain the difference in relapse rates between our cohort and those of other authors (Table 3).

Meat and alcohol were reported to be associated with relapse of UC in a follow-up study,<sup>31</sup> and legumes and potatoes were inversely associated.<sup>32</sup> Our PBD is

consistent with these observations: Meat and alcohol are limited, and legumes and potatoes are recommended. In this study, PBDS+ and PBDS- in the short-term (median = 1 year) were significantly higher and lower than baseline, respectively. Consequently, PBDS was significantly higher than baseline. Similarly, significantly higher PBDS than baseline was observed even in the long-term (median = 6 years 5 months, Table 2). On the basis of median PBDS 31.0 and 20.0 in the short term and long term respectively, it seems that patients tend to lose their determination to stay on the PBD over time. This illustrates the difficulty of maintaining PBD lifelong. On the other hand, patients experienced normalization of diarrhea and/or bloody stool while on the PBD in the hospital setting, leading to appreciation of the PBD and its benefits. It was frequently heard that adherence to the PBD improved when patients feared relapse. Hospitalization seemed to enhance their self-management skills. We speculate that experience and appreciation of PBD during hospitalization contributed greatly to prevention of relapse.

The relapse rate for initial episode cases at 1 year (14%) in this study was higher than that for cases of educational hospitalization (4%) in a prior study.<sup>10</sup> The study participants were different. Participants who underwent educational hospitalization were patients with mild

UC or in remission who did not need immediate treatment.<sup>10</sup> In the present study, participants were in the active phase with severity ranging from mild to severe. Although there are reports that the severity at diagnosis is irrelevant to the relapse rate,<sup>33</sup> our data indicate that severe cases tend to relapse more than do mild cases. Significantly higher relapse rates in relapse cases (at 1 year: 36%) than in initial episode cases (14%, Figure 2) could be also explained by the difference in severity between subjects (Table 1).

Of note, medication was not provided in 11 cases in the present study. Two of the 11 cases were moderate in severity. Adverse events caused by 5-aminosalicylic acid-exacerbated diarrhea, and withdrawal of the drug resulted in remission. The other 9 patients not receiving medication were mild in severity, similar to cases of educational hospitalization.<sup>10</sup> They achieved remission in about 2 weeks. We further confirmed a previous observation: A subset of patients with mild UC achieve remission by replacing an omnivorous diet with PBD. The proportion was about one-third of mild cases (9/31).

Our study had some limitations. There was no control group, and the sample size was small. Although PBDS is available for each patient at baseline, the PBDS was developed at the late stage of the study.<sup>8</sup> Therefore, short- and long-term chronic changes in PBDS were not obtained from the same patients. Patients with

... patients experienced normalization of diarrhea and/or bloody stool while on the PBD in the hospital setting, leading to appreciation of the PBD and its benefits.

**Table 3. Cumulative relapse rate at 1 and 5 years for patients presenting with their first episode of ulcerative colitis**

Source	Country of study	Subjects			Cumulative relapse rate, %	
		Study period	Age, y	Current smoker, % (n/N)	1 y	5 y
Moum et al, 1997 <sup>16</sup>	Norway	1990-1993	NA	14	50	NA
Höie et al, 2007 <sup>18</sup>	7 European countries, Israel	1991-1993	NA	12.6 (97/771)	28 <sup>a</sup>	58 <sup>a</sup>
Romberg-Camps et al, 2009 <sup>23</sup>	Netherlands	1991-2003	Mean = 42.0	NA	44	NA
Vester-Andersen et al, 2014 <sup>24</sup>	Denmark	2003-2004	Median = 37.3 (IQR = 1.5-93.5)	15 (45/300)	51	75
Kitano et al, 2011 <sup>25</sup>	Japan	1970-2011	Mean = 28.5 (SD = 38.5)	NA	68.1	NA
Chiba et al, 2018 <sup>10</sup>	Japan	2003-2016	Median = 34 (IQR = 22-51)	NA	4	17
Present study	Japan	2003-2017	Median = 35 (IQR = 22-56)	18 (9/51)	14	27

<sup>a</sup> Estimated from a Kaplan-Meier plot.

<sup>b</sup> Cases of educational hospitalization provided a plant-based diet.

IQR = interquartile range; NA = not available; SD = standard deviation.

short-term PBDS ( $n = 41$ ) and those with long-term PBDS ( $n = 41$ ) were different: 24 patients overlap (Table 2). Comparison of PBDS at 3 time points—baseline, short-term, and long-term—from the same patients would have been more appropriate.

Many other modern diseases are chronic and caused by an unhealthy lifestyle,<sup>34,35</sup> of which diet is one component. Therefore, treating these diseases only with medication and surgery will not be able to prevent or fully resolve them unless we also address the problematic lifestyle. Bodai et al<sup>35</sup> described the dramatic effect and the need for lifestyle medicine in a variety of chronic diseases. Our modality is indeed lifestyle medicine.<sup>36</sup>

Changes in lifestyle including dietary habits are not easy.<sup>37</sup> Considering that maximum weight loss typically is greatest 6 to 12 months after initiation of a weight loss diet, with steady regaining of weight subsequently,<sup>38,39</sup> significant adherence to PBD compared with the baseline even 6 years later in this study was remarkable. We believe that hospitalization plays a critical role in replacement of an omnivorous diet with PBD. Hospitalization helps limit risk factors for IBD and our health such as smoking, alcohol, sweets, and animal foods, and patients benefit from preventive factors every day such as intake of vegetables and fruits. Although most of the developed world restricts hospitalization to severe cases and surgical intervention, mostly treating mild cases and educational interventions on an outpatient basis, hospitalization can be an effective approach for dietary replacement in lifestyle medicine.

## CONCLUSION

The relapse rate for initial episode cases of UC after treatment incorporating PBD on an inpatient basis during the induction phase was 14% at 1 year and 27% at 5 years, which were far lower than those reported with conventional treatment. Significantly higher PBDS was observed compared with baseline even after 6 years of follow-up. A PBD was found to be effective in prevention of UC relapse, and hospitalization seemed to be effective at inducing habitual dietary changes. ❖

## Disclosure Statement

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

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Kathleen Loudon, ELS, of Loudon Health Communications performed a primary copy edit.

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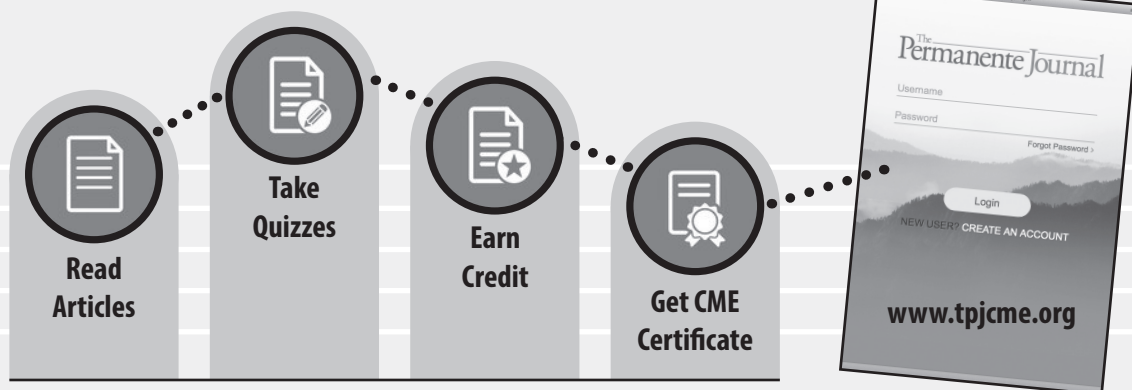
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**View from Hospital Window—Spring**  
photograph



**View from Hospital Window—Winter**  
photograph

**Lewis Mehl-Madrona, MD, PhD**

In a series of 4 photographs taken from his hospital window in the residency program training area, Dr Mehl-Madrona documents his view of the river through the changing seasons. Spring and Winter are shown here. Dr Mehl-Madrona says, "I find the river fascinating in all of its manifestations and a constant source of inspiration and peace for all of us."

Dr Mehl-Madrona is a Faculty Physician at the Eastern Maine Medical Center in Orono, ME, and an Associate Professor at the University of New England College of Osteopathic Medicine in Biddeford, ME.

## ORIGINAL RESEARCH &amp; CONTRIBUTIONS

# Progel Use is Not Associated with Decreased Incidence of Postoperative Air Leak after Nonanatomic Lung Surgery

Rebecca C Gologorsky, MD<sup>1</sup>; Amy L Alabaster<sup>2</sup>; Simon K Ashiku, MD<sup>2</sup>; Ashish R Patel, MD<sup>2</sup>; Jeffrey B Velotta, MD<sup>2</sup>

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<https://doi.org/10.7812/TPP/18-059>**ABSTRACT**

**Context:** Progel Pleural Air Leak Sealant (CR Bard, Warwick, RI) is a US Food and Drug Administration-approved hydrogel designed for application to surgical staple lines to prevent air leak after lung surgery. This product has demonstrated efficacy in reducing intraoperative air leaks compared with standard air leak closure methods. However, the impact on chest tube duration and length of hospital stay has not been reported.

**Objective:** To evaluate the effect on rates of postoperative air leak, chest tube duration, and hospital stay in surgical patients with and without use of Progel.

**Design:** Retrospective study of 176 patients aged 18 to 80 years who underwent video-assisted thoracoscopic wedge resections between 2014 and 2016. Eighty-four (48%) cases using Progel were included, as well as a representative sample of non-Progel cases (n = 92; 52%).

**Main Outcome Measure:** Presence of postoperative lung air leak.

**Results:** No difference existed between the Progel and non-Progel groups in the rate of postoperative air leak (20/84, 23.81% Progel; 16/92, 17.39% non-Progel; p = 0.33). The length of time patients had a chest tube was similar (23.5 vs 23 hours, p = 0.721), as was percentage of patients with a less than 2-day hospitalization (77.17% non-Progel vs 82.14% Progel, p = 0.414).

**Conclusion:** Our results suggest that Progel, used routinely in patients undergoing non-anatomic lung resection, does not have a significant impact on postoperative air leak, chest tube duration, or length of hospital stay. Further studies are warranted to evaluate the utility of Progel in reducing postoperative complications after thoracoscopic wedge resection in those treated for air leak or in the reduction of postoperative air leak in high-risk patients.

air leak after lung surgery. In a single prospective, randomized clinical trial, this product has demonstrated efficacy in reducing intraoperative air leaks during open, anatomic and nonanatomic lung resections compared with standard air leak closure methods, as well as in decreasing length of hospital stay.<sup>6</sup> A second study, a retrospective chart review of patients undergoing open or minimally invasive, anatomic or nonanatomic lung resections reported decreased rates of postoperative air leak and chest tube duration. Again, Progel was used only on patients with visible intraoperative air leak.<sup>7</sup> The utility of Progel in video-assisted thoracoscopic surgery and nonanatomic resections has not been determined, to our knowledge.

We performed a retrospective analysis of patients who underwent video-assisted thoracoscopic wedge resections with and without the use of Progel to evaluate the effect on the rate of postoperative air leak, chest tube duration, and hospital stay.

**INTRODUCTION**

Postoperative parenchymal air leak is one of the most common complications of lung surgery and when prolonged may result in substantial morbidity and mortality. The incidence of air leak after nonanatomic lung resection is variably reported to be between 30% and 60%, and *prolonged air leak*, defined as persisting greater than 4 days after surgery, has an incidence of 5% to 10%.<sup>1,2</sup> Intraoperative air leaks are not typically clinically significant and resolve spontaneously within hours of surgery by apposition of the lung to the parietal pleura. However, persistent air leaks increase the length of hospital stay, duration

of chest tube use, expense to hospitals and patients, and risk of other postoperative complications such as pneumonia and empyema.<sup>3,4</sup> Air leak after lung resection has been described as the most important factor in determining the length of postoperative hospital stay.<sup>2</sup>

Several intraoperative maneuvers, such as use of buttressed staples, oversewing staple lines, and use of sealants, are often employed. However, the utility of each method is poorly understood. Cochrane Database Review meta-analyses report that sealants reduce postoperative air leak and chest tube duration but have no effect on length of hospital stay.<sup>5</sup> However, these reports evaluate multiple studies simultaneously and do not distinguish type of sealant used, protocol followed, or type of surgical procedure performed.

Progel Pleural Air Leak Sealant (CR Bard, Warwick, RI, formerly by NeoMend Inc) is a US Food and Drug Administration-approved hydrogel designed for application to surgical staple lines to prevent

**METHODS**

We performed a retrospective study of patients aged 18 to 80 years who underwent video-assisted thoracoscopic wedge resections performed by board-certified thoracic surgeons from 2014 to 2016. Surgeries were performed at 1 of more than 10 hospitals within a single institution. We initially identified 491 qualifying wedge resections performed by 4 surgeons known to use Progel sealant. Eighty-four cases using Progel were identified by searching for the terms *Progel*, *sealant*, or *glue* in the operative report and then verified by close clinical review. A random sample of 92 Progel-unexposed patients were chosen from the remaining cases using a proportional sampling method stratified by surgeons (Figure 1). Progel was used at the discretion of the operating surgeon, whether or not a visible intraoperative air leak was present. Patients were excluded after careful clinical review if they had

**Author Affiliations**

<sup>1</sup> University of California, San Francisco-East Bay Department of Surgery, Oakland, CA

<sup>2</sup> Kaiser Oakland Medical Center, CA

**Corresponding Author**

Jeffrey B Velotta ([jeffrey.b.velotta@kp.org](mailto:jeffrey.b.velotta@kp.org))

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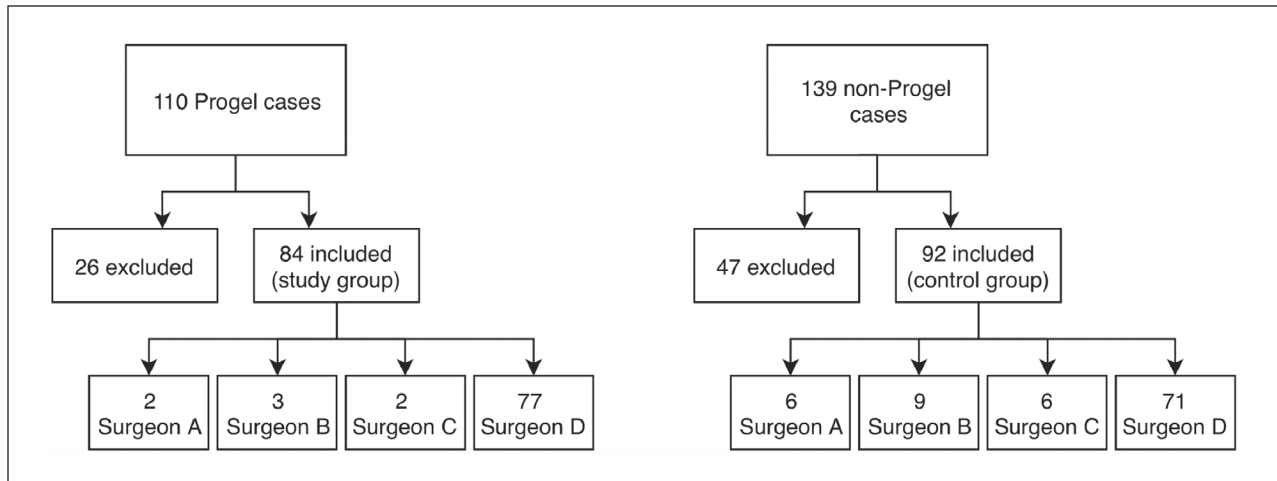


Figure 1. Patient selection for Progel and non-Progel groups.

other forms of staple line reinforcement, pleurodesis, open surgery, or postoperative positive pressure ventilation. The study was approved by the Kaiser Permanente Northern California institutional review board.

When used, Progel was applied to staple lines in an even coat, in the manner indicated by the manufacturer. All patients received chest tubes intraoperatively, which were placed to  $-20$  mmHg suction. Each patient underwent an upright plain film of the chest within 90 minutes of completion of surgery to evaluate chest tube location and for presence of pneumothorax. Chest tube removal was performed when patients demonstrated no *air leak*, defined as air passing through the water seal chamber, and no clinically significant pneumothorax. Patient comorbidities were indexed, including type 2 diabetes mellitus and chronic obstructive pulmonary disease, as was a history of thoracic radiotherapy, exposure to chemotherapy, or ipsilateral thoracic surgery.

Patient characteristics by Progel exposure status were described and compared using  $\chi^2$  or Fisher exact test for categorical variables and the Kruskal-Wallis test for continuous variables.

The primary endpoint was the presence of postoperative lung air leak identified at any time during hospitalization. Secondary endpoints included postoperative *pneumothorax* (defined as pneumothorax seen on chest radiography performed within 90 minutes of surgery completion), length of time with chest tube, discharge

to home with chest tube, length of hospital stay, 30-day readmission, 30-day pneumothorax, and 30-day mortality. Patient outcomes by Progel exposure status were compared using the same bivariate statistics described in the previous paragraph.

## RESULTS

Clinical features of both Progel-exposed and unexposed groups are shown in Table 1. The median patient age was 66 years for the unexposed group and 65 years for the Progel-exposed group. Most patients in both groups underwent surgery for removal of a lung nodule. Both groups were evenly divided between men and women. Type 2 diabetes mellitus was the most common of the tracked comorbidities, affecting approximately one-fourth of both groups. After exclusions were made, 77.17% of Progel-unexposed surgeries and 91.67% of Progel-exposed surgeries were done by a single surgeon (Table 1). There were no further statistical or clinically relevant differences in demographics, diagnoses, history, or indication for surgery in comparing Progel-exposed and unexposed groups. Two patients in the Progel group (2.38%) had an intraoperative air leak, 1 of whom also had a postoperative air leak. No patients in the non-Progel group had a documented intraoperative air leak ( $p = 0.2264$ ).

No statistically significant difference between patients who did or did not receive Progel was found in the primary endpoint or any secondary endpoint (Table 2).

Patients in the control and study groups had similar rates of postoperative air leak (20/84, 23.81% in the Progel group; 16/92, 17.39% in the unexposed group;  $p = 0.33$ ). Approximately half of these air leaks were clinically significant, defined as necessitating discharge to home with a chest tube in place (9.52% of Progel group vs 6.67% of unexposed group,  $p = 0.49$ ). Thirty-four patients in each group had a pneumothorax visible on chest radiography performed in the upright position within 90 minutes of surgery completion ( $p = 0.632$ ). Operative mortality was 1% in both unexposed and Progel-exposed groups and was secondary to ischemic stroke and colonic perforation in the setting of high-dose corticosteroid administration. This study was not powered to detect variation in outcomes stratified by comorbidities.

## DISCUSSION

Postoperative air leak after lung resection is a common complication, with a reported incidence as high as 60%.<sup>1-3</sup> Reduction of postoperative air leak is a significant target to reduce morbidity and cost associated with lung surgery.<sup>3</sup> There are several methods designed to reduce the incidence of air leak, including use of buttressed staples and sealants. Progel is a hydrogel sealant intended for intraoperative application to staple lines to reduce air leaks. It is applied with a blunt syringe, readily adheres to lung parenchyma, and stretches as the lung is reinflated, allowing maintenance of staple line coverage.

Studies evaluating its efficacy are limited, but the results suggest its use is associated with reduced intraoperative air leak for open anatomic lung resections, and with superiority to use of buttressed staples and staple line reinforcement with sutures. A single retrospective study of 121 consecutive patients who underwent any type of lung surgery and demonstrated

an intraoperative air leak with or without use of Progel showed marked reduction in postoperative air leak, chest tube duration, and length of hospital stay.<sup>7</sup>

The use of Progel has not been studied specifically in patients undergoing non-anatomic lung resection or video-assisted thoracoscopic surgery. To our knowledge, no study has evaluated the prophylactic

use of Progel in this patient population. We evaluated 176 patients undergoing video-assisted thoracoscopic wedge resection with or without the use of Progel, regardless of visible intraoperative air leak. No statistical or clinically meaningful difference was demonstrated in the rates of postoperative air leak, chest tube duration, or length of hospital stay between the 2 groups. Complication rates between the study and unexposed groups were similarly low. Routine use of Progel as a prophylactic agent to prevent postoperative air leak and to reduce hospitalization time is not supported by this study.

This study is limited by study size, which was not powered to detect variation in outcomes related to comorbidities. Although there was no statistically significant difference between participating surgeons, there was a trend toward significance ( $p = 0.078$ ), despite sampling efforts employed to ensure a similar distribution by surgeon. Unequal case distribution between surgeons could introduce selection bias, and it limits generalizability of the outcomes.

There were 2 Progel-exposed patients for whom intraoperative air leak was noted, 1 of whom also had a postoperative air leak. The absence of intraoperative air leak in the non-Progel group may represent a source of selection bias. However, the number of patients with a postoperative air leak was exponentially higher than the small number of patients with an intraoperative air leak, which minimizes this effect and questions the association between the presence of intraoperative and postoperative air leaks. Equalization of postoperative outcomes despite the higher incidence of intraoperative air leak may be suggestive of a benefit to the use of Progel. Patients in the Progel and non-Progel groups had similar rates of postoperative air leak, few of which affected clinical management. It is possible that low rates of clinically significant postoperative air leak further limited the study power, although the proportions are very similar. Variability in the time from decision to remove a chest tube to the time of removal may also skew the mean chest tube duration. Furthermore, this patient group underwent thoracoscopic wedge resection for diagnosis of interstitial lung disease or for

**Table 1. Descriptive characteristics of the Progel<sup>a</sup> and non-Progel cohorts**

Descriptor	Non-Progel (n = 92, 52.27%)	Progel (n = 84, 47.73%)	p value <sup>b</sup>
Age, y			
Median	66.5	65.0	0.568
Interquartile range	60-71	55-71.5	
Sex, no. (%)			
Women	47 (51.09)	41 (48.81)	0.763
Men	45 (48.91)	43 (51.19)	
Diagnoses and History, no. (%)			
History of radiation	4 (4.44)	4 (4.76)	> 0.99
History of chemotherapy	3 (3.33)	5 (5.95)	0.485
History of thoracic surgery	0 (0)	3 (3.57)	0.110
History of DM type 2	25 (27.78)	21 (25.00)	0.678
COPD	12 (13.33)	12 (14.29)	0.856
Indication for surgery, no. (%)			
Interstitial lung disease	32 (34.78)	25 (29.76)	0.477
Nodule	60 (65.22)	59 (70.24)	
Surgeon, no. (%)			
A	6 (6.52)	2 (2.38)	0.078
B	9 (9.78)	3 (3.57)	
C	6 (6.52)	2 (2.38)	
D	71 (77.17)	77 (91.67)	

<sup>a</sup> Progel Pleural Air Leak Sealant (CR Bard Inc, Warwick, RI).

<sup>b</sup> Categorical p values calculated using  $\chi^2$  or Fisher exact test; continuous p values calculated using Kruskal-Wallis test. COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus.

**Table 2. Postoperative and 30-day outcomes among Progel<sup>a</sup> and non-Progel cohorts**

Outcome, no. (%) unless noted otherwise	Non-Progel, n = 92 (%)	Progel, n = 84 (%)	p value <sup>b</sup>
Intraoperative leak	0 (0)	2 (2.38)	0.226
Postoperative pneumothorax	34 (36.96)	34 (40.48)	0.632
30-dy pneumothorax	1 (1.12)	0 (0)	> 0.99
Postoperative leak	16 (17.39)	20 (23.81)	0.326
30-d readmission	8 (8.89)	4 (4.76)	0.283
30-d mortality	1 (1.12)	1 (1.19)	> 0.99
Discharge with chest tube	6 (6.67)	8 (9.52)	0.489
Length of stay < 2 d	71 (77.17)	69 (82.14)	0.414
Chest tube duration, h			
Median	23.5	23	0.721
Interquartile range	20-29	20-27	

<sup>a</sup> Progel Pleural Air Leak Sealant (CR Bard Inc, Warwick, RI).

<sup>b</sup> Categorical p values calculated using  $\chi^2$  or Fisher exact test; continuous p values calculated using Kruskal-Wallis test.



nodule resection. The broad inclusion criteria could mask a statistically significant result among patients with certain pulmonary pathologic findings or comorbidities.

## CONCLUSION

Future studies should evaluate the utility of Progel to reduce postoperative air leak by surgery type, in open vs video-assisted thoracoscopic surgery, and in patients with elevated risk of postoperative air leak. Patients with comorbidities that increase the risk of air leak are at particular risk of prolonged postoperative air leak, including those with chronic obstructive pulmonary disease, with impaired wound healing, or those receiving positive pressure ventilation. Understanding the potential benefit of lung sealant in these patients would be of particular utility. Additionally, Progel should be evaluated against other established methods to reduce postoperative air leak, including buttressed staples and over-sewing. Chest tube duration, length of stay,

and cost should be secondary endpoints in follow-up studies. Additional studies with greater power are required to determine efficacy in reducing complications when Progel is used prophylactically. ❖

## Disclosure Statement

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

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## Five Things

Five things are proper to the duty of a Chirurgien: To take away that which is superfluous; to restore to their places such things as are displaced; to separate those things which are joined together; to join those things that are separated; and to supply the defects of nature.

— Ambroise Paré, 1510-1590, French barber surgeon

# “Prevention Produce”: Integrating Medical Student Mentorship into a Fruit and Vegetable Prescription Program for At-Risk Patients

Jane Marie Forbes, MD<sup>1</sup>; Cameron Russell Forbes, MD<sup>1</sup>; Erik Lehman, MS<sup>2</sup>; Daniel R George, PhD<sup>1</sup>

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## ABSTRACT

**Introduction:** Fruit and vegetable prescription (FVRx) programs provide increased access to produce to food-insecure, at-risk populations, yet many lack the educational and social components to support long-term disease prevention.

**Objectives:** To address these barriers, students at Penn State College of Medicine designed “Prevention Produce”—a modified FVRx program that integrated a community-based, month-long educational curriculum—and undertook preliminary evaluation.

**Methods:** Nine families deemed by clinicians as at risk of chronic disease and food insecurity received weekly \$40 “prescriptions” for produce at partnering farmers markets. Participants were paired with medical student mentors who delivered weekly nutrition education modules and assisted in produce shopping. Preprogram and postprogram surveys were administered, categorizing perceptions and practices of healthy eating. All participants were interviewed by phone 3 years later to assess long-term impact. Medical students provided written reflections via online survey.

**Results:** Postprogram fruit and vegetable consumption increased, and more patients expressed efforts to include produce in every meal. More participants strongly agreed that fruits and vegetables prevented chronic diseases. In reflective interviews, participants praised the program’s ease of use, mentor-patient relationship, and increased access to produce. Student mentors expressed gratitude for one-on-one interaction and felt empowered to learn and deliver nutrition education.

**Conclusion:** Integration of an FVRx program with education, mentorship, and community-based focus may increase produce consumption and improve opinions about healthy eating. This program serves as a model for integrating preventive strategies within larger health care systems. Additionally, the model can facilitate early clinical interventions that may benefit medical trainees’ professional development.

## INTRODUCTION

Fruit and vegetable prescription (FVRx) programs<sup>1</sup> are emerging as clinical-community interventions to address the epidemic of obesity-related chronic disease in the US and to strengthen prevention efforts.<sup>2,3</sup> Such programs allow clinicians to “prescribe” fruits and vegetables via vouchers that can be redeemed for produce at participating farmers markets, grocery stores, and Community Supported Agriculture (CSA) programs. Several studies have found an increase in consumption of fruit and vegetables as a

result of giving at-risk patients subsidized coupons to farmers markets.<sup>4,5</sup> However, access to produce does not appear to be in itself sufficient to promote long-term behavioral changes surrounding healthy eating habits,<sup>6</sup> and studies on government-subsidized coupons for fresh produce have shown that nutrition education is needed to increase utilization.<sup>7-9</sup> Meaningful change resulting from FVRx and other food access programs requires other contextual barriers to be addressed for at-risk patients, including lack of time, inadequate cooking skills/equipment, resistance to change, lack of motivation, lack of social/household support, and environmental barriers (eg, food deserts).<sup>10-14</sup> Efforts to improve nutrition cannot be confined to the clinical setting alone.

Indeed, it has been established that almost 60% of physicians spend between 13 minutes and 24 minutes with

each patient,<sup>15</sup> an inadequate amount of time to properly and effectively address diet and nutrition education in patients with chronic disease, let alone other social- and community-oriented preventive strategies that might address contextual barriers for patients. As such, there is a clear need to develop comprehensive community-based interventions outside the clinic that can augment the benefits of increased access to produce through FVRx programs.<sup>16,17</sup>

One such model, Prevention Produce, was developed by students at Penn State College of Medicine. Building on the traditional FVRx model, Prevention Produce offers vouchers for fruits and vegetables to participants living in US Department of Agriculture (USDA)-identified “food deserts” but includes an additional intervention: A month-long, one-on-one weekly mentorship by medical students, formal education and shopping sessions at a farmers market, and inclusion of family members to provide additional infrastructure supporting behavioral change. Although the feasibility of the model has been established,<sup>18</sup> evaluation of the program has not yet been undertaken. This study undertook a preliminary evaluation to begin understanding how participation in a more comprehensive program such as Prevention Produce might change behaviors and perceptions about healthy eating. Additionally, we sought to assess the effects of an early mentorship experience on the professional development of medical students.

## METHODS

### Study Site

This pilot program was conducted in partnership between the Penn State Hershey Medical Center (PSHMC) in Hershey, PA, and 2 farmers markets located within 10 miles of the hospital: The Farmers Market in Hershey (PA), and the

### Author Affiliations

<sup>1</sup> Penn State College of Medicine, Hershey, PA

<sup>2</sup> Public Health Sciences at Penn State College of Medicine in Hershey, PA

### Corresponding Author

Jane Marie Forbes (jtrinkkeller@pennstatehealth.psu.edu)

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Broad Street Market in Harrisburg, PA. The PSHMC is a Level I pediatric and adult trauma center and academic hospital serving 8 counties in central Pennsylvania. The Farmers Market in Hershey is a seasonal market open from May through October, located across from PSHMC. The Broad Street Market is a year-round farmers market. All aspects of the study were approved by the Penn State College of Medicine institutional review board.

### Study Sample and Recruitment

In 2015, we began recruiting families or individuals aged 5 to 75 years who were existing patients in the Penn State Health system identified by their primary care physician as being at risk of chronic illness or metabolic disease. Difficulty obtaining fruits and vegetables, as determined by their primary care physician or care manager, also served as a strict inclusion criterion. Patients who were not local, not able or willing to meet at the farmers markets, unable to complete the required surveys, or non-English speaking were excluded. After giving informed consent, 10 families were enrolled in the pilot program and were paired with medical students who served as nutrition mentors and were trained to deliver a curriculum at the farmers markets. The sample size for this study was not powered for statistical significance.

### Mentor Training and Curriculum

Each medical student underwent an orientation and training with project leaders that included logistics of the program and a review of nutrition concepts. Each mentor was given a curriculum designed by medical student leaders that consisted of learning objectives, recipes, and optional shopping lists revolving around weekly themes. The curriculum was developed using USDA MyPlate resources and basic nutrition concepts regarding vitamins and minerals, differences between healthy and unhealthy carbohydrates and fats, glycemic index/load, and the relationship between dietary intake and the development of chronic disease.

### Market Intervention

For the duration of the 6-week program, participants met with their medical student mentors for 4 farmers market

visits as was convenient in the participants' schedules. During each visit, students outlined specific educational modules addressing the curriculum topic of the week. The families then exchanged their "prescription" vouchers to receive \$40 of tokens to be spent on produce, along with an optional healthy recipe and shopping list. Student mentors accompanied families to the market, helping them shop for fresh produce and answering additional questions regarding healthy eating. Visits lasted an average of 1 hour.

### Data Collection and Interpretation

Before their participation in the program, the head of each household completed a program survey, which included demographic information, frequency of fruit and vegetable consumption, exercise frequency, and perceptions and practices of healthy eating and food preparation. Questions were compiled from several standardized survey instruments: The 2012 USDA Household Food Security Survey Module,<sup>19</sup> the 2011 Behavioral Risk Factor Surveillance System questionnaire from the Centers for Disease Control and Prevention (modified to a self-administered format),<sup>20</sup> the 2007 Health Survey for England survey,<sup>21</sup> and the 2011 CookWell initiative survey.<sup>22</sup> The same survey was also administered at the conclusion of the program. Although not specifically addressed in the curriculum, we also assessed whether or not exercise behaviors changed throughout the course of the program using a simplified version of the 2002 International Physical Activity Questionnaire.<sup>23</sup> Additionally, medical student mentors were given an online survey approximately 1 year after program completion assessing via free-form response the weaknesses and strengths of the program as well as what they perceived to be the most important benefits to both themselves and the patients. Patient participants were also contacted for follow-up via phone interview approximately 3 years after program completion for subjective comments on their overall experience and the long-term impact of the program. Interviews were digitally recorded and transcribed.

Survey questions regarding food preparation/cooking skills and opinions on healthy eating were administered on a

5-item Likert-type scale. The responses were assigned a value of 1 to 5, with "strongly agree" valued at 1 and "strongly disagree" valued at 5. Survey responses regarding fruit and vegetable consumption were based on frequency of consumption for the previous month and were assigned values of none, less than once per week, 1 to 6 times per week, once per day, and greater than once per day. The responses were divided for analysis by consumption of 1 or more times per week, except for fresh fruit consumption, which was divided by 1 or more times per day. Questions regarding exercise behavior were analyzed by assigning a value of 0 to 7 to the number of days engaged in activity. Because of the small sample size of this pilot study, analyses for statistical significance were not of value.

Qualitative data from medical student and participant reflection were read over and thematically analyzed by the research team. Apposite quotes were selected to provide insight into each major theme.

## RESULTS

### Demographics

Nine of the 10 families completed the pilot program, with 4 men and 5 women serving as head of household. One family could not complete the program because of scheduling constraints. Six identified as "African-American or black," 2 identified as "Caucasian [white]," and 1 wished to have race remain unidentified. Six participants indicated a total family income below \$40,000; 2 between \$50,000 and \$59,000, with 1 remaining participant not wishing to disclose this information. All 9 participants had seen their primary care physician within the last 6 months. Self-rating of health quality before the program was rated as "good" by 4 participants and "fair" by 3 participants.

### Food Insecurity and Barriers

All respondents received a score denoting "low food security" according to the USDA's 6-item US Household Food Security Survey Module,<sup>19</sup> with 1 participant scoring "very low food security." With regard to the query about the biggest obstacles to eating fresh food, the top response was "affordability" (77.8%) followed by "lack of desire" (22.3%).

**Views about Healthy Eating, Food Preparation, and Cooking Skills**

The comparison between pre- and postprogram responses to statements regarding the effects of fruits and vegetables on overall health is detailed in Table 1 along with views on food preparation and cooking skills.

Of note, all respondents either agreed or strongly agreed that eating fruits and vegetables is “satisfactory,” “essential,” and “tasty.” After the program, more participants strongly agreed with the statements that “fruits and vegetables kept them from getting sick” (25% preprogram vs 78% postprogram; preprogram median 2.00 vs postprogram median 1.00) and “prevented chronic diseases” (50% preprogram vs 78% postprogram; preprogram median 1.50 vs postprogram median 1.00). In general, participants were willing to try new foods, would rather cook their meals, and were trying to incorporate fruits and vegetables in every meal. Notably, 78% of participants strongly agreed they felt “more confident” in cooking a main dish from a recipe after the program vs 50% before the program (median = preprogram 1.50, postprogram 1.00).

**Fruit and Vegetable Consumption**

Differences between before and after the program were based on daily consumption for fruits and weekly consumption for vegetables (Table 2).

Daily fresh fruit consumption increased from 37.5% before the program to 62.5% after the program. Green vegetable consumption of at least once per week increased from 62.5% to 87.5%, as did orange-colored vegetable consumption from 38% to 87.5%. “Other” vegetable consumption also increased, with more respondents reporting consumption of greater than 1 per week from 75% to 100% day (from 13% to 33%). Fruit juice consumption decreased, with more participants reporting “never” after the program (25% preprogram vs 44% postprogram).

**Exercise Behavior**

Differences between pre- and postprogram medians are detailed in Table 3. Of note, more participants were involved in vigorous exercise for 3 days or more after

the program (44% postprogram vs 12% preprogram; preprogram median 0.5, postprogram median 2.50).

**Narrative Feedback from Participants**

Overall, subjective responses from our 3-year postprogram follow-up with participants were positive. A major theme that emerged with regard to the Prevention Produce model was ease of use.

One participant stated, “That program was excellent. It was informative; it really helped with trying to see how much the difference would be to eat healthy vs eating more ready-made food for my children.” The same participant felt as if “the amount of produce was perfect; it didn’t go bad. I like that we had provided recipes and they were easy. ... I liked having the medical student with me; it just made

**Table 1. Survey responses regarding food preparation, cooking skills, and perceptions about healthy eating in Prevention Produce program participants, Fall 2015<sup>a</sup>**

Variable	Preprogram median	Postprogram median
It is essential that I eat fruits and vegetables	1.00	1.00
Eating fruits and vegetables can keep you from getting sick	2.00	1.00
Eating fruits and vegetables can prevent chronic disease like heart disease and diabetes	1.50	1.00
Fruits and vegetables are tasty	1.00	1.00
I really care about what I eat	2.00	2.00
Eating fruits and vegetables is satisfactory	2.00	2.00
Eating fruits and vegetables is expensive	2.00	2.00
If you do enough exercise, you can eat whatever you like	4.00	4.00
The tastiest foods are the ones that are bad for you	3.50	3.00
I get confused over what’s supposed to be healthy and what isn’t	4.00	4.00
I am willing to try new foods	2.00	2.00
I feel confident cooking a main dish from a recipe with basic ingredients	1.50	1.00
I feel confident cooking vegetables from scratch with basic ingredients	1.00	1.00
Cooking meals from scratch is inconvenient	3.00	3.00
I would rather eat packaged foods or premade meals than cook them	5.00	4.00
I am currently trying to include fruits and vegetables in every meal I prepare	1.00	1.50

<sup>a</sup> Responses were assigned a value of 1-5, with “strongly agree” = 1 and “strongly disagree” = 5.

**Table 2. Summary of fruit and vegetable consumption in Prevention Produce program participants, Fall 2015**

Variable	Preprogram responses, %	Postprogram responses, %
Consumption of salad/dark green vegetables (≥ 1 per week)	62.5	87.5
Consumption of fruit juice (≥ 1 per week)	50	37.5
Consumption of fresh fruit (≥ 1 per day)	37.5	62.5
Consumption of orange-colored vegetables (≥ 1 per week)	37.5	87.5
Consumption of other vegetables (≥ 1 per week)	75	100

**Table 3. Summary of changes in exercise behavior in Prevention Produce program participants, Fall 2015<sup>a</sup>**

Variable	Preprogram median	Postprogram median
Number of days of vigorous activity (≥ 10 min)	0.50	2.50
Number of days of moderate activity (≥ 10 min)	1.50	3.00
Number of days walking (≥ 10 min)	6.50	5.50

<sup>a</sup> Responses were coded 0-7, such that 0 = zero days of physical activity and 7 = 7 days of physical activity.

things easier ... to shop for produce for my family when [the educational module] was over." Similarly, another participant stated, "I enjoyed the young people who came to help. ... I really did like my mentor, [and] they learn more about people they aren't [usually] around and more about the medical field." Participants also seemed to retain what they learned in the program. One participant stated, "I eat more vegetables now and not a lot of fruits because of the sugars in them. I give my grandkids less fruits and more green leafy vegetables. Four oranges is like a candy bar!"

However, participants did acknowledge feeling limited in their ability to eat healthy after the program's subsidization ended, largely because of cost and affordability. As one participant said, "My son just started college, and we are in the same predicament. It's not that you don't want to get the fresher products and stuff like that ... it's just more costly ... it's hard to make ends meet, and you have to compromise and cut corners, and usually the corners that you cut aren't healthy." Another participant said, "[The cost of] produce is high. We got \$40 of produce every week, and my family doesn't usually buy that amount at one time. ... People don't always have the money or resources to eat right and that causes a lot of illnesses. ... It's just expensive. I still go down to Broad Street Market and get food locally when I can."

### Narrative Feedback from Medical Student Mentors

Medical students cited the formal nutrition education and their one-on-one relationships with patients as the strongest aspects of the program. As one student expressed, the program was "a chance to be trained and interact with the community and get to know a patient on a personal level over several weeks." Students were heartened by the material benefit they observed in patients. For instance, one student expressed that, for patients "access to a tremendous amount of fresh produce ... and the guidance of a medical trainee ultimately provided healthful sustenance as well as [hopefully] education." The physical space of the farmers market also appeared to confer a benefit to participants. As one student

mentor noted, by gradually navigating the market together during the month-long experience, the patient learned that "eating more produce isn't impossible."

Mentors commonly identified reciprocal benefits for themselves, frequently expressing that being entrusted to facilitate an in-depth, sustained encounter with a patient provided a valuable learning experience that can be rare in the preclinical years. As one participant expressed, "As a younger medical student, this experience was some of the most involved interactions I've had with a patient/client. It honed my early skills of interacting, answering questions." In addition to relationship building, students felt they gleaned important and enduring skills from the experience. One student expressed gratitude at "learning more about educating individual patients and how to personalize the nutritional information to their situation."

Students also identified a few programmatic weaknesses. For instance, one participant reflected on the relatively short and discrete duration of the 1-month program: "[I] wish it could be longer so we could work with more patients." Students also felt that they could have had a greater impact had they been able to longitudinally work with the patient across their 4 years in medical school.

### DISCUSSION

This pilot study built on the traditional FVRx model in an effort to implement and evaluate a more comprehensive intervention to address persistent contextual barriers potentially preventing the behavioral changes necessary to reduce the risk of chronic disease. The Prevention Produce program increased access and affordability of produce for low-income families living in a USDA-identified food desert, while offering formal education, one-on-one weekly mentorship support from medical students, shopping sessions at a farmers market, and a review of healthy recipes to prepare produce. The program included the household unit for added support.

Preliminary data showed increases in produce consumption and exercise habits as well as improved opinions regarding healthy eating. The comprehensive nature of our program makes it difficult to delineate where the exact benefits stemmed from; however, narrative feed-

back from both mentors and participants provided insight into the value of information received from an educational curriculum and one-on-one mentorship in addition to subsidization of cost through the vouchers. Both the student mentors and patient participants enjoyed the one-on-one pairing and felt the program ran smoothly, yet perhaps

ended too quickly. Patients retained the nutrition concepts learned in the program at 3-year follow-up, yet remained constrained by the affordability of fresh produce. Medical students valued the opportunity for an individualized patient-centered encounter that empowered them as leaders in patient care early in their education.

Healthier eating behaviors have been shown to be associated with a more future-oriented perspective.<sup>24,25</sup> Education is a powerful and vital component for enriching such perspective, underscoring the value of a programmatic focus on relationship-based nutrition education with an emphasis on disease prevention. Indeed, we believe that the relationships built between study participants and medical student mentors as part of the pilot program were important to its success, as shown by the quotes given in the Discussion. The hour-long market visits not only provided dedicated time to learn and digest information but also facilitated a partnership in a nonclinical setting where the perceived hierarchies inherent to clinical medicine were perhaps less pronounced. The patient-centered nature of the "intervention" in a farmers market provided a safe environment for families to self-direct their experience at the markets, often driven by their own curiosities and questions rather than the "expertise" of students. It is perhaps through such an environment that participants gained self-efficacy

**... the relationships built between study participants and medical student mentors as part of the pilot program were important to its success ...**

and confidence in food preparation and choices, which has previously been shown to be an important psychological influence that promotes healthy eating.<sup>26</sup>

Our innovation on the traditional FVRx model provides a logistical example of how clinicians at a large academic medical center who participate in FVRx programs can supplement conversations initiated at the point of care about healthy diet and lifestyle with more supportive community-based follow-up. This is a unique health care experience in which one-on-one mentorship can provide greater opportunities to facilitate behavioral change.

An important secondary benefit from our program was an increase in exercise frequency for participants, particularly because none of the formal curriculum addressed exercise behavior. Previous studies have found the inverse—when young adults were prescribed an exercise regimen and stuck to it, their fruit and vegetable intake naturally increased. Thus, it is possible that the observation in our preliminary study could be owed to a similar sort of "transfer effect," where exercise influences nutrition behavior by application of self-regulatory psychological resources across behaviors.<sup>27</sup>

Methodologically, our preliminary study was limited by its short duration and small sample size. Positive results may be owed to a "desirability effect" because student mentors also administered the pre- and postprogram questionnaires. Future inquiry might evaluate the Prevention Produce model using a randomized controlled trial design. Potential study designs might comparatively evaluate groups that receive a standard FVRx experience vis-à-vis groups who receive a self-guided curriculum and groups who receive the curriculum and in-person mentorship. There would be value in undertaking quantitative assessment of biomarker changes (eg, hemoglobin A<sub>1c</sub>, lipid panels, waist circumference, and body mass index), and in evaluating follow-up of these biomarkers at 3 months and 6 months after the program's conclusion. Incorporation of supplemental components such as cooking classes at community kitchens, budgeting workshops, social media utilization, and school engagements are logical additions to the mentoring intervention.

Future studies might look to build interdisciplinary teaching approaches with other health care trainees (eg, students in nursing, physician assistance, dietetics, and social work) who might add further value to an FVRx intervention for both participants and mentors. Indeed, trainees who participate in service-learning experiences in such community-based programs can build practical skills in preventive care and health coaching for patients while acquiring experiences that may be professionally formative. Additionally, more rigorous qualitative analysis can further elucidate the themes identified in this preliminary evaluation, particularly with regard to participants' learning and the professional development of medical students.

## CONCLUSION

The Prevention Produce program represents an innovation on the FVRx model that can be employed in at-risk communities to increase nutrient-dense produce consumption while potentially aiding patient and physician education. This program has the potential to be adopted into a longer-term initiative in which quantitative biomarkers can be followed and assessed for change. Collaboration with other nonprofit or federally funded organizations might engender greater sustainability and efficacy of this program in the long term, which will further support long-term change. ♦

## Disclosure Statement

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

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## Weapon

Hunger is actually the worst weapon of mass destruction.  
It claims millions of victims each year.

— Luiz Inácio Lula da Silva, b 1945, Brazilian politician and 35th President of Brazil

# Ensuring Mentorship of New Physicians in Their First Year: Constructs for New Mentoring Processes

Wynnyee Tom, MD<sup>1</sup>; Wynnian Tom, MD<sup>1</sup>; Daisy Albarran<sup>1</sup>; Nina Salman, MSHA<sup>1</sup>; Aneema Van Groenou, MD<sup>1</sup>

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## ABSTRACT

**Introduction:** The importance of mentoring new physicians is well established.

**Objectives:** To evaluate and improve use of a competencies-based mentoring checklist to help new physicians understand the basic work environment and resources in their daily jobs as well as achieve needed competencies.

**Methods:** Literature searches, process improvements, and a review of curricula and mentoring from both inside and outside our large Medical Group were conducted to understand the workflow for new physician orientation, onboarding, and mentoring processes. We aimed to achieve a structured framework for mentor training, evaluation of the mentor-mentee relationship, and development of a bridge for the knowledge gaps and needs of the individual physicians in their departments. Finally, we surveyed new physician hires/mentees in 2017 about their competencies using the new checklist.

**Results:** The new mentoring process was improved compared with the current mentoring process. Polling of physician mentees after implementation of the checklist showed a 75% completion rate of checklist competencies from January 2017 to April 2018, compared with a baseline of 0%.

**Conclusion:** Review of performance data and addressing deficiencies in a mentoring relationship can lead to active participation and meaningful change in competencies among new physicians.

## INTRODUCTION

The benefits of mentoring newly hired physicians have been recognized by many health care organizations, including The Permanente Medical Group, Inc (TPMG) in Northern California.<sup>1,2</sup>

In our group, mentoring during the first year of hire is designed to help physicians improve their efficiency, reduce their stress, and understand our culture. To accomplish this, we use a 13-item mentoring checklist for all new physician hires: 1) managing

Topic (modify for your department)	Priority (#1 – 14)	Target Date	Date Accomplished
<b>Managing Patient Flow in each care setting</b> Approaches to managing care: working with your support staff, responding to urgent requests, secure messaging			
<b>Handling Messages</b> Understanding priority designation and effectively managing messages to meet time frames			
<b>Utilization of Support Roles</b> Utilizing support staff for excellent care (PCC, social work, BMS, CHE, PT, DNE, and Pharmacy Drug Education Coordinators)			
<b>Physician Wellness</b> Managing work flow and work load following time off. Time off policies and procedures. Processes for ensuring wellness, such as building time off into schedules.			
<b>Improving Patient/Physician Communication</b> Development of communication and listening skills. MPS scores as a measurement.			
<b>Consults</b> Utilizing consult process in appropriate manner.			
<b>Clinical Quality</b> Aligning practice with organization guidelines. Utilization of Clinical Practice Guidelines. Understanding quality measures in your department			
<b>Building Relationship and Trust with Members and Staff</b> Promotes member comfort and reassurance. Communicates and works with team members to enhance collaborative approach to care.			
<b>Getting Along/Fitting In</b> Adheres to team agreements and project guidelines. Key relationships.			
<b>Lab, Pharmacy, Radiology Utilization</b> Understanding expectations and efficiencies in my department.			
<b>Forms, Documentation</b> Familiarity of available forms (POLST, Advance Directives) Utilizing tools for efficient documentation (dot phrases)			
<b>Utilization of Data Base Systems</b> Health Connect tips, Econsult, Microsoft Outlook and Skype			
<b>TPMG Culture</b> Awareness of political structure and priorities and impact on practice. Governance in practice (local & Regional)			
Mentor and Mentee Names: _____			
Date Accomplished: _____			

Figure 1. New Physician Mentoring Checklist.  
1) Asking "Does your department have current written onboarding documents?"  
2) Asking: "Was this mentoring checklist effective?"

BMSD = Behavioral Medicine Specialist; CHE = Clinical Health Educator; DNE = Dietary Nutrition Educator; Lab = laboratory; MPS = Member Patient Satisfaction; PCC = Patient Care Coordinators; POLST = Physician Order for Life-Sustaining Treatment; PT = Physical Therapy; TPMG = The Permanente Medical Group.

## Author Affiliations

<sup>1</sup>The Permanente Medical Group, Oakland, CA

## Corresponding Author

Wynnyee Tom, MD ([wynnyee.tom@kp.org](mailto:wynnyee.tom@kp.org))

Keywords: competencies, competencies-based mentoring checklist, mentor, mentoring, processes, process improvement



patient flow; 2) handling messages; 3) utilization of support staff; 4) physician wellness; 5) physician-patient communication; 6) consults; 7) clinical quality; 8) relationship building; 9) social cohesion; 10) laboratory, pharmacy, and radiology utilization; 11) forms and documentation, 12) utilization of database systems, and 13) TPMG culture. The full checklist is shown in Figure 1.

On the premise that ineffective mentoring<sup>3,4</sup> can contribute to turnover, we decided to examine our mentoring process. We aimed to achieve a structured framework for mentor training,<sup>5</sup> evaluation of the mentor-mentee relationship, and development of a bridge for the knowledge gaps and needs of the individual physicians in their departments.

## METHODS

Initially, we mapped our current workflow for new physician orientation, onboarding, and mentoring processes. We also conducted a literature search on mentoring processes and contacted other health systems to understand their processes. We then determined the rates of completion of the 13 checklist competencies shown in Figure 1. Our 2016 data from the Greater Southern Alameda Area service area, a division of TPMG servicing more than 343,000 patients and staffed by approximately 650 physicians, showed only an 8.5% completion of the new physician-mentoring checklist based on mentor self-report.

Because of this low response rate, we determined mentoring process opportunities (gap analysis; Figures 2 and 3). We defined an ideal model focusing on 1) human resources onboarding, 2) new physician orientation workshops, 3) new physician and mentor matching, and 4) mentor and mentee completion of competency topics. Then we developed and implemented the model to improve the completion rate experienced by new physicians. Competency checklists were provided more widely to include new physicians, as well as mentors and department chiefs rather than only mentors.

A physician director had oversight of the mentoring process (Figure 4) and checked in with mentors and mentees to remove any gaps or barriers in onboarding,

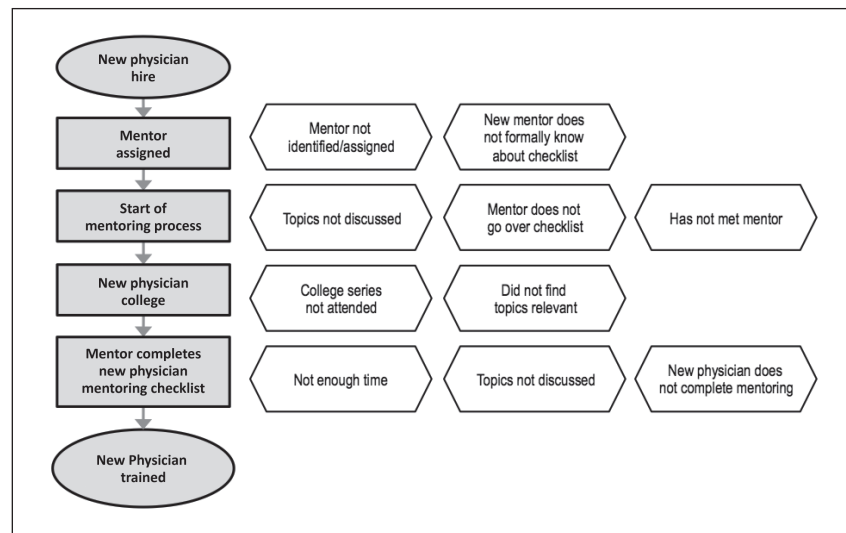


Figure 2. Current process map for training new physicians; gaps are identified on the right.

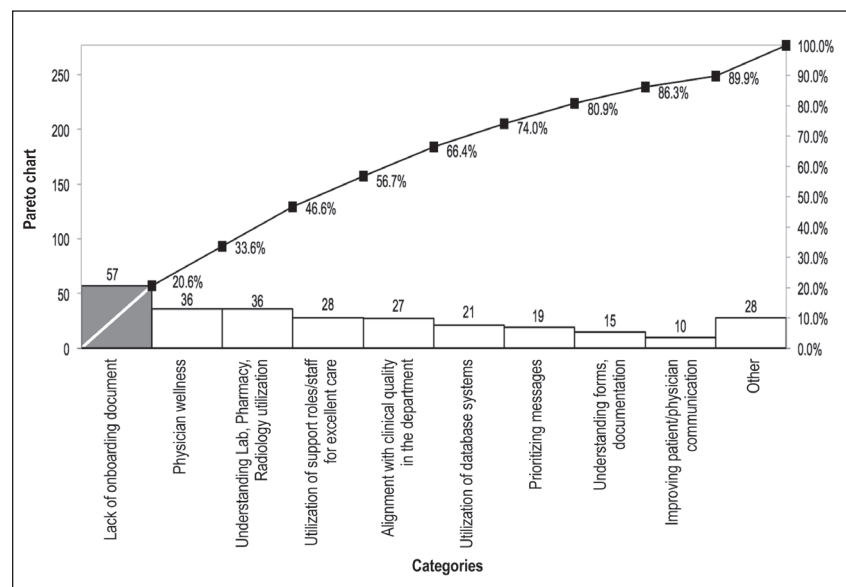


Figure 3. Pareto chart of issues/concerns identified as areas for needed improvement for new physicians hired in 2017.

Lab = laboratory.

such as meeting with department chiefs, managers, mentors, and mentees. These meetings discussed giving physicians sufficient mentor time and training (also referred to as mentoring boot camp), providing department chiefs the new physician-mentoring checklist, and so on. Furthermore, the director presented the new physician checklist and processes at the new physicians' college (specific for service area resources) and new chiefs'

orientation. To complete the mentoring process, 26 hours of mentoring time was suggested and given to each mentor and mentee pair. Several timelines exist that mentoring pairs could follow to assist in setting time aside for adequate training.

We sent the physician mentoring checklist by email with 2 additional questions (Figure 1) to new physician hires in 2017. We re-sent surveys to those who did not complete the survey after 1 week. The

survey was sent up to 4 times on February 3, 2018; February 10, 2018; February 17, 2018, and March 10, 2018. An unannounced reward of a box of chocolates was sent to responders as a positive reinforcement for completing the new physician checklist. The checklist was sent to the new physicians via email from the Director of Physician Mentoring who received the results. A survey was considered valid on completion of all 15 questions.

**RESULTS**

After the enhanced mentorship process began, polling of 60 2017 physician mentees showed 75% of mentees completed their checklist competencies from January 2017 to April 2018, compared with a baseline of 0% due to no data collection before to this new process (Figure 4).

**DISCUSSION**

Mentoring is a proven way to improve competency and enculturation of new physicians into a medical group, in addition to increasing job satisfaction and job performance.<sup>1,6</sup>

This article describes our process for examining the completion of our mentoring process and how we substantially improved the competency completion rate. Revising and widely distributing the checklist contributed to a surplus of new physicians achieving competency completion.

Tracking of competency completion by new physicians and their mentors will continue in 2018, after additional formal leadership training for mentors. The goal is to continually improve the competency completion rate. Furthermore, the director will address departmental gaps (eg, lack of current onboarding documents, must reflect topics such as physician wellness, utilization of support staff for excellent care, and alignment with clinical quality) at a meeting of the department chiefs.

**CONCLUSION**

It is necessary for health care organizations to support new physicians in all aspects. By identifying the gaps early on, there are chances to improve work processes to ensure efficiency and positive health outcomes for practitioners and

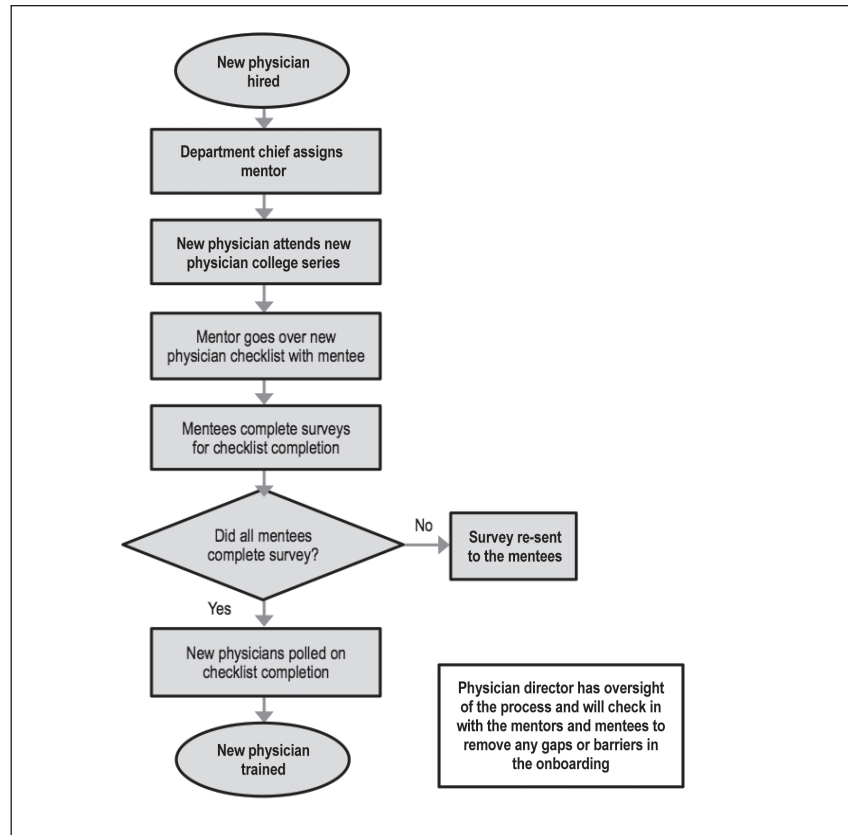


Figure 4. Future process map for training new physicians.

patients. Eliminating the barriers and supporting the mentoring relationship allows for lifelong learning and performance improvement. ❖

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# Promising Methods for Improving Quality Through the Faster Spread of Best Practices

Michael H Kanter, MD<sup>1,2,3</sup>; Patrick T Courneya, MD<sup>4</sup>

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Improving quality in medical care has always been a challenge, and the identification and spread of best practices that improve care can be particularly complex. On average it takes 17 years from publication of high-quality research findings to their widespread usage in clinical settings.<sup>1</sup> Faced with this significant delay, it is incumbent on organizations to find quicker, more effective, and more systematic ways to translate research into clinical practice.

From education through system design, several models have emerged to speed the dissemination of best practices while ensuring necessary rigor around quality, safety, and an evidence-based approach. One such example is Kaiser Permanente's (KP's) use of the E-SCOPE (Evidence Scanning for Clinical, Operational, and Practice Efficiencies) system<sup>2</sup> to accelerate identification and implementation of new evidence-based practices in Southern California. E-SCOPE expedites the spread of newly published, high-quality clinical and operational practices through systematic evidence searches, fast-track decision making, implementation support, and ongoing monitoring of process and outcome metrics. An example of the program's success: In 2015, research was published connecting weight loss interventions to reduction in severity of psoriasis symptoms.<sup>3</sup> Within 8 months, KP reached out to nearly 18,000 members with psoriasis about weight management classes.

Another means to get farther faster is the publication of abstracts from the KP National Quality Conference (NQC). We began this practice in 2017, publishing 25 selected abstracts out of 134 that were submitted.<sup>4</sup> Demonstrating a growing interest in submitting promising work to the NQC, these numbers increased in 2018 to 43 published abstracts out of nearly 170 submissions.<sup>5</sup> This year we are pleased to again publish 44 abstracts out of nearly 200 total submissions.

These abstracts reflect the critical importance of a forum for presenting promising quality efforts. Meetings focused on quality improvement, such as those hosted by the Institute for Healthcare Improvement, the American Medical Group Association, and many other organizations, represent a relatively small percentage of all scientific medical meetings. The publication of abstracts from a dedicated quality event such as the NQC allows those within and outside of KP to learn about new and potentially unfamiliar practices that could improve care.

A third method of identifying and implementing new evidence-based practices is the creation of medical education that supports quality improvement projects.<sup>6</sup> To date, KP has more than 130 ongoing quality improvement projects and more than 5000 physicians have completed such projects for Maintenance of Certification credit.<sup>7</sup> New ways of educating future clinicians will embed quality improvement into the medical school curriculum from day one. The KP School of Medicine just received preliminary accreditation from the Liaison Committee for Medical Education and will be accepting its first class to start in 2020.<sup>8</sup> As part of the curriculum, students will be required to perform scholarly work, which may include quality improvement projects. Other medical schools also promote such activities, although the KP system is perhaps uniquely suited to excel in this arena because of our integration, access to data, and ability to spread and scale good practices.

Another way to accelerate the adoption of new evidence-based practices is to engage high-performing unit-based teams to identify and share successful quality improvement projects.<sup>9</sup> To facilitate spread, KP provides unit-based team

leads with comprehensive assessment tools to understand if a group is ready to share or receive a successful evidence-based practice outside of its area. Teams are also required to adopt or distribute a successful practice as part of the progression path to "high-performing" status.

Organizations can also benefit from the use of embedded researchers in quality improvement projects.<sup>10</sup> In this case, researchers join quality improvement teams from the beginning and bring their analytic skills to the project. This participation improves the rigor with which the project is conducted and evaluated, and increases the likelihood of publication and spread. Organizations can also bring this same discipline to study the spread of best practices. By more precisely understanding the factors that improve the identification and spread of these practices, we can continue to improve care.

This ability to learn is what defines the learning health system.<sup>11</sup>

The goal of all these efforts is not simply to reduce the 17-year time lag, but to do so while assuring safety, quality, and fidelity to the solid research findings in which the work is rooted. Although we have only provided a partial listing of ways for organizations to learn, learning at an institutional level can be done using any

**These abstracts reflect the critical importance of a forum for presenting promising quality efforts.**

## Author Affiliations

<sup>1</sup> The Permanente Federation, Oakland, CA

<sup>2</sup> Southern California Permanente Medical Group, Pasadena

<sup>3</sup> Departments of Clinical Science and Health System Science, Kaiser Permanente School of Medicine, Pasadena, CA

<sup>4</sup> National Health Plan and Hospitals Quality, Kaiser Foundation Health Plan and Hospitals, Oakland, CA

## Corresponding Author

Michael H Kanter, MD ([michael.h.kanter@kp.org](mailto:michael.h.kanter@kp.org))

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of the previously mentioned means. It is key to effectively addressing the Institute of Medicine's 6 domains for health care quality: Safe, timely, effective, efficient, equitable, and patient centered.<sup>12</sup> ❖

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# Abstracts from the Kaiser Permanente 2019 National Quality Conference

## BEHAVIORAL HEALTH

From Northern California

### 1. The Impact of an Innovative Patient-Practitioner Therapeutic Community on the Management of Chronic Pain

Karen Peters, PhD; Barbara Gawehn, RN, LAc

DOI: <https://doi.org/10.7812/TPP/19-039-1>

**Background:** The opioid epidemic begs for advances in chronic pain treatment. Literature suggests chronic pain and addiction share motivational and reward circuitry. To date, there is no treatment model addressing this connection in the long-term management of chronic pain. Kaiser Permanente Santa Clara bridges the gap with an innovative model that combines standard multidisciplinary chronic pain management approaches with a modality commonly used in addiction treatment to motivate patients, the therapeutic community. Initial outcomes are very promising.

**Methods:** Using mixed methodology, a comparative analysis of utilization (Emergency Department visits, Primary Care office visits, benzodiazepine and opioid prescriptions) was conducted on 2 patient groups. One group (n = 286) completed the Region's standard chronic pain treatment at Santa Clara: Level 2, 9 to 12 sessions, years 2007 to 2011. The other group (n = 193) completed a therapeutic community-based program: The Pain Management Rehabilitation Program (PMRP) at Santa Clara, intensive phase/24 sessions with ongoing rehabilitation, years 2015 to 2017. Wilcoxon rank sum tests compared utilization, 1 year pre- and postintervention. A qualitative approach using constructivist-grounded theory compared 47 patients' responses with program assessment questionnaires used in both models. Staff responses to the same questions were also analyzed.

**Results:** The reductions in utilization were greater in the PMRP group: Opioid prescriptions decreased 83%, compared with the Level 2 group at 34%. Benzodiazepines decreased 80% in the PMRP group, while they decreased 39% in the Level 2 group. Emergency Department visits decreased 52% in the PMRP, whereas they increased 15% in the Level 2 program. Group differences were statistically significant. In the PMRP primary care office visits decreased 21%. In the Level 2 group they decreased 14%, with no statistically significant difference between groups. Level 2 increased understanding of chronic pain yet patients wanted more time to interact and practice techniques. Disappointment that pain did not go away was common. PMRP participants voiced that belonging to an ongoing community that practices techniques eases suffering and increases motivation to self-manage pain. They reported changes in attitudes, humor returning, and appreciation for comprehensive care and practitioner enthusiasm. Practitioners echoed with comprehensive care and a practitioner-patient community as being peak career experiences.

**Discussion:** Reduction of opioid and benzodiazepine prescriptions, along with Emergency Department visits and Primary Care office visits, and ongoing participation in a patient-practitioner therapeutic

community motivates patients to self-manage pain, thus decreasing costs and potential fatalities. Patient and staff narratives suggest community is an intervention that affects motivation and engenders understanding and support in a way that is inherently rewarding to patients and staff. We surmise that community membership is an interpersonal neurobiological intervention that therapeutically affects brain mechanisms common to chronic pain and addiction. Narrative themes point to it having a revitalizing effect, both upon patients' lives and practitioners' passion to provide care to this difficult population.

From Northwest

### 2. Zero Suicide Implementation

Jacqueline Ryan, MPH; Pavan Somusetty, MD; Han Liang, MD;  
Eli Pahl, LCSW, CADC III;

DOI: <https://doi.org/10.7812/TPP/19-039-2>

**Background:** Suicide claims more than 47,000 American lives each year, with each death leaving devastating and immeasurable impacts on surviving loved ones for decades or longer. Research shows that nationwide, almost half of those individuals had sought medical care in the last month before their death, often for other unrelated health care needs. In Oregon and Washington, suicide has risen to become the 8th leading cause of death. Kaiser Permanente Northwest's (KPNW's) Zero Suicide Initiative seeks to strengthen its health care system to prevent these tragic deaths by identifying its highest-risk members and by ensuring they receive timely and appropriate evidence-based interventions once identified.

**Methods:** The population included members of KPNW seen in Mental Health, Addiction Medicine, Primary Care, Pain Clinic, Obstetrics and Gynecology, and Pediatrics who answered a Patient Health Questionnaire (PHQ-9) used for screening and monitoring depression or those who otherwise indicated suicidal ideation directly to health care providers. We increased depression screening in Primary Care to all members and created consistent and reliable escalation pathways for anyone seen in the above departments who indicated a positive 9th question (the screening question for suicide) on the PHQ-9 by applying the Columbia-Suicide Severity Rating Scale (C-SSRS) during the visit before the patient left the office. The answers to this tool were collected as discrete data. Those who were seen outside of Mental Health and Addiction and scored a 3 or higher on the C-SSRS were provided a warm transfer to a behavioral health clinician (either in person or by phone) to collaboratively develop a safety plan intervention with rapid follow-up in a specialty mental health clinic. Those who were already being seen in a specialty mental health or addiction medicine clinic collaborated with their provider directly on the safety plan before leaving the office. Our outcome measures were: Depression screening rate, C-SSRS Utilization and Completion in Response to Elevated PHQ-9 9th item, and Suicide Incidence Rate in Mental Health and Addiction Medicine.

**Results:** Updated workflows in documentation for Pediatrics in April 2018 resulted in a significant increase in the depression screening rate from a baseline of 17.6% to 35.8% in September 2018. Universal screening for depression in the adult population began in August 2018, and we anticipate a similar increase in depression screening rates for adults in the coming months. Our baseline C-SSRS utilization rate (in response to a positive response to the 9th question on the PHQ-9) in December 2017 was 0.4% and by Q3 of 2018, this rate had increased to 60.1%. In May 2018, all mental health and addiction medicine clinicians were trained in the Stanley & Brown Safety Planning Intervention. Since this training, the Mental Health and Addiction Medicine Department has seen 2 calendar months of 0 suicides within the department.

**Discussion:** Tying the C-SSRS to the PHQ-9 workflows in departments that already use the PHQ-9 was a successful strategy in rolling out widespread suicide risk assessments. Collecting and reporting on measures and investing in training all mental health and addiction medicine clinicians in an evidence-based safety-planning intervention proved to reduce suicide incidence and helped to shift the culture at KPNW around suicide prevention. Our next steps include data collection for when safety plans are being used in response to an elevated C-SSRS score by capturing safety plans in the electronic medical record as discrete data, exploring the use of a risk calculator to further help determine those who would benefit from a C-SSRS even with a negative response to the PHQ-9, and engaging more departments in suicide risk identification, including the Emergency Medicine and Urgent Care.

*From Hawaii*

### 3. Implementation and Dissemination of Cognitive Behavioral Therapy for Depression in Kaiser Permanente Hawaii: Impact and Lessons Learned

Bradley E Karlin, PhD, ABPP; Gregory K Brown, PhD; Shari Jager-Hyman, PhD; Kelly L Green, PhD; Michi Wong, PhD; Diane S Lee, LCSW, CSAC; Andrew Bertagnolli, PhD; Thekla Brumder Ross, PsyD

DOI: <https://doi.org/10.7812/TPP/19-039-3>

**Background:** When delivered, cognitive behavioral therapy (CBT) is generally provided with low fidelity. This pilot initiative implemented a CBT approach adapted for the Kaiser Permanente system with a focus on depression and co-occurring anxiety to bridge the research-to-practice gap, with emphasis on fidelity, the therapeutic alliance, and individualization of training and treatment to enhance treatment outcomes and engagement. The initiative involved a state-of-the-art approach to competency-based training in CBT designed to establish internal and ongoing capacity to deliver CBT.

**Methods:** Competency-based training in CBT for depression (CBT-D) among Kaiser Permanente Hawaii mental health practitioners included training and implementation of the protocol by therapists in training, along with system implementation and sustainability supports. Evaluation of training and implementation included assessment of both therapist and patient outcomes. Changes in therapist competency in CBT were assessed by expert raters using the Cognitive Therapy Rating Scale (CTRS). Changes in depression and anxiety among patients were assessed using the Patient Health Questionnaire-9 (PHQ-9) and the Generalized Anxiety Disorder-7 (GAD-7), respectively.

**Results:** In the initial training cohort, 3 out of 14 therapists demonstrated minimum competency in CBT at baseline. At the end of CBT training, 14 out of 14 therapists reached competency. In the second training cohort, 0 out of 11 therapists demonstrated competency in CBT. At the end of CBT training, 11 out of 11 therapists reached competency. Among patients enrolled in the initial training cohort ( $n = 36$ ), there were statistically and clinically significant decreases in depression and anxiety symptoms from pre- to posttreatment.

**Discussion:** Although CBT is highly recommended in clinical practice guidelines, few therapists exhibited minimum CBT competency at the start of training. At the end of training, all therapists demonstrated CBT competency (and improvements in general therapy skills), providing support for the utility and effectiveness of this competency-based training approach. The implementation of CBT-D by therapists in training was associated with clinically significant reductions in depression and anxiety among patients. Findings provide additional support for training in and implementation of CBT in health care systems. Limitations of this program included lack of a control group, given the nature of the project as an effectiveness evaluation within a real-world treatment setting, and the relatively small numbers of participants. Next steps include focus on CBT-D sustainability and sharing of learnings and resources to promote spread to other regions.

*From Washington*

### 4. Lessons from Implementation of Behavioral Health Integration in Kaiser Permanente Washington

Rebecca Parrish, MSW; Ryan M Caldeiro, MD; Amy Lee, MPH

<https://doi.org/10.7812/TPP/19-039-4>

**Background:** Behavioral health conditions and psychosocial and resource barriers to accessing care are ubiquitous in primary care settings and are associated with poor physical health and increased health care costs when undertreated or unaddressed. Kaiser Permanente (KP), like other health systems in Washington and across the country, is working to improve access, reliability, and quality of care for patients with mental health and substance use concerns through behavioral health integration (BHI) within primary care clinics.

**Methods:** Primary care-based universal screening for adults age 18 years and older for depression and unhealthy alcohol, marijuana, or other drug use. Positive test screenings are assessed with evidence-based tools with results documented in the electronic health record, resulting in patient-centered care including preventive advice and shared decision making to determine appropriate treatment. Licensed clinical social workers and community resource specialists function as core members of the primary care team who can help support the care needs identified from screening. Outcome measures include screening and assessment rates for depression, alcohol- and substance-use disorders, as well as suicide risk assessment and decrease in referrals to specialty mental health.

**Results:** Screening and assessment rates for common and easily treatable mental health conditions improved significantly following implementation of BHI. Prelaunch, 10% of patients received depression screening vs an organizationwide 90% screening rate in September 2018. Similarly, 6% of patients received depression

assessment prelaunch vs organizationwide assessment rate of 97% in September 2018 when BHI was launched in all KP Washington (KPWA) clinics. Improved screening and assessment rates have been sustained for more than 3 years in clinics that led the development of the work in 2015. In a recent KPWA provider poll, BHI was rated in the top 5 primary care investments that supported improved patient experience, improved practitioner experience, improved quality, and decreased costs.

**Discussion:** Integrating behavioral health into primary care has substantially improved the ability of KPWA to identify and to treat common mental health and substance-use concerns. Key facilitators to success include: Intentional staff engagement around implementation; defined standard work to support screening, assessment, and treatment of identified conditions; and the addition of staff members dedicated to supporting the needs identified via screening. Well-executed BHI results in: Improved patient care and experience, improved organizational performance on mental health quality measures, and increased practitioner satisfaction. KPWA learnings applied in your Region can support more fully integrated health care.

## WELL BEING

*From Northern California*

### 5. 100,000 Quitters and Counting— Striving for a Tobacco-Free Generation

Renee Fogelberg, MD; Mariko Muzzio, MPH; Annida Brunato;  
Karin Dove, MPH; Debora Sawyer, MD; Christopher Lee, MHSA

DOI: <https://doi.org/10.7812/TPP/19-039-5>

**Background:** Given the known morbidity and mortality of tobacco use, and the multiple touch points in our system, we can dramatically reduce usage rates with targeted intervention.

**Methods:** Northern California tobacco cessation work covers a population of more than 4 million members. In 2012, Kaiser Permanente Northern California had a tobacco-use prevalence of 9.4%. To address this known issue, we developed an intervention strategy to target any member with a documented history of active smoking or tobacco use. This strategy employed a multipronged approach:

- Inreach—defining and codifying workflows to discuss quit options and resources with relevant patients during every visit with their primary care physician
- Outreach—systematic engagement with relevant patients that highlights quit options and helpful resources in between visits
- Strategic engagement—defining and codifying workflows to discuss quit options and tailored resources to relevant patients during “teachable moments” (pregnancy, inpatient admissions, perioperative discussions, etc).

Success of this multipronged strategy was measured through quit rates, medication-use rates, counseling rates, longer-term hospital readmissions, and perioperative complications.

**Results:** Within 7 years, our tobacco prevalence dropped from 9% to 7.4%; our medication-use rate increased from 3% to 7% (prescription fill rates); the number of smokers we counsel increased dramatically (telephonic coaching service); and perioperative quit rates approached 50%.

**Discussion:** Smokers represent a small subset of our members yet the associated immediate and long-term consequences owing to first- and second-degree exposure are significant. For those reasons, we chose to adopt an every-patient, every-visit approach, which included assessing and intervening with personalized cessation aids as appropriate. Ideally inreach and outreach approaches should be designed to identify at-risk populations. Workflows to support relapse prevention are also critical.

*From Mid-Atlantic States*

### 6. The POWER Journey of a Mid-Atlantic Permanente Medical Group Physician (Pursuit of Wellness, Engagement, and Resilience through Social Support)

Susan Leggett-Johnson, MD, MBA; Gene Gincherman, MD; Mary Zmuda, MPH

DOI: <https://doi.org/10.7812/TPP/19-039-6>

**Background:** A 2018 Medscape Report of 15,000 physicians averaged 42% reporting burnout; burnout rates vary: Physicians younger than age 45 years at 35%, age 45 to 54 years at 50%, age 55 to 69 years at 41%. Burnout can be caused by work demands, difficult interactions, limited access to resources, and lack of social support. The symptoms are emotional exhaustion, depersonalization, and low sense of meaning in work and life, leading to a decrease in joy in the workplace, which affects patient care, collegiality, turnover, and personal well-being.

**Methods:** The methods employed to impact burnout and cultivate joy in the workplace through social support are two-fold: 1) obtain leadership buy-in and lay the organizational foundation for a supportive culture—A) Value Equation updated to include “Physician Experience” as a component of organizational success; B) Physician Opinion Survey enhanced to include validated questions from Physician Wellness Inventory and American Medical Association’s Mini-Z Burnout Survey; 2) develop a diverse package of programs and events, offered at various touch-points, that enhance social support among colleagues and are in alignment with the Stanford WellMD Model of Professional Fulfillment.

**Results:** Although Mid-Atlantic Permanente Medical Group (MAPMG) collects event-specific feedback, MAPMG recently added a multitude of wellness-related measures to the Physician Opinion Survey. The following measures will be used for evaluation of the impact of the social support journey (T1-T2 comparison available in 2019). “I feel valued as a physician in MAPMG.” “My Chief does a good job of recognizing people for their accomplishments and contributions.” “I have the support I need from others in my department to do my work.” “I have meaningful and supportive relationships with others in my department.” “I actively participate in my community or [Kaiser Permanente’s] volunteer opportunities, or in one of MAPMG’s Wellness Program activities.” “My work brings joy into my life.” “Feeling compassion for others is a regular part of how I work.”

**Discussion:** The overarching goal of providing a comprehensive social support journey throughout the career span of a MAPMG physician is to improve joy in the workplace, which directly correlates to outcomes such as increased engagement, resilience, health, and satisfaction. An important learning is that cultivating “joy,” “well-being,” and “support” mean different things to each unique

individual, so it is necessary to be broad, but focused, in the approach. The next steps with MAPMG's social support journey are to continue to reinforce the message that all offerings are cohesive and connected to a larger goal, and are not just individual offerings.

*From Hawaii*

## 7. Malama Ola—Taking Care of Your Well-Being

**Sharin Sakurai Burton, MD, PhD; Casey Akana, RN; Sandra Tompkins, RN; Kristy Yoshikawa; Julia Gregory, RN; Hyewon Jun, MD; Mae Lynne Swoboda, MPH; Courtney Farris, MA, MINTee; John Banagan, MPH, CHES; Eric Kamimura, DPT; Steve Nakata, COTA, MBA; Derek Chee, DPT; Quyen Nguyen, PhD; Jennifer Davis, RD; Kimberly Oshita, RD; Merle Miura-Akamine, MD; Kaipo Pau, MD; John Sheehan, MD**

DOI: <https://doi.org/10.7812/TPP/19-039-7>

**Background:** One person dies every 12 minutes of an opioid-related overdose. Our practitioners have decreased opioid utilization in chronic pain patients; however, recent guidelines for managing chronic pain emphasize nonopioid medications and access to complementary and alternative treatment protocols. Increasing function is now a focus of assessing therapeutic response to treatments for pain. Our patients with chronic pain need assistance with developing skills to increase their functional status while managing their pain with decreased opioid use.

**Methods:** Any patient with chronic (on opioid therapy for > 90 days) nonmalignant pain will be eligible for referral to the Malama Ola chronic pain wellness program. Those who enroll in the program will be offered access to complementary treatment options that emphasize self-care and increasing function. We will compare patients who enroll in the Malama Ola program to patients not enrolled in the program. Outcome measures include decrease opioid usage and increase function using the Brief Pain Inventory—Pain, Enjoyment, General Activity, Sleep questionnaire.

**Results:** With advice from the Patient and Family Center Care member advisors, we created Malama Ola, a chronic pain wellness center that is part of the Integrated Physical Rehabilitation clinic (staff include pain and psychiatry practitioners). The patient is at the center of care. By removing the word "pain" from the clinic name we redirect the focus of opioid-based therapy to treatment-based on rehabilitation and integrated care. Patients with chronic pain can be referred directly to Malama Ola and a lifestyle coach navigates their care. We changed the name of our 6-week lifestyle program to active coping and training, which focuses attention on increasing function. Patients actively engage in self-care skills to increase function while managing pain that is not based only on opioids.

**Discussion:** Opioids are only 1 part of a multimodal treatment plan for chronic pain. Helping patients understand the mindset shift to increasing function and managing pain while reducing opioid use is a crucial part of managing pain. Member advisors from the Patient and Family Center Care committee were enlisted during the development of our Malama Ola class presentation and attended our first session. Their input allowed for more effective communication strategies to engage patients in our chronic pain wellness program. The next step is to develop patient-centered support groups with the Patient and Family Care Center to ensure sustainability of the self-care skills our members have learned.

*From Northwest*

## 8. Increasing Team Safety and Response to the Threatening Member

**Bradley Christie, PhD; Laura Ketterman, HEM**

DOI: <https://doi.org/10.7812/TPP/19-039-8>

**Background:** Health care worker violence or injury rates are 4 to 6 times that of other professions. Every assault has potential "stop" points to de-escalate and/or provide effective care. Assault prevention is not completely effective with standard security or violence-prevention models. Kaiser Permanente Northwest (KPNW) has a co-ownership and joint-responsibility model that addresses and integrates the quality, service, security, and clinical elements, which all contribute to risk solutions including: Staff reporting, notifications, preparations, with shared safety and care briefings for high-risk incidents, along with health care focused de-escalation and defense training.

**Methods:** The KPNW program is building data dashboards, and best-practice standards from clinical, security, and quality sources. Population data sets are being collected including injuries, reported incidents and levels, alongside training efforts with pre-post measures (showing a marked improvement in usability and support of our training efforts). This integrative approach supports member relations, quality, service data, patient and staff satisfaction data, and although quantitative data sets are difficult to measure, this integrative approach is built as a broad-based preventive strategy that supports improving security data outcomes and reducing the need for a traditional security "fix the problem" approach.

**Results:** The KPNW has experienced 4- to 5-fold increases in reporting potential and actual threat events with fewer unmanaged events, lower injury data, reduced charting of events, with increased staff satisfaction of threat management and team support.

**Discussion:** In this session we will discuss how an integrated culture of threat management and safety influences the reporting, response, and risk-reduction strategies for provider teams while also increasing member satisfaction and clinical outcomes.

The elements of safe engagement include reporting any incident however minor, with clear response and support processes for safety needs, service recovery efforts, and a threat management response. We will provide safety and support tips, scenario reviews, and team engagement strategies.

## CARE MANAGEMENT

*From Southern California*

## 9. Continuing Care Quality Management: Practice, Performance, Proof

**Peter Khang, MD, MPH, FAAFP; Jennifer Cortez; Christine Jordan, LCSW; Artem Aghourian, MBA**

DOI: <https://doi.org/10.7812/TPP/19-039-9>

**Background:** The postacute care marketplace is segmented with high degrees of variability among skilled nursing facility (SNF) leadership, care quality, and outcomes. Appropriate and adequate governance of the care provided and oversight of our members in



SNFs, ensures they receive care that is consistent with what they received in the hospital.

**Methods:** Continuing Care Quality Management (CCQM) aims to improve the quality outcomes and utilization of skilled nursing care for members in SNFs or to those considered for it (most often Medicare/65+ members). To do so the Kaiser Permanente Southern California Region implemented CCQM, which emphasizes appropriate and timely care for members in SNFs and ensures the appropriateness of SNF placements from the hospital. We compared our results with historic outcomes and utilization, and other utilization trends in the organization. To track our outcomes, we measured SNF patient day rate, SNF discharge rate, average lengths of stay, and 30-day readmissions (posthospital and post-SNF discharge).

**Results:** The primary metric for success has been the SNF patient day rate—measuring the number of skilled days per 1000 members. During the course of nearly 3 years (2015-2018), we have seen the SNF patient day rate drop by nearly 33%. This metric is comprised of the volume of members entering a SNF and the length of stay. As CCQM and Inpatient Quality Management work together to send patients home when possible, our volume of SNF members has decreased, while our average length of stay remained the same. We have observed a modest decrease in the Healthcare Effectiveness Data and Information Set readmission observed/expected ratio, despite a 12% increase in the expected rate in the 2 years; and a significant reduction in our 30-day post-SNF readmission rate.

**Discussion:** The CCQM model enhances the timeliness and appropriateness of care for members, improves working relationships (internal and external), and produces patient satisfaction and business outcomes. Throughout the implementation process the Southern California Region has been able to identify multiple practices that help drive CCQM performance for various medical centers. Understanding those practices, why they are important, and what impact might be expected supports other Regions in the implementation as well.

*From Mid-Atlantic States*

## 10. The Hepatitis C Care Cascade: Increasing Comprehensive Screening and Diagnosis

M Cabell Jonas, PhD; Michael Horberg, MD; Jacquelyn Redd, MD; Dana Sloane, MD; Eric Wollins, MD; Carla Rodriguez, PhD; Bernadette Loftus, MD

DOI: <https://doi.org/10.7812/TPP/19-039-10>

**Background:** Chronic hepatitis C is the most common US blood-borne infectious disease, affecting the large baby boomer-age population (born 1945-1965) and those at-risk because of blood exposure. Hepatitis C virus (HCV) kills more Americans than any other infectious disease. Significant gaps persist for screening, diagnosis, triage to care, and curative treatment.

**Methods:** The Kaiser Permanente Mid-Atlantic States (KPMAS) HCV Pathway is a technology-driven, coordinator-supported process to screen at-risk patients for HCV chronic infection (initial testing with HCV antibody, confirmed by HCV RNA), coinfection testing, liver assessment (including staging), and physician referral. The multistep pathway closes patient care gaps, improves quality, and eliminates unnecessary physician work.

**Results:** The HCV Pathway has improved regional screening rates, increased the percentage of total baby boomers screened, and

improved testing quality across the testing cascade (including HCV RNA testing, coinfection testing, HCV genotype testing, and liver stiffness assessment).

**Discussion:** Modeling studies in the literature indicate programs that simultaneously address multiple points along the HCV care cascade result in better outcomes and higher value than interventions that target single steps. Broader implementation of a multistep technology and coordinator-assisted HCV Pathway, such as the KPMAS program, can improve regional HCV screening rates (particularly among the at-risk baby boomer-age population), can improve HCV testing efficiency (and coinfection testing), and can link patients to care more consistently. Resources are available to spread this program to other sites.

*From Southern California*

## 11. Measuring Diagnostic Error: A Review of Patient Complaints

Michael H Kanter, MD; Lawrence D Lurvey, MD; Kerry C Litman, MD; Ronald K Loo, MD; William Strull, MD; Mimi Hugh, MPH, MA; Maverick Au

DOI: <https://doi.org/10.7812/TPP/19-039-11>

**Background:** Diagnostic error, as defined by the Institute of Medicine's 3 key elements (failure to establish a *timely, accurate* diagnosis that is appropriately *communicated* to the patient), is increasingly recognized as an important contributor to delayed diagnosis and can be a source of serious medical harm, yet measuring diagnostic error can be a challenge. Although claims data can give an indication of missed diagnoses long after the fact, measuring diagnostic error from the patient's perspective provides insights and opportunities to identify and potentially to mitigate diagnostic issues at an earlier stage. Member Services is the first portal to collect patient complaints; non-clinical staff summarize and code each complaint; 7-code description categories fit the definition of diagnostic error and contain significant volume to allow useful analysis.

**Methods:** From the 7-code description categories that fit the definition of diagnostic error, 158 cases were randomly selected for review from 2 perspectives: 1) the *patient*—via review of the intake summary, and 2) the *physician*—via review of the patient's medical record. These cases were evaluated for any of the 3 elements of diagnostic error in the intake summary and in the patient's medical record. Ten physicians reviewed and assessed the cases using a uniform evaluation tool to document their findings. Tabulated results determined whether the diagnostic-related codes of complaints were accurate indicators of potential diagnostic error.

**Results:** From the patient's perspective, 2 categories, Diagnosis Delayed/Missed/Incorrect and Test Results Delay, yielded high specificity (81% and 93%) of diagnostic errors. Other categories had low volumes or did not meet the definition of diagnostic error. From the physician's perspective, diagnostic error was identified at much lower rates on the basis of documentation in the medical record of accurate and timely diagnosis and communication to the patient. In the routine review of complaints, the majority had potential quality issues (94% and 63%) and were forwarded to the Quality Department for further investigation, but only a few cases had quality issues that led to peer review scoring of a minor or significant opportunity for improvement; most had no quality issues. Perception of the quality of communication may explain this difference; it may be assumed by

the physician that adequate communication occurred if documented in the medical record, whereas patients may not have felt they were adequately informed.

**Discussion:** The addition of *communication* to the definition of diagnostic error has shed light on a common problem. The patient's perspective should be the gold standard regarding adequate communication, and whether the diagnosis was well understood, its implications, and a plan of care. Adequacy of communication may be documented in the medical record, but may not convey the patient's true perceptions. In addition, the Institute of Medicine definition does not define *timely*; the patient's perspective should be used in determining timeliness, because it is less subject to interobserver variation from physician reviewers. Identifying diagnostic error rates from patient complaint data may be a useful way to measure diagnostic error over time in a more rapid manner than current methods, allowing more timely investigations and system improvements to reduce future harm.

*From Northern California*

## 12. No Place Like Home: Surgical Home Recovery

**Michele Knox, MD; Wendy Rabinov, MD; Michael Nwynn, MD; Ashima Garg, MD, PhD; James Chang, MD; Claire Spanbock, MBA, RN, CNOR; Edgar Servais; Bijal Shah, MHSA; Tamar Fendel, MPH; Annie Davis, MPH; Jeffrey Hatton, MBA**

DOI: <https://doi.org/10.7812/TPP/19-039-12>

**Background:** Surgical home recovery builds on total joint home recovery and enhanced recovery after surgery, both of which focus on decreasing opioid use and improving pain control resulting in decreased length of stay. Similar techniques were used to improve same-day discharge rates to: Improve patient experience by enabling recovery at home with familiar food, environment, surroundings, and loved ones; free up hospital beds; and reduce exposure to hospital associated harm (eg, infection).

**Methods:** We identified lower acuity procedures with variation in current discharge practice. Specific criteria were applied to exclude patients with medical necessity for hospital admission including patients with a hospital stay of 2 or more nights. We identified surgeons with high rates of home recovery and identified best practices supporting home recovery. These were shared with all relevant surgeons through various forums. We developed an extensive performance reporting tool including: Statistical control charts trending 2-year performance for home recovery by Region, facility, procedure type, and surgeon, plus return to care data (return to Emergency Department, Operating Room, and/or hospital admission) with similar breakdowns.

**Results:** Procedures included: Anterior cervical discectomy and fusion Level 1 and 2, ankle fractures, 1-level laminectomy and discectomy, laparoscopic appendectomy, mandible osteotomy, mastectomy, parathyroidectomy, prostatectomy, thyroidectomy, tonsillectomy, shoulder arthroplasty, and vaginal hysterectomy. Between October 2017 and October 2018, home recovery for all procedures increased from 68% to 84%, statistically significant deviation from the mean for the past 8 consecutive months. This resulted in 2300+ bed days saved, representing annualized cost savings of approaching \$7 million. During this same time frame, procedures with the highest increase in home recovery were: Prostatectomy or transurethral resection of the prostate (47% to 92%), mastectomy (37% to 79%), shoulder arthro-

plasty (38% to 74%), and laparoscopic appendectomy (66% to 83%). The most improved medical centers were San Rafael (68% to 96%), San Jose (59% to 85%), and Roseville (58% to 82%).

**Discussion:** Surgical home recovery can be accomplished without compromising quality, is preferred by most patients and families while hospital beds are freed up for others. We achieved statistically significant higher rates of home recovery within a few months. Success is attributable to: 1) self-nominated surgeon champions; 2) dedicated time for surgeons to discuss best practices, surgical techniques, and review data; 3) revealing reports identifying unknown variation in physician practice and highlighting opportunities by facility and procedure; 4) additional tools to share best practices: Video and written guidelines. These practices could quickly be adopted by other Kaiser Permanente Regions.

*From Mid-Atlantic States*

## 13. Mid-Atlantic States Chronic Heart Failure Program

**Farzaneh Sabi, MD; Mabelle Behzadi, MHA; Betty Rice; Jessica Kane; Blair Van-Horn**

DOI: <https://doi.org/10.7812/TPP/19-039-13>

**Background:** Heart failure (HF) is a chronic condition affecting millions of people every year. During the course of this condition, heart function may deteriorate, especially in people with poor diet and exercise habits, other chronic conditions, and poor compliance with medications. Investments in the early diagnosis and treatment of heart failure, including support with medication adherence, improving diet and reducing sodium intake, as well as increasing daily physical activity, can improve the overall quality of life and decrease the morbidity and mortality rates associated with heart failure.

**Methods:** The HF Program focuses on outreach and support for members with HF who demonstrated signs of decompensation or progression of their chronic condition. The goal of the program is to have high-frequency outreach with members to support them in gaining the knowledge to manage their HF. In collaboration with the members' primary care physician/cardiologist, the nurses work closely with the members to review their compliance with medication, diet, and exercise recommendations by their physicians. This is achieved by performance improvements and monitoring of medication titration and adherence, lifestyle management, nutrition counseling, and life care planning through a combination of in-person consultations, telephone appointments, and classroom education by program registered nurses.

**Results:** The Regional HF Program launched in March 2018, and approximately 900 members were enrolled in the program as of December 31, 2018. This represented 11% of all Kaiser Permanente Mid-Atlantic States members with the diagnosis of heart failure. Members enrolled in the program had a 65% reduction of urgent care/clinical decision unit (CDU) utilization, a 19% reduction in their Emergency Department utilization, and a 56% reduction in their hospital utilization. Forty-nine percent of members in this program also had diabetes, and 98% were up to date on their annual hemoglobin A<sub>1c</sub> measurements. Eighty-one percent of members in this program had documentation of life care planning discussions, and 17% had an advanced directive on file. One hundred seventeen members successfully graduated from this program through demonstration of improvements in their clinical conditions, demonstration of understanding and adherence to medication regimens, daily

weight and blood pressure measurements, and sustained lifestyle changes to improve their overall health and outcomes.

**Discussion:** Intensive outreach programs focusing on medication adherence and understanding and changes in lifestyle including diet, exercise, and smoking cessation, led to improvements in overall health and reductions in avoidable Emergency Department and hospital visits for members with decompensating HF.

*From Northern California and Southern California*

#### 14. Patient-Centered Management for Chronic Disease—A Model Applied to Parkinson Disease Care in Southern California

Jason Cheves, MSBA; Steve Cedrone, MBA; Todd Sachs, MD; Kathy Kigerl, RN, MN

DOI: <https://doi.org/10.7812/TPP/19-039-14>

**Background:** Recent research indicates specialized physical, occupational, and speech therapy can help delay the progression of Parkinson disease (PD) and can help patients manage disease symptoms. Furthermore, evidence from ParkinsonNet in the Netherlands suggests specialized therapy correlates to reduced fracture rates and Emergency Department (ED) visits. Additionally, our “Voice of the Customer” work has shown patients and caregivers want relevant and abundant information about their disease, along with inclusion in the decision-making process of their care.

**Methods:** There are currently more than 11,000 Kaiser Permanente patients with PD in Southern California. Intervention includes disease-specific training for select ancillary practitioners; refinement of existing workflows to ensure patient referrals to these experts for care; creation of multidisciplinary expert teams to prioritize and coordinate care; a Web site platform designed to provide information to patients, caregivers, and practitioners; and involvement and sponsorship of community events. Patients also complete questionnaires to inform the physician as to their current emotional and physical state and to provide an overall patient perspective of the level of care and service they are receiving. All data are collected, analyzed, and reported monthly.

**Results:** Parkinson’s Care was implemented regionwide between 2014 and 2015. Since its inception, more than 125 Southern California ancillary practitioners have received PD-specific training. Data suggest patients are receiving more frequent ancillary therapies, and referrals and visits for therapy have approximately doubled regionwide. Approximately 67% of therapist visits are with PD-trained therapists, higher than the rates observed by ParkinsonNet at Radboud University (Nijmegen, The Netherlands). ED visits and inpatient admissions have decreased approximately 22% and 17%, respectively, and fracture rates have decreased approximately 56% for this population. Patient and caregiver feedback has been positive regarding improved access to care, patient-centered and collaborative visits, and information received. These successful results have garnered Kaiser Permanente-authored article publications and submissions in leading global public health journals.

**Discussion:** Parkinson’s Care has demonstrated successfully that a patient-centered model, with input from patients, caregivers, and specialized care, coupled with relevant and abundant information, can improve quality of care, patient safety, and member satisfaction in dealing with chronic diseases. Key components of this approach

include: 1) a Web site platform, used for collaborative communication, information, and support; 2) specially disease-trained ancillary practitioners; 3) patient-centered care to collaboratively treat the “whole person,” not just one symptom; and 4) and community involvement. Given these compelling results, we believe the Parkinson’s Care model could be implemented and spread to other Regions and conditions.

*From Northwest*

#### 15. Coordinated Regionwide Care Management Intervention for Patient with Chronic Obstructive Pulmonary Disease at Risk of Acute Exacerbation Reduces Hospital Days

Richard Mularski, MD, MSHS, MCR; Sanja Uskokovic, MS, PMP; David M Mosen, PhD; Bryan L Skalberg, MS; Achikam Haim, PhD; Marianne C Turley, PhD; Nancy L Lee, RPh; Wui-Leong Koh, MD

DOI: <https://doi.org/10.7812/TPP/19-039-15>

**Background:** Chronic obstructive pulmonary disease (COPD) affects 12 million to 29 million individuals resulting in 800,000 yearly hospitalizations in the US. Implementation deficits for COPD care results in excess acute exacerbations (AEs), lowered quality of life, reduced functional status, and compromised survival. We developed and tested a targeted intervention across the Northwest Region to identify patients at high risk, provide guideline-recommended proactive care, and evaluate process and outcome metrics for this population.

**Methods:** We identified an at-risk COPD population in 2 phases for implementation defined by (phase 1) age older than 65 years by International Classification of Diseases-10 visits and 2 or more AEs in the prior year with systemic steroid dispensing or (phase 2) age older than 40 years with any COPD AE hospitalizations in the previous year. Multiple coordinated care management teams completed an action plan (standardized symptoms linked to actions such as start medications) with patients, facilitated influenza/pneumococcus vaccines, and provided rescue medications. Process measures assessed care delivery components; outcome metrics (included AEs, utilization, and death) were compared with historical controls and completers (received all planned interventions/medications) were compared with noncompleters.

**Results:** We identified 149 patients in phase 1 and 264 in phase 2; respective historical cohorts had 118 and 149 patients. Action plans were delivered in 55% of outreached patients; vaccine rates improved from < 50% to 65% ( $p < 0.01$ ); and rescue medication orders improved from < 1% to 20% ( $p < 0.0001$ ). Nonsignificant trends were seen in hospital admissions (26% postimplementation vs 31% preimplementation) and 30-day readmission (18% vs 35%). Hospital days were reduced in completers ( $0.94 \pm 2.51$  days) vs those who did not receive all components ( $1.90 \pm 5.58$  days,  $p < 0.05$ ). Similar trends were seen in other measures of utilization. Additionally, in the completer group, mortality trended down from 6.0% to 1.3% (not significant), as did overall AEs from 25.0% to 20.5% (not significant) compared with noncompleters.

**Discussion:** Our analysis showed that a proactive program coordinating care management for at-risk COPD patients had a favorable impact on care delivery and utilization. We completed a second year of the intervention (evaluation pending summer 2019) and are preparing for regionwide spread of these improvements in care delivery with all primary care providers to further attempt to reduce AEs and

hospitalizations for patients with COPD. Using a population-based strategy supported by our Region's learning health system work, we identify individuals for preventative services. Multiple coordinated care management teams are trained; using electronic medical record-based strategies clinicians contact patients, complete an action plan, facilitate vaccine completion, and provide rescue medications to be used at early signs of AE.

*From Southern California*

### 16. Decreasing Sleepless Nights for Patients and Practitioners by Fast Tracking Patients with Diagnostic Images Highly Suspicious for Cancer

Rischl Alindogan, BSN; Brian Doerning, MD; Robert Lin, MD; Jamie Difiori, MD; Harold Chow, MD; James Carter, RPA; Cynthia Payne, PhD

DOI: <https://doi.org/10.7812/TPP/19-039-16>

**Background:** Development of the No Sleepless Nights program began in 2015, with a goal of streamlining the patient's care experience after receiving diagnostic images highly suspicious for cancer. A chart review of the top 10 diagnosed cancers within the Baldwin Park service area showed a 35-day average between the time of highly suspicious diagnostic imaging to specialty appointment. This chart review also revealed variances with examinations and referrals ordered for the same type of cancer.

**Methods:** A committee of hospital administrators, specialists, primary care practitioners, radiologists, pathologists, and nurses organized to analyze current processes and formulated the No Sleepless Nights program. The program entails the use of a closed-loop system, and under specialty-developed protocols and direct supervision of specialty services, a nurse coordinator contacts the patient with examination results, places orders for tests and referrals on behalf of primary care, and assists with scheduling these appointments. After program implementation, the length of time from highly suspicious diagnostic imaging to specialty appointment was tracked and reported to the committee throughout the year.

**Results:** Implementation of the No Sleepless Nights program has reduced the average number of days from highly suspicious diagnostic imaging to specialty appointment from 35 to 10 days. In addition, this program has developed standardized guidelines for cancer workup, optimized use of the organization's resources, and improved patient care. The program exceeds 1050 participants, has captured 39 different cancer types, and has wide acceptance and appreciation by patients, families, primary care practitioners, and specialists. As a byproduct of this program, patients are reaching the specialty department with the necessary workup completed, therefore, saving precious time for both the patient and physician. Furthermore, patients have an additional resource of support as they navigate this uncertain and frightening time involving their health.

**Discussion:** This program has been limited to patients within the Baldwin Park service area. Because this program has been chosen for regional spread, we anticipate an expansion of its utilization and overall development. With regional spread, access to services outside of the Baldwin Park service area, such as positron-emission tomography scans and radiation therapy, will enhance and further streamline the No Sleepless Nights program. We have identified the importance of forming a multidisciplinary team committed to the

program's goal, along with excellent leadership and administrative support, as keys for the successful development and implementation of the No Sleepless Nights program.

*From Northwest*

### 17. Combining Minimally Invasive Thoracic Surgery Techniques and a Multidisciplinary Care Model Leads to Superior Outcomes

Brian Timm, PA-C; Christopher Mutrie, MD; Piotr Starosta, PA-C; Julie Faulk, PA-C; German Collazo, PA-C; Yong Shin, MD; William Shely, MD; Thomas Lampros, MD; David Tse, MD

DOI: <https://doi.org/10.7812/TPP/19-039-17>

**Background:** The mission of Kaiser Permanente (KP) is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve. Combining skilled minimally invasive surgical techniques and a multidisciplinary approach to caring for complex patients has proved successful in serving this mission, which benefits our members and the health care team that serves them.

**Methods:** Of the lobectomies performed in the KP Northwest Region, 96% are minimally invasive, compared with the Society of Thoracic Surgeons (STS) average of 76%. All thoracic surgery patients are cared for by a multidisciplinary team. Our team, physicians (surgeons, intensivists, internists), physician assistants, nurses, pharmacists, physical therapists, dietitians, care coordinators, and social workers, round twice daily on each patient. The commitment to skilled surgical techniques and the multidisciplinary care model has established a culture of clear communication, daily goal setting, team accountability, and group decision making, and has resulted in proven excellent outcomes including: Low mortality rate, decreased length of stay, and lower-than-average pneumonia rates.

**Results:** Combining our minimally invasive surgical techniques and multidisciplinary care model has led to the following excellent results: Overall mortality rate of 0.0%, postprocedure length of stay of 1 day compared with the STS average of 4 days, and postoperative pneumonia rates of 1.1% compared with the STS average of 3.7%

**Discussion:** Modeling the KP Northwest approach to caring for complex thoracic surgery patients will result in improved program quality and patient outcomes which further serves KP's mission of providing high-quality, affordable health care services and improving the health of our members and the communities we serve. Quality is becoming an increasing driver of reimbursement, therefore sustainability is directly linked to quality outcomes.

*From Colorado, Georgia, Hawaii, Mid-Atlantic States, Northern California, Northwest, Southern California, and Washington*

### 18. Patient-Centered Redesign of Total Joint Replacement Care: Achieving the Quadruple Aim

Kate Koplan MD, MPH, FACP, CPPS; Violeta Rabrenovich, MHA, CHIE

DOI: <https://doi.org/10.7812/TPP/19-039-18>

**Background:** The National Total Joint Replacement Initiative (NTJRI) Home Recovery Program was implemented across Kaiser Permanente—in the inpatient and ambulatory setting with a purpose of

improving patient and physician experience, quality, and affordability of orthopedic care. The NTJRI team provides consultative support and facilitates spread throughout the program. Locally, each Region built on ongoing efforts within orthopedic services by carefully engaging orthopedic patients and clinical teams in proactive patient care and discharge planning, streamlining perioperative services, and designating a Total Joint Replacement Initiative (TJRI) case manager to ensure coordination of services throughout the whole episode of care.

**Methods:** The population includes patients who are clinically eligible based on evidence-based clinical recommendations and who agree to pursue a same-day elective unilateral hip or knee replacement. A method to spread and to implement the NTJRI program is an NTJRI playbook that includes preoperative evaluation, shared decision-making tools, home safety evaluation where available, patient education, pain control protocols, and instructions for follow-up care with physicians and physical therapy. A key intervention is having a TJRI case manager or an equivalent resource in care coordination and/or follow-up. Key inpatient components include appropriate anesthetic technique, and trained postsurgical physical therapy and ambulation. NTJRI metrics include an average length of stay (LOS) and the percentage of 0-day, 1-day, and 2-day stay procedures. In addition, we carefully monitor hospital readmissions, returns to Emergency Department or Urgent Care services, and surgical complications. The NTJRI dashboard incorporates all NTJRI safety measures and regional LOS targets. We also developed methodologies to assess physician and patient satisfaction with the NTJRI Home Recovery Program.

**Results:** As of third quarter (Q) 2018, programwide results were: 1) average LOS declined to 0.74, compared with 1.37 in Q4 2016; 2) 44.1% 0-day LOS surgeries, an increase of 34.7% from Q4 2016; 3) 44.0% 1-day LOS surgeries, a decrease of 15.3% from Q4 2016; 4) 30-day readmissions rate (2.4%) has decreased 0.2% since Q4 2016, whereas return-to-care rate (6.3%) has decreased 0.5% since Q4 2016; 5) For 0-day LOS, return to care was < 8% in 5 of 7 Regions and readmissions were < 3% in all participating Regions. The 2018 NTJRI Physician Satisfaction Survey results demonstrated improved physician experience compared with 2017 results: 93% vs 80% in 2017 of respondents agreed that they are welcomed to contribute to improvement efforts; 80% vs 76% in 2017 of respondents reported that the overall changes in the last 6 months has made the total joint replacement service better; and 83% vs 76% in 2017 of respondents reported that they are satisfied with their own practice. The results also improved physicians' perception about NTJRI Home Recovery Program LOS (ie, 62% of respondents reported they are comfortable with a planned 0-day LOS). According to the 2018 NTJRI Patient Satisfaction Survey results, overall experience for total joint replacement was highly rated by most patients (93% report excellent/very good; approximately 80% reported extremely satisfied); shorter LOS (or same-day discharge) is associated with better care experience and patient reporting feeling ready to leave the facility; patient satisfaction with surgeons and other medical staff was 99% and 97%.

**Discussion:** As an integrated care delivery system, Kaiser Permanente is well positioned to codesign and integrate input received from patients and clinicians in an evidence-based care delivery program. The NTJRI Program provides a model that can be replicated in other programwide improvement efforts. Both patient and clinician engagement strategies and monitoring of their experience with the program are important outcome and balancing indicators of successful spread and implementation.

*From Washington*

## 19. HIV/AIDS: A 30-Year History of Care Delivery

Patricia L Philbin, RN; Karen Lewis Smith, MHA; Susan McDonald, RN, MSN; Kathy Brown MD, FACP, AAHIVS; Dan Kent, PharmD

DOI: <https://doi.org/10.7812/TPP/19-039-19>

**Background:** The ability to manage a chronic disease is critical to the Triple Aim. HIV is a chronic disease and with successful management of the disease we can offer the individual the ability to live longer and have a higher quality of life. We can also improve both health outcomes and cost. When we successfully reduce the transmission of HIV to others, we improve our community.

**Methods:** The HIV program at Kaiser Permanente Washington is based in primary care. The program provides consultative services to the primary care practitioners/champions as well an annual HIV training and monthly updates. In addition, the HIV program works closely with the Special Medication Pharmacy to follow adherence to treatment regimens. The HIV program has taken the key elements of its success and has added a Pre-Exposure Prophylaxis (PrEP) program in the last 3 years. These programs continue to demonstrate a high-quality, cost-effective care model.

**Results:** Since its inception in 1988, the HIV program has been managed in primary care with an HIV chief expert. The program has evolved from an Excel (Microsoft, Redmond, WA) spreadsheet with a few practitioners to a program with an extensive Epic (Epic Systems Corp, Verona, WI) registry and primary care champions in all our primary care clinics. The program has had many iterations but critical components of the program include establishing a close partnership with our HIV clinical pharmacist, our Special Medication Pharmacy, our Epic partners as well as the HIV community at large. We work diligently with our state, county, and city to assure safety nets for our HIV population. We have used the knowledge we have gained from our HIV model to develop a successful PrEP program.

**Discussion:** One of the most important take-home messages is the role primary care can and does play in managing HIV as a chronic condition. It does work. One of the limits and learnings of the program is the ability to assure new practitioners are always aware of the resources the program offers. This is particularly true for patients who enter the system with stable HIV disease and have not chosen an HIV champion. Another challenge, as funding sources change, is to continue to be vigilant about community resources that have provided safety nets. Finally, we hope to replicate this model as we further develop our care for the transgender population.

*From Northern California*

## 20. Enhancing Dispositions from the Emergency Department—the Northern California Journey to Care for Increasingly Complex Populations

Rayne Soriano PhD, RN; Vivian Reyes, MD; Jo-Ann Griffin, RN

DOI: <https://doi.org/10.7812/TPP/19-039-20>

**Background:** Amidst the challenges with overcrowding, Emergency Departments (EDs) across the nation, including Kaiser Permanente's, are experiencing an increase in utilization from complex patient cases such as the frail and elderly, the homeless, and those with behavioral

health conditions. Homeless patients, for example, are 50.8% more likely to be readmitted to hospitals and stay 2.3 days longer, resulting in increased utilization and costs.

**Methods:** Focusing on complex patient populations, 6 ED engagements were conducted to highlight systemwide opportunities to reduce ED length of stay, ED admission rates, ED visits, ED readmissions, and to improve care for our diverse patient populations, while also defining standard work for all medical centers. As part of the design, a new role—care without delay director—was formed to work during the ED’s busiest times to be a catalyst in enhancing patient dispositions. This work also facilitated the development of a comprehensive Enhanced ED Disposition scorecard to monitor and sustain quality care in the ED.

**Results:** These engagements generated systemwide enhancements: AllScripts technology in the ED; standard work for leaders and front-line staff; role clarity for the continuum aligned with a “pull strategy” from the ED; and an insight-driven scorecard for ED Care Without Delay performance. Throughout the pilots, we learned qualitative and quantitative outcomes revealing continued opportunities to improve our design and measurement strategy for Enhanced ED Disposition. Feedback from leaders and frontline caregivers have been positive, and as we finalize the design and evaluation of a model for spread, our pilot sites have shown improvements in ED admit rates and ED length of stay. Work plans for local leaders were also developed to sustain a culture of care without delay in the ED.

**Discussion:** This work raised the awareness for the need of systemwide solutions and a measurement strategy to guide next steps of enhanced ED disposition. The details gleaned from the engagements validated the depth of the challenges of complex dispositions from the ED and provided a new line of sight into ED operations while strengthening partnerships between the ED, rehabilitation medicine or risk management, home-based support, and the continuum to solve problems in real time. These enhancements will be incorporated into the foundational hospital model of care for 2019. The following opportunities were also revealed: Specialized geriatric ED care, homeless pathways, nonmember workflows, and enhancing ED behavioral health.

*From Mid-Atlantic States*

## 21. Mid-Atlantic States Hospital Patient Day Rate Reduction

**Farzaneh Sabi, MD; Pam Galley, MAOL; Claire Pagano, MHA; Blair Van-Horn**

DOI: <https://doi.org/10.7812/TPP/19-039-21>

**Background:** Between 2015 and 2017, the Kaiser Permanente Mid-Atlantic States (KPMAS) patient day rate (PDR) rose by 18.25% (251.5 in 2015 to 307.5 in 2017). The increase in the PDR was multifactorial, including variables of increased membership, changes in member mix (Medicaid, Affordable Care Act), in the setting of ongoing capacity restraints in their partnering hospitals. KPMAS does not own or operate any Kaiser Foundation Hospitals in their Region.

**Methods:** KPMAS reduced avoidable hospital days by improving care coordination in the ambulatory and acute settings. This included proactive outreach and enrollment of high-risk populations into case management (CM), an investment in the CM workforce, and efficiencies through standardization of workflows and documentation. Rounding and care coordination in the acute setting was standardized across the Region with pairing of hospitalists and patient care coordinators, twice daily huddles, bedside multidisciplinary rounds, utilization manage-

ment reviews, and standardized handoffs from the acute teams to the ambulatory teams. Appropriate surgical procedures were internalized to Ambulatory Surgery Centers (ASC). Investments were made in the pharmacy team to support members’ medication reconciliation.

**Results:** A 4.4% decrease in overall PDR was achieved in 2018. The major driver of the reduction in PDR was a 6.6% decrease in the admission rate. This is a result of the work done by improving care coordination in the ambulatory setting through the KPMAS complex care program, proactive care management programs, case management, and access to urgent care and clinical decision units. Internalization of appropriate surgical procedures to the ASC led to a 19.7% decrease in the surgical admission rate. The rate of medication reconciliation by transitional pharmacists for all members discharged from the hospital doubled in 2018. In addition to the support of the transitional pharmacists in the inpatient setting, transitional pharmacists provided medication reconciliation and support for members in the clinical decision units and skilled nursing facilities.

**Discussion:** Hospital utilization rates are multifactorial and impacted by membership mix, management of chronic conditions in the ambulatory setting, access to care in the ambulatory setting, care coordination, and engagement of members with their health care teams. KPMAS has been on a journey of investments in the ambulatory infrastructure, which improves quality, access, and member satisfaction while driving down avoidable outside medical services utilization.

*From Northwest*

## 22. Preventing “Silent Droppers”: Standardizing Interventions to Prevent Lung Function Decline in Patients with Cystic Fibrosis

**Jennifer Bass, MD; Adrienne Aldredge, MS; Ashley Addington; Richard Cohen, MD; Megan Danish; Susan Mikkelsen, MD; Kay Pasquesi; Kimberly Rondeau; Megan Wackford; Eric Walter, MD**

DOI: <https://doi.org/10.7812/TPP/19-039-22>

**Background:** Patients with cystic fibrosis (CF) often experience progressive declines in lung function over time as measured by the forced expiratory volume in 1 second (FEV<sub>1</sub>). To account for age, race, and lung size (height), FEV<sub>1</sub> is reported as a percentile of expected for that individual (FEV<sub>1</sub>%). The more a patient’s FEV<sub>1</sub>% declines, the higher the risk of poor outcomes including hospitalization, infection, and ultimately respiratory failure. By intervening early and carefully tracking follow-up when FEV<sub>1</sub>% declines occur, the care team can help patients better maintain lung function over time and reduce hospitalizations and complications.

**Methods:** All children and adults followed by the Kaiser Permanente Northwest CF Center who were able to do pulmonary function testing (age 6 and up) were included in the project. Our center developed an algorithm to recognize and treat pulmonary exacerbations (decreases in FEV<sub>1</sub>% of 5% or more from baseline). We tracked practitioner/patient adherence to the standardized protocol as well as scheduled follow-up. We monitored posttreatment FEV<sub>1</sub>% and compared it with baseline FEV<sub>1</sub>%. We reviewed monthly run charts tracking FEV<sub>1</sub>%, adherence to protocol and follow-up visits. We compared patients on standardized protocol with patients not adherent to protocol. Our outcomes were relative decline in FEV<sub>1</sub>% over time compared with

baseline FEV<sub>1</sub>%, adherence to protocol, and percentage of patients with a follow-up visit in 2 to 6 weeks.

**Results:** From January 1, 2017 to December 31, 2018, there were 218 pulmonary exacerbations in which FEV<sub>1</sub>% decreased by 5% or more. Adherence to the protocol was associated with a better chance of posttreatment FEV<sub>1</sub>% recovery. Posttreatment, patients who adhered to the protocol (183) had a relative decline of 5.1% compared with those who did not adhere to the protocol (35) who had a relative decline of 13.7%. Children (< 18 years) had the best FEV<sub>1</sub>% recovery with relative decline of 0.4% upon follow-up. Those treated with intravenous antibiotics had a better chance of recovery than those who took oral antibiotics or only increased chest therapy (-3.9% vs -7.7% and -6.6%). Overall protocol adherence improved from 76.6% in year 1 to 91.7% in year 2. The percentage of patients with a follow-up appointment scheduled in 2 to 6 weeks averaged 80% to 82%. Median FEV<sub>1</sub>% for pediatric patients has improved from 80.3% in 2015 to 87.3% in 2017 and 91.3% in 2018.

**Discussion:** The CF patient population is small but medically complex. Patients require frequent interaction with the health care system. By standardizing our interventions for these patients, we ensured that clinic visits were used effectively to track progress, modify treatments, and schedule follow-up appointments. Protocol adherence was associated with improved outcomes, especially for children and those on intravenous antibiotics. FEV<sub>1</sub>% in our pediatric population is improving. Engaging all members of the care team to help design, implement, problem solve, and analyze the results from this project was key to our success. We have shared our project with other Kaiser Permanente Regions at an interregional CF meeting and at the North American Cystic Fibrosis Conference.

## EQUITY

*From Program Offices*

### 23. Igniting an Inclusive Movement—Utilizing ILEaD (Inclusively Leading Through Equity and Diversity)

**Laura Long, MBA; Susan Terrill**

DOI: <https://doi.org/10.7812/TPP/19-039-23>

**Background:** Kaiser Permanente (KP) aims to cultivate an inclusive climate beginning with the Inclusively Leading Through Equity and Diversity (ILEaD) program. This learning experience is part of a greater effort launched in late 2018—The Inclusive Climate Shift. This enterprisewide effort was informed and inspired by the feedback from KP employees and our bold ambitions from the Shared Agenda. ILEaD is a way for KP to cultivate an inclusive climate that makes our employees feel a sense of belonging, psychological safety, and empowerment.

**Methods:** We have an inclusive climate problem. By helping participants understand that each person's identity is an amalgamation of our shared experiences, we overcome biases, build trust and connectivity, and minimize blind spots—all vital to increased engagement and shifting mindsets. Through a series of exercises, microlearnings, and facilitated discussions that can be replicated, Leading Inclusively is a necessary tool for developing agents of change.

**Results:** In our Leading Inclusively Executive Round Table pilot, we conducted a pre-self-assessment inclusion survey. The aggregate

survey results were then distributed and discussed among participants and followed-up by individual assessment results. The findings were fascinating; for example, in every trait of the 7 attributes assessed, there was a large disparity between one's own perceptions and the perceptions made by one's peers. Since its inception, ILEaD workshops have been facilitated across all Regions in the enterprise and 2000 KP employees have engaged with this workshop and tool kits to date.

**Discussion:** In our efforts to increase engagement in the Inclusive Climate Shift across the enterprise and ultimately to create a more inclusive climate for all current and future KP employees, we strove to build engagement and excitement around inclusion, and to create and practice tangible new habits of inclusive leadership, building inclusive practices into regular team meetings, and generating commitment and behavior change.

*From Hawaii*

### 24. Addressing Disparities in Health with Motivational Interviewing

**Deborah Baker, PhD; Hyewon Jun, MD, MPH; Dee Keyser; Peggy Latare, MD**

DOI: <https://doi.org/10.7812/TPP/19-039-24>

**Background:** Behavioral change is a key intervention in treating chronic disease, such as diabetes or obesity. Our patient population is diverse as evidenced by our health care disparities, and this requires many approaches. Motivational interviewing (MI) is fundamental in personalizing care and discovering a patient's motivation in changing behavior toward wellness. With the rate of physician burn out, this technique helps clinicians connect to patients, build resiliency, and find joy in practice.

**Methods:** Codesign started with a patient advisor who had expertise and passion for this work. We chose to adapt the curriculum on the basis of the MI work of Steven Malcolm Berg-Smith, MD, as well as The Permanente Medical Group Regional Health Education. We cotaught this work with a patient advisor rather than using actors for skills practice in the 3 medical office buildings where we piloted the program. We started with two 2.5-hour sessions offered with continuing medical education credits and meals on 2 islands: Oahu and Maui. Clinicians volunteered to attend. We invited primary care physicians, psychiatrists, therapists, health coaches, dietitians, and pharmacists. Each session was limited to 10 participants.

**Results:** We have 600 practitioners in our Medical Group and approximately 75 primary care physicians in the 3 medical office buildings in which we piloted the program. Thirty-three practitioners participated and gave positive feedback. We had mixed disciplines in each of the groups. We collected information from participants before and after the workshop. On the basis of their feedback, we adapted our curriculum over the 3 pilot sites, which resulted in two 2-hour sessions. After-hours sessions were challenging for clinicians and our last pilot was performed during an extended lunch. On the basis of this pilot, this program will now be offered regularly to all staff in addition to Art of Medicine, Shared Decision Making, Communicating Unanticipated Adverse Outcomes, and Communication Skills Intensive.

**Discussion:** A patient advisor codesigning and teaching an evidence-based model with clinicians resulted in an effective and efficient program. MI helps clinicians cultivate a stronger relationship with patients, thus finding a deeper joy in their practice. Witnessing the

resilience in their patients through their stories results in practitioners rediscovering this resilience in themselves. With the diversity of patients in Hawaii, MI is the patient- and family-centered way to engage with patients in their health care. As a Region, we already rank high in quality (National Committee for Quality Assurance rankings and Medicare 5-Star status). MI will reduce disparities hidden within these measures.

*From Southern California*

## 25. The Community Action Poverty Simulation

Lakiesha C Tidwell, Madalynne Wilkes-Grundy, MD; Shari G Chevez, MD; Anna Khachikyan

DOI: <https://doi.org/10.7812/TPP/19-039-25>

**Background:** The Community Action Poverty Simulation promotes a greater understanding of poverty in breaking down stereotypes and allowing participants to experience poverty and step into the real-life situations of others. During the simulation, participants role-play the lives of low-income families from single parents trying to care for their children to senior citizens trying to maintain their self-sufficiency on Social Security. The simulation opens your eyes to poverty and barriers to health care access.

**Results:** According to the Official Poverty Measure, 14.9% of all Californians, and 20.3% of California children, lived in poverty in 2013. California had the 16th highest overall poverty rate of the 50 states, and the 17th highest child poverty rate. The 2014 US Census has 16.4% of California population living in poverty. Poverty is a major cause of ill health and a barrier to accessing health care when needed. This relationship is financial: The poor cannot afford to purchase those things that are needed for good health, including sufficient quantities of quality food and health care. More than 90% of children living in the US and living in poverty were born in the US. Children from lower socioeconomic backgrounds have poorer health outcomes.

**Discussion:** The Community Action Poverty Simulation is a powerful, interactive experience designed to help participants understand what a typical low-income family goes through just trying to survive from month to month. A goal is to sensitize participants to the realities faced by low-income people and how those social and cultural contexts impact health care. A deeper understanding of barriers to health care access, as well as of their causes and impacts on people living in poverty's experience of care would help physicians and health care workers overcome these challenges and provide socially responsive care. Most importantly, it moves people to make a difference.

## MEDICATION MANAGEMENT

*From Colorado, Georgia, Hawaii, Mid-Atlantic States, Northern California, Northwest, Southern California, Washington, Program Office*

## 26. Reducing Opiate Use in Children and Teens: A Strategic Approach to a National Challenge

Anna Grosz, MD

DOI: <https://doi.org/10.7812/TPP/19-039-26>

**Background:** Opiate overuse and abuse is a national concern. One area that has received little attention is in pediatrics, even though

many opiate addictions start in childhood or teenage years. Opiate addiction often starts in adolescence from a physician's prescription. Additionally, codeine is known to increase risk of respiratory depression and death in children, especially after a tonsillectomy. Patient safety, particularly that of our youngest and most vulnerable patients, was the critical driver of this project.

**Methods:** Starting in Kaiser Permanente (KP) Northwest (KPNW) and spreading to all other KP Regions, electronic health record tools and opioid-reduction protocols were shared with head and neck surgery and other leaders in other Regions and with KPNW surgical services, pediatrics, and pharmacy committees. Electronic health record tools included order sets, smart groups, restriction locators, alternative alerts and patient instructions. Champions were identified, and leaders were engaged to spread this work throughout KP Regions. Pediatric opioid use has been measured from 2012 to 2018 with ongoing modification of protocols to further reduce usage.

**Results:** Starting with KPNW in 2012 and expanding to include KP Colorado, KP Hawaii, KP Northern California, and KP Southern California, there has been an overall 6-fold reduction in opioid use in young children after tonsillectomies through 2017. Opioid prescriptions for children younger than age 7 undergoing tonsillectomies dropped from an average of 72% to 13%. Post-tonsillectomy opiate use in young children went from 79% to 9% in KPNW; 88% to 7% in KP Colorado; 83% to 2% in KP Hawaii; 80% to 21% in KP Northern California; and 64% to 4% in KP Southern California. Additionally, several Regions have achieved meaningful reductions in overall pediatric opiate use stemming from interregional collaboration. KP Washington, KP Mid-Atlantic States, and KP Georgia have now joined this work.

**Discussion:** Keys to successful spread include starting with a passionate leader, identifying regional champions, using strategic interpersonal alliances, and using data to drive change. It is also important to identify and address barriers and resistance to change as well as a plan to maintain success. This interactive seminar will provide tools to drive change, receptivity, and appreciation of the new protocols; audience participation through guided-reflective inquiries and scenarios; small group discussion about related change management initiatives; and audience question and answer sessions.

*From Mid-Atlantic States, Northern California*

## 27. Impact of Medication Reconciliation Programs on Reducing Readmission Rate and Enhancing Medication Safety During Transitions of Care

Alfonso Becerra, PharmD; Donald Yee, RPh; Karen Cham, PharmD; Sheireen Huang, PharmD; Shubhi Nagrani, PharmD; Adenola Akilo, PharmD; Karina Briones, PharmD; Kelvin Chan, PharmD; Carolyn Woo, PharmD; Chad Friday, RPh

DOI: <https://doi.org/10.7812/TPP/19-039-27>

**Background:** Medication reconciliation upon hospital and skilled nursing facility (SNF) discharge allows for early identification of medication discrepancies and improves transitions of care, which affects hospital readmission. The Mid-Atlantic Transitional Care Clinical Pharmacy and Continuing Care Team focuses on the Comprehensive Medication Reconciliation (CMR) program for more than 35,000 members per year. Similarly, Northern California Regional Pharmacy



and Continuum Teams has focused on the SNF Medication Reconciliation program for SNF patients discharged to the community. Health and safety outcomes are trended to evaluate impact.

**Methods:** The Kaiser Permanente (KP) Mid-Atlantic States (KPMAS) CMR program targets all patients discharged from the hospital. At discharge, hospitalized patients with a calculated LACE score (length of stay, acuity of admission, comorbidities, number of Emergency Department [ED] visits) and patients with no LACE score are tracked. This is compared with baseline measures in prior years. The outcome measure includes readmission rates. The KP Northern California (KPNC) SNF Medication Reconciliation program targets all patients discharged from 27 contracted SNFs. Medication reconciliation is provided following SNF discharge. The comparator includes baseline hospital readmission and ED visits. The outcome measures include hospital readmission and ED visits, the number of medication interventions, and intervention types (ie, adherence, omissions, etc).

**Results:** Medication reconciliation in both the KPMAS CMR program and KPNC SNF Medication Reconciliation showed potential impact on hospital readmission. In the KPMAS CMR program, patients with a LACE score and medication reconciliation are up to 20% less likely to be readmitted than patients without. Among discharged patients with LACE  $\geq 10$ , 16% of patients with medication reconciliation were readmitted compared with 37% of patients without medication reconciliation. In the KPNC SNF Medication Reconciliation Program, preliminary pilot results show a reduction in inpatient readmission by 4.4% and overall ED utilization rate by 11.8%. Almost 80% of SNF patients discharged had at least 1 medication intervention with an average of 3 interventions per patient. The most common intervention included gap in drug therapy followed by vaccination recommendations.

**Discussion:** Medication reconciliation has a positive impact on health outcomes. Both programs have demonstrated how medication reconciliation can be leveraged to facilitate transitions of care with minimal disruptions. The KPMAS Region has surpassed the regional goal of completing medication reconciliation for 95% of patients discharged from a core hospital. The Transitional Care Clinical Pharmacy and Continuing Care Teams will continue to collaborate with health care practitioners, and track readmission data. KPNC Regional Pharmacy, Continuum teams, centralized outpatient pharmacists, and contracted SNFs, have identified the need for medication interventions throughout transitions of care. This program is being implemented to the remaining approximately 50 contracted SNFs.

## PATIENT ENGAGEMENT

*From Program Office*

### 28. Human-Centered Design at Kaiser Permanente: A Creative Approach to Problem Solving

**Jeff Hall; Connor Shea; Estee Neuwirth, PhD**

DOI: <https://doi.org/10.7812/TPP/19-039-28>

**Background:** Human-centered design (HCD) has been identified as a key strategic capability across multiple industries. Member and customer experience are crucial to the success of transforming organizations. HCD at Kaiser Permanente (KP [HCD@KP]), in particular,

is important in health care where the member voice is critical to delivering relevant and high-quality outcomes. HCD@KP is an internal effort to equip employees with best-in-class skills that empower them to deliver on KP's mission to provide high-quality, affordable, health care experiences for our members.

**Methods:** HCD@KP is for all employees of KP with a particular focus on quality. The program customizes and spreads the HCD and codesign processes within KP's unique cultural environment and the health care industry.

**Results:** As of 2018, HCD@KP programs have reached more than 5000 KP employees. The 2017 HCD@KP advanced program scored a 9.3/10 average satisfaction rating from participants from across KP in the program that included clinicians, staff, and program administrators. In the same survey, 100% of the 26 newly trained HCD@KP practitioners reported that they felt they could get better customer engagement with HCD@KP and that learning HCD tools and methods was instrumental in improving work outcomes. Eighty-eight percent also felt that they were able to produce solutions that were more innovative; 85% felt that using HCD will enable solutions that better meet customer needs. HCD@KP capability building programs are continuing to be in high demand across KP, reflecting the rapid spread HCD@KP application of processes, mindsets, and methods to deliver innovative customer-centered outcomes across KP regionally and nationally.

**Discussion:** Truly delivering person-centered care involves engaging with members and end-users such as clinicians and staff at every stage of our work. To deliver on person-centered care, individuals and teams within KP must be supported with best-in-class mindsets, methods, and tools. HCD@KP's robust framework and proven ability to bring member and customer experience into projects ensures that practitioners and members are alongside KP employees building solutions that are truly relevant to their needs. HCD@KP represents 1 core initiative working in partnership with other groups within KP to put the member and customer at the center of everything we do.

*From Southern California*

### 29. Meeting Members' Wishes in the Last Year of Life: A Journey Toward Concordance in Southern California

**David Glass; PhD Michael Kanter, MD; Paul Minardi, MD; Susan Wang, MD**

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**Background:** There is a large body of literature that posits that much of the medical care delivered during the last year of life is unneeded and unwanted. However, there is little evidence about how members view the amount of care, the types of care received, and whether that care matches their wishes. This study fills that gap. It provides insight into where Southern California does well and not so well from the member perspective, and why that occurs.

**Methods:** The results are based on 2 samples. The first was a survey with next of kin of 715 Southern California members (age 65 years or older) who died in April and May of 2017. The second involved administering the same survey to next of kin of 332 deceased members who died between June 2016 and May 2017 and whose costs during the last year of their life were in the top 10% of the costs of all members who died during this period. We examined the wishes, values, and health care experiences of the random sample of deceased members, then compared them with high-cost deceased members.

**Results:** The Southern California Permanente Medical Group (SCPMG), by and large, delivers care and treatments that strongly match the values and desires of its members at the end of their life. SCPMG does quite well on meeting members' wishes overall, the amount of treatment, the specific types of treatments, avoiding delivery of unwanted treatments, and providing desired treatments. However, 3 areas stand out in which SCPMG might improve its performance: A) enabling those desiring to die at home to do so; B) avoiding cardiopulmonary resuscitation, mechanical respiration, or artificial feeding for those not wanting it; and C) managing the levels of pain. Surprisingly, those who received the most care (in the top 10% of costs) were less satisfied with almost all aspects of their care and treatments.

**Discussion:** A key quality metric is the degree to which members' wishes and values are honored. It is reassuring that during the fraught period of the last year of life, SCPMG performs reasonably well and for the first time we have a comprehensive overview of our performance. There are several surprises underneath this broad finding, including 1) most members had engaged in end-of-life discussions with next of kin and physicians, contrary to claims that patients avoid these discussions; 2) most members said the amount of care was "just right," again contrary to much of the literature; and 3) 38% of those receiving cardiopulmonary resuscitation did not want it.

*From Colorado, Georgia, Hawaii, Northern California, Northwest, Southern California, Washington, Program Office*

### 30. Using Insights from End-of-Life Care Survey to Drive Improvement of Care at the End of Life

Margaret C Wang, PhD, MPH; Diane Brown, PhD, RN, FNAHQ, FAAN; Peter S Khang, MD; Ruma Kumar, MD

DOI: <https://doi.org/10.7812/TPP/19-039-30>

**Background:** Patient-centeredness, a key aspect of high-quality health care, is especially important among patients with advanced illness. However, there are very few measures available to enable consistent assessment of a patient's care experience across various care settings at the end of life. To address this knowledge gap and Kaiser Permanente (KP) organizational need, we developed, field-tested, and implemented a 21-question survey administered to deceased members' next of kin in 7 KP Regions, including KP Northern California, KP Southern California, KP Colorado, KP Georgia, KP Hawaii, KP Northwest, and KP Washington.

**Methods:** Survey respondents included the next of kin of recently deceased KP members who were age 18 years or older. Some of the deceased members received various forms of supportive services (eg, palliative care, hospice care, or both). Survey results were compared between those who received supportive services and those who did not, and across other factors of interest. Primary outcomes were: 1) overall rating of end-of-life quality, adopted from Veterans Administration's Bereaved Family Survey and endorsed by National Quality Forum; 2) KP providing care that met members' wishes; and 3) physicians and staff including members' preferences when discussing treatment options and care plans.

**Results:** There were 2701 surveys completed (25.6% response rate). Respondents were close family members (81.8%); familiar with the decedents' health issues (92%) and discussed end-of-life care preferences with them (87%). Overall care in the last month of life was rated

"Excellent" or "Very Good" by 80% of respondents. Respondents for members who received supportive services were more likely to rate care "Excellent" or "Very Good" (82%), compared with those who did not (69%). Care experience varied meaningfully across KP Regions (eg, overall care rating of "Excellent" or "Very Good" ranged from 74% to 84%). Regions are using the data to inform and validate strategic planning, implementation, and for further understanding (eg, drill down to service level or patient-specific circumstances) to enhance care for members at the end of life.

**Discussion:** The End-of-Life Care Survey provides KP's first inter-regional patient-centered quality measure for this important and sensitive care. Insights are used to facilitate learning across Regions and to support leaders in Specialty Palliative Care and Life Care Planning initiatives to assess aspects of care aligned with Specialty Palliative Care and Life Care Planning and to better understand the relationship between program participation and care experience. Additional opportunities to leverage this rich data to improve end-of-life care should be explored (eg, analyzing data from open-ended comments to guide further focus group explorations, linking survey and clarity data to better understand the relationship between care delivery and care experience).

*From Colorado, Georgia, Hawaii, Mid-Atlantic States, Northern California, Northwest, Southern California, Washington, Program Office*

### 31. Reducing Preventive Flips to Diagnostic—A Holistic Approach to Improving the Financial Experience for Members

Peter Gazanian; Erin Bilvado, MBA

DOI: <https://doi.org/10.7812/TPP/19-039-31>

**Background:** Rising medical costs are in the national spotlight and have been a growing concern for our members. Kaiser Permanente (KP) surveys show 50% of members are surprised by bills they receive. Contact centers report more than 20% of service billing complaints are a result of visits scheduled as preventive, then billed as diagnostic. Members are reaching out for help, even to the office of Bernard J Tyson. Improving our members' financial experience is of utmost importance as we transform internal operations to uphold the KP mission of providing affordable health care.

**Methods:** The study targeted preventive encounters that commonly result in surprise diagnostic charges and member complaints. Member complaints are identified through the financial service recovery program, which provides a stopgap by empowering contact center representatives to resolve issues and, if appropriate, adjust charges within set guardrails. On the basis of the documented reasons for complaints, cross-functional teams, including Patient Financial Services, Permanente Medical Groups, Revenue Cycle, and Benefits, review accounts and conduct data analysis to determine key root causes and options for resolution of the issues. The initial focus is reducing negative experiences and member complaints around preventive examinations.

**Results:** Analysis of complaints received for scheduled preventive visits billed as diagnostic revealed 70% were indeed preventive examinations. In the KP California Regions, 3.4 million preventive examinations occurred in 2018 with 617,000 visits (18%) resulting in additional patient cost share. Of the 617,000 visits, 16% resulted in members reaching out to the contact center with 9% resolved through

an adjustment of charges and 1% through a formal grievance. Analysis of these member complaints revealed 2 major scenarios: 1) cases where preventive services were documented and system alignment could potentially resolve the issue, and 2) cases where nonpreventive services were present.

**Discussion:** Solutions to the complex issues in our organization and industry will not be determined or designed while staying within the silos of our departments or functions. We must work together—holistically and iteratively—with shared accountability to achieve a truly integrated care and coverage experience that has our members at the center. As next steps, priority opportunities are being identified and driven to address the preventive examination issue under executive leadership across Patient Financial Services, Permanente Medical Groups, Revenue Cycle, and Benefits. Additional improvement efforts are in the queue, including vision and laboratory services.

## TOTAL HEALTH

*From Colorado, Georgia, Hawaii, Mid-Atlantic States, Northern California, Northwest, Southern California, Washington, and Program Office*

### 32. How Healthy Is My Community—Designing a Measurement System for Leaders and Implementers

**Pamela M Schwartz, MPH; Elisa Wong, MPH; Allen D Cheadle, PhD; John M Vu, MPH**

DOI: <https://doi.org/10.7812/TPP/19-039-32>

**Background:** How does a health care organization measure the health of the communities it serves? How can it track the impact of its strategies on community health and use the information to drive decision making and planning? The Kaiser Permanente (KP) Community Health (CH) measurement framework provides a vehicle for monitoring the health of KP communities, tracking the impact of our work, and facilitating shared accountability.

**Methods:** The KP CH strategy reaches beyond the CH Department to bring in contributions from the entire organization, including purchasing, hiring, clinical care, and environmental stewardship. Two questions guide the measurement framework for the CH strategy: 1) how healthy are KP communities? and 2) how does KP contribute to community health? To answer question 1, the CH report compares health indices for KP communities based on the County Health Rankings with national benchmarks computed using data from all 3000+ US counties. To answer question 2, a CH dashboard provides a snapshot view of performance on key community health efforts on a quarterly basis and tracks the short- and long-term outcomes of each initiative to help us better understand our impact.

**Results:** We will present selected data from the 2018 CH report showing percentile rankings for the health indices, along with data from the 2018 CH dashboard showing initiative progress. We will describe how these data are used throughout the organization for planning, program improvement, and accountability.

**Discussion:** The KP measurement framework provides senior leaders with information to understand impact and make decisions, while at the same time providing staff implementing the work with information for monitoring and program improvement. The panel discussion and interactive activities will describe the measurement

strategy; the implementation and communications plan; and the challenges, barriers, and lessons learned to date. The activities should be useful for other health care organizations seeking to both improve community health and document their progress toward achieving this challenging goal.

*From Program Office, Colorado, Georgia*

### 33. If You Want to Know How Mrs Smith is Doing, Ask Her! KP's Improved Medicare Total Health/Social Risk Assessment

**Tracy Lippard, MD, FACP; Carole Gardner, MD, AGSF; Matt Stiefel, MPA, MS; Ranu Pandey, MHA; Juliana Oronos, MPH**

DOI: <https://doi.org/10.7812/TPP/19-039-33>

**Background:** Older adults are an important growing member demographic. Of the US population, 20% will be age 65 years or older by the year 2030. Our recommended approach for the Medicare Total Health Assessment (MTHA) aims to improve members' physical, mental, social, and functional health and well-being and positively impact what matters most to them. Our approach aligns with Kaiser Permanente's mission to provide high-quality care while managing utilization and cost. It has the potential to improve Health Outcomes Survey (HOS) performance. Because the MTHA responses are highly correlated with HOS items, the MTHA serves as a reasonable proxy for the HOS, enabling examination of factors associated with HOS performance, prediction of HOS scores, and evaluation of interventions.

**Methods:** The MTHA collects self-reported information about Medicare members' overall health and functional status, health conditions/symptoms, behavioral and psychosocial risks, and activities of daily living. The current version does not include a robust social risk assessment, but we need and value this information for providing quality care and to help identify interventions to support HOS performance to address issues identified by the MTHA, a systematic approach to follow-up and documentation is recommended. The intervention includes use of the revised MTHA questionnaire (integrating social needs items, simplifying language) and implementation of a systematic approach to follow-up and documentation. The comparison is the MTHA version 1.0 or no MTHA. Outcome measures include member-reported health risks and health outcomes including Kaiser Permanente's Your Current Life Situation questionnaire or HOS.

**Results:** The MTHA has demonstrated the ability to identify older adults struggling with urinary incontinence, pain, sleep problems, mental/emotional health issues, increased fall risk, and food insecurity. The revised version will expand screening for social/economic risks and health literacy/numeracy issues that can negatively affect health, patient activation, and self-care. A survey of physicians and staff using the current MTHA found that 56% of primary care physicians and 78% of nurses and medical assistants believe that having members complete the MTHA before the annual wellness visit is extremely or very valuable. Additionally, 70% of members surveyed believe that health issues not typically addressed by their primary care physician were discussed during their annual wellness visit because of the MTHA. MTHA data are also being used for population health management (eg, assessing and reporting prevalence of health-related functional and social/economic risks), quality improvement, and predictive analytics.

**Discussion:** The MTHA is a tool for population management, highlighting risks that may not otherwise be identified in a standard visit. It was developed to meet Centers for Medicare and Medicaid Services requirements for the annual wellness visit-covered benefit that provides health-risk assessment and a personalized prevention plan. The MTHA collects self-reported information about overall health, functional status, health conditions/symptoms, and behavioral and psychosocial risks. It identifies important health issues, social concerns, and functional disabilities for clinical, operational, and research purposes. Using the revised MTHA and enhancing processes to address positive triggers, will even further enable identification of important medical and nonmedical risks, positively impact HOS measures, and allow us to improve the lives of our members.

*From Mid-Atlantic States*

### 34. Bridging Barriers to Care Access and Delivery: The Automation of Nonemergent Transportation in Kaiser Permanente Mid-Atlantic States

Kyle M Heidenberger; Rachel E Hill; Melissa Baldwin, MS, MBA; Jason C McCarthy, PharmD, MBA

DOI: <https://doi.org/10.7812/TPP/19-039-34>

**Background:** Transportation remains a major care delivery barrier for Kaiser Permanente Mid-Atlantic States (KPMAS) members. Through partnering with an external vendor, SafeRide Health, care team members are able to leverage an online platform to arrange rides for members requiring nonambulance transportation assistance. The SafeRide Health platform also provides on-demand analytics to report actionable ride utilization behaviors and patterns.

**Methods:** To automate and to centralize transportation arrangements, SafeRide Health was launched in KPMAS. Implementing SafeRide Health has allowed for integration of a Web-based platform to arrange rides on the basis of level of need with real-time analytics. Other considerations included ride share vendors, which could be only used to transport staff, and other health care transportation vendors that did not include an adequate level of reporting or potential for integration into the electronic health record. Reportable outcome measures tied to the overall initiative include decreases in outside medical spending, avoidable delays in hospital discharge caused by transportation-related conflicts, missed appointments owing to failed or lacking transportation, and Clinical Decision Unit/Emergency Department or hospital visits. There will also be an expected reduction in ambulance volume by offsetting with nonemergent medical transportation alternatives.

**Results:** Within the first few months of implementation, SafeRide Health has resulted in reduced transportation expenses, increased efficiencies for care delivery staff, and real-time analytics. It has also saved staff time as the online, centralized booking platform has replaced a manual, fragmented process that required staff to enter in member information for tracking and to place phone calls to members to arrange transportation. Utilization patterns are also tracked by reason, geography, and line of business coverage, allowing for appropriate planning and budgeting, as well as providing valuable data in anticipation of transportation-benefit exploratory discussions. The platform is expected to generate \$68,064 in transportation cost savings for ambulatory rides via Lyft and \$648,470 in savings

for nonemergent medical transportation with hospital transfers in year 1. Additional metrics are being monitored for further reported care delivery impacts.

**Discussion:** By leveraging technology via SafeRide Health, care delivery teams can efficiently arrange transportation for members at varying levels of need. The platform is also generating insight into regional transportation-demand drivers, which is growing our transportation program to appropriately meet member needs and to support access to comprehensive care delivery. To track key metrics, an interactive, actionable dashboard was developed to track utilization metrics against key population health indicators, such as age, race, and chronic disease program enrollment. Data reported through the dashboard, in addition to trending use patterns from SafeRide Health's analytics, will support planning and development discussions going forward, in addition to meeting specific strategic operating plan goals.

*From Colorado, Georgia, Hawaii, Mid-Atlantic States, Northern California, Northwest, Southern California, Washington, Program Office*

### 35. Addressing Social Needs: Organizational Learnings and Connecting with Our Communities

Sarita A Mohanty, MD, MPH, MBA; John F Steiner, MD, MPH; Nicole Friedman, MS; Briar Ertz-Berger, MD, MPH

DOI: <https://doi.org/10.7812/TPP/19-039-35>

**Background:** Social determinants of health account for 40% of health outcomes. Within Kaiser Permanente (KP), 30% of members live below 250% of the federal poverty level. KP lacks a systematic approach to assess social needs, to refer members to resources, to confirm that needs have been met, and to collaborate with community-based organizations (CBOs). The Social Needs Network for Evaluation and Translation (SONNET) promotes shared learning by helping design projects that employ effective measures, incorporate successful staffing and information-technology solutions, and evaluate outcomes rigorously to inform leadership decisions.

**Methods:** Social interventions have proliferated across KP, but outcomes are rarely evaluated. SONNET gathered information about program goals, design, measures, and outcomes and compiled this information into an online inventory, using a "care-continuum" model to report the findings in an online scoping review. These findings influenced key features of the Social Services Resource Locator (SSRL), including identification of member needs, submission and tracking of referrals to CBOs, reporting and analytics, and development of community partner networks. Staff, practitioners, members, and caregivers will have access to this tool and will work closely with community networks. The SSRL will provide extensive data to deepen the understanding of the effectiveness of social interventions.

**Results:** SONNET identified 35 KP programs, most of which included patients with complex needs or high costs. Food insecurity (8%-38%), housing instability (3%-11%), energy/utility needs (7%-24%), transportation barriers (16%-34%), and medical cost concerns (8%-37%) were common. Of members, 13% to 45% with basic needs were referred to community organizations, and 12% to 23% indicated that basic resource needs were met. One program found 7% to 12% reductions in utilization for members with predicted high costs. SSRL predeployment activities have included design sessions, review of

vendor tools, and assessment of and planning with deployment sites. Evaluation in early deployment sites will include characteristics of members, description of needs and community resources, referral counts, and communication with CBOs. Qualitative assessment will describe the experience of staff and clinicians, members, and community partners.

**Discussion:** KP has accumulated substantial organizational knowledge in program planning and implementation, but significant gaps remain in outcome assessment. The SSRL provides an opportunity to fill these knowledge gaps, and particularly to assess the health outcomes of social interventions. Anticipated benefits of the SSRL program include improved health outcomes; staff and practitioner satisfaction; and confidence in addressing total health, member satisfaction, and alignment with new federal and state regulatory requirements. The SSRL enables KP to be a leader in health care delivery by understanding and supporting the social needs of its members, while promoting system transformation and community-level capacity development and partnership-building.

## TEAMS

*From Northern California and Northwest*

### 36. The Kaiser Permanente Northwest Ventricular Assist Device Program

**Barbara Amos, RN, MSN, CNS; Timothy Jacobson, MD; Yong Shin, MD; Ryan Morrissey, MD; Siobhan Gray, MD; Pamela Montes, RN, MSN; Allison Lipnick, LCSW**

DOI: <https://doi.org/10.7812/TPP/19-039-36>

**Background:** Approximately 670,000 people in the US are diagnosed with heart failure each year, with half dying within 5 years of diagnosis. The ventricular assist device (VAD), an implanted mechanical pump, is a promising treatment. Although VAD therapy is complex, high risk, and expensive, it has been shown to improve survival and quality of life.

**Methods:** Kaiser Permanente (KP) Northwest (KPNW) launched its VAD program to improve outcomes and patient satisfaction, with an eye toward creating a national model. Candidates are rigorously evaluated for degree of illness, ability to undergo implant, and availability of postdischarge support. Evidence-based protocols guide the interdisciplinary team, and detailed scripts ensure smooth transitions at each point of the care journey. This approach has yielded impressive results. The VAD program exceeds national standards for hospital length of stay, 30-day readmission, and 1-year survival. Patients also score higher on quality-of-life measures.

**Results:** Average length of stay is 12 days, compared with 23 days nationally. Thirty-day readmissions are 0%, compared with 28% nationally. Survival at 38 months is 100%, compared with 60% nationally. In addition, the KPNW VAD program has implanted in 17 patients without using blood transfusions during the operative phase; although this is not reported data, this is an outlier among all implanting centers.

**Discussion:** The KPNW multidisciplinary approach to VAD patient care with proven successful outcomes can stimulate a national discus-

sion among KP Regions who are involved in VAD therapy to improve outcomes, decrease variability, enhance patient selection, standardize protocols, decrease the financial impact to KP, and improve the lives of our members nationally.

*From Mid-Atlantic States*

### 37. In-Basket Management: Empowering Nurses to be First Responders for Patient Messages, Providing The Right Care at The Right Time

**Dones M Trojillo, MSN, RN; Maia M Patel, MD, ScM**

DOI: <https://doi.org/10.7812/TPP/19-039-37>

**Background:** Patients increasingly send email messages regarding their health care, but not all messages require physician input. Our prior state routed all incoming messages through the bottleneck of overloaded physician in-baskets, increasing response times and lowering both physician and patient satisfaction. Launching our project in August 2017 helped us meet the needs of our rapidly growing membership and achieve our operations goal to “deliver exceptional care” and “deliver an extraordinary consumer experience” in the Mid-Atlantic Region.

**Methods:** Over 10 months, high-touch in-basket message management training was provided to 205 nurses in adult and family medicine. Patient vignettes were used to train each new functionality, including the use of standardized SmartPhrases and QuickActions created specifically for patient message replies. We continue to follow weekly and monthly metrics, tracking “hours to first touch” for each incoming message, the percentage of messages “screened out” by nurses (messages handled to completion without any physician input), and the percentage of messages researched and staged by nurses well enough that only “one touch” is required by physicians to complete the message.

**Results:** We saw an 83% decrease in the time to first touch for all incoming messages, cutting our regional response time from an average of 22.3 hours at baseline to 3.8 hours. Addressing the goal to have all health care team members working at the top of their licenses, we saw a 207% increase in the number of messages able to be handled entirely by nurses, moving from a baseline screened-out rate of 14%, to an average of 43% of all incoming messages screened out by nurses. Anecdotally, nurses are happier being empowered to triage and to manage patient requests from the outset, and our data confirmed that some of our top-performing nurses have truly taken ownership, screening out 70% of all incoming messages.

**Discussion:** Although we already had an optimal message pool design within Kaiser Permanente HealthConnect, we relied on physicians to “edit in” to those pools to manage incoming messages. By redefining our regional workflows, we are better leveraging the skills of our highly trained nurses in providing more timely responses to patient inquiries. In Adult Family Medicine, we are continuously monitoring outcomes, and evaluating the staffing model to sustain this success. We have extended our in-basket message management to the Pediatric and Obstetrics/Gynecology Departments, and will expand to specialty services in the Mid-Atlantic Region in 2019.

From Northern California

### 38. The Implementation of High-Reliability Organization Model for the Environmental Services Department at Santa Clara Medical Center

Eric Williams, MHA; Kari Frank, MS; Marc Smith, MHA

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**Background:** Establishing a strong foundation that is supported from executive leadership down to the front lines is necessary to achieve a high-reliability organization. Once a reliable health care system is achieved, the organization will be able to quickly identify sources of problems and be able to quickly and effectively respond to unexpected events. This resiliency leads to reduction in patient harm and workplace safety events.

**Methods:** In 2018, Santa Clara Medical Center's Environmental Services (EVS) underwent a process improvement journey. EVS found itself with high workplace safety accepted claims rates (ACR) and *Clostridium difficile* standard infection ratios (CDiff SIR) that were higher than regional standards. The EVS leadership team, consisting of directors and managers, participated in a value stream analysis in which they focused on hardwiring certain tools including leader standard work, daily management system, visual boards, and defining process metrics and outcome metrics. These efforts allowed them to increase their ratings in quality and safety by reducing CDiff SIR to meet regional benchmarks and improving their workplace safety ACR.

**Results:** For workplace safety, we looked at our ACR, total incidents, and supervisor first report. We compared our last quarter with our first 3 quarters of the performance year. We used this because we started to implement our tools and standard work at the beginning of the final quarter. For ACR, we went from an average of 8.98 for the first 3 quarters and dropped our ACR to 0.0 for the final quarter. For CDiff SIR, we had a SIR of 0.9 for the 2017 performance year. We were able to reduce our CDiff SIR to 0.79 for the 2018 performance year.

**Discussion:** The leader standard work that is developed and directly tied to leading indicators and outcome metrics helps the staff reconnect the "why" behind the work that they are responsible for. It highlights the meaning to their roles and allows them to fully understand their purpose. Our journey has consisted of implementing our strategies at the management level. As we continue our journey, the next steps will be to have our managers champion the work and create daily management systems for the front-line staff so that staff from executive leadership down to the front lines find their work to be meaningful and worthwhile.

From Northern California

### 39. Building A Virtual Nursing Team: Implementation of the Advance Alert Monitor

Laure E Lisk, RN, MS, CPHQ, CPHRM; Elizabeth Scruth, RN, PhD, MPH, CCNS, CCRN, FCCM; Vanessa Martinez, MSN, MPH, RN; Bronwyn Cox, MSN, RN; Kris Wilson, RN, MSN, CPHQ

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**Background:** Implementation of the Advance Alert Monitor (AAM) program has allowed us to create and to operationalize a virtual nursing care team that provides 24/7 support and consultation for inpatient adult medical/surgical population. The program comprised

more than 30 critical care-experienced registered nurses with post-graduate education and leadership skills. Regionwide adoption of the AAM program resulted in the need to develop the infrastructure to manage a series of complicated workflows that ensure systematic implementation and feedback mechanisms for the virtual team.

**Methods:** Virtual team development began in July 2016 concurrently with the AAM pilot implementation at a single medical center. A small nursing team was formed to provide oversight up to 16 hours per day. Additional AAM implementation occurred throughout 2017. Significant staffing increases supported 24/7 monitoring beginning in October 2017. Full implementation to all 21 facilities will be completed by December of 2018. The virtual team developed structured work processes and communication techniques to build best practices and enhance their relationship with the hospital-based team, composed of the hospital-based specialist, rapid response team nurse, and leadership; this was paramount to the success of our team.

**Results:** Recent data released by Gabriel Escobar, MD, and the Department of Research revealed a statistically significant reduction in hospital and 30-day mortality rates for the patients who triggered the early-warning alert relative to a similar patient population at hospitals without the intervention. AAM has proved its ability to predict patients who may decompensate within a 12-hour time frame since 2017. Creation and continual evaluation of a sustainable workflow, virtual team growth to accommodate 24/7 coverage, and meeting rigorous timelines have been significant milestones throughout 2017 and 2018. We also simultaneously transitioned our program from a Web-based application to a dashboard built within our own electronic medical record system (Kaiser Permanente HealthConnect).

**Discussion:** Some key identified areas for successful team engagement include developing clear communication techniques, a rhythm within the team including regularly scheduled meetings, and leveraging available technologies. A shared leadership model, which creates opportunities to involve others, has been shown to increase engagement. When creating a clinical virtual nursing team, professional experience is essential, and the ability to use critical thinking skills and independent decision making is paramount. Specific competencies required for these nurses include technical training, critical thinking, and problem-solving skills, additionally, interest in looking to future opportunities, willingness to change, and a passion for providing safe care for our members.

From Northwest, Southern California, Washington

### 40. Improving Quality and Safety Together: Reducing Primary Cesareans Perinatal Core Measure Collaborative

Lyn Yasumura, MD; Cheri Lowre, MD; Leslie Casper, MD; Marianna Volodarskiy, RN, MSN, NE-BC

DOI: <https://doi.org/10.7812/TPP/19-039-40>

**Background:** In 2014, the Pacific Business Group on Health, San Francisco, CA, and the Leapfrog Group, Washington, DC, reviewed cesarean sections and determined a mother's chances of having a cesarean related to the hospital she was admitted to more than any other medical factor. Cesarean rates varied (18% to 84%). These groups set a goal of preventing unnecessary cesareans in low-risk mothers. This followed by the Joint Commission adopting the target rate of 23.9% as a publicly reported core measure.

**Methods:** Within Kaiser Permanente Southern California, NTSV (nulliparous, term, singleton, vertex) cesarean rates varied by hospital from less than 20% to more than 35%. To address regional gaps, Southern California Regional Core Measure Collaborative was formed in 2015. The Collaborative is driven by local champions and regional leadership. We adopted practices recommended by the California Maternal Quality Care Collaborative (CMQCC), set up a mentor group with Kaiser Permanente facilities, analyzed the data in the California Maternal Data Center, and recommended specific interventions for outlier medical centers. We then met with the outlier hospitals, coached them through a set of personalized recommendations, and helped them overcome specific barriers.

**Results:** In summer 2016, the CMQCC issued a tool kit to support vaginal birth. The Southern California Region embarked on implementation through the Perinatal Patient Safety Committee in collaboration with the Perinatal Core Measure Collaborative team. Development of tools and implementation extended through 2017. In 2017, we evaluated the status of CMQCC recommendations implementation and utilization at bedside and identified gaps and opportunities to reinforce. In 2018, we developed and implemented a coaching and accountability strategy to address medical center specific gaps. By using the process of analyzing fall outs, developing personalized recommendations for outlier hospitals, and 1:1 mentoring and coaching, we were able to drop our regional NTSV rate below 23.9% for the first time.

**Discussion:** Implementing and hardwiring the use of evidence-based standard tools is critical for success and can be challenging when working with multiple individual practitioners. By using the process of analyzing data, in-depth chart analysis of fallouts, developing personalized recommendations for hospitals, and 1:1 mentoring and coaching, a large and diverse region can lower their NTSV cesarean rate below the target goal of 23.9%. These strategies will continue to be implemented to assure safe and quality care is provided to all patients. Achieving this goal requires a combined effort from the entire labor and delivery team.

## TECHNOLOGY

*From Southern California*

### 41. Leveraging Technology to Improve Appropriate Imaging Studies: There's an App for That!

**Peter Huynh, MD; Paymann Moin, MD; Michael Flores; Pamela Galvan; Steven Ethington**

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**Background:** The use of radiographic imaging has steadily increased over the years and has become a routine patient-evaluation component in health care delivery. Unnecessary medical imaging tests result in increased health expenditure and ionizing radiation exposure, and can lead to poor clinical outcomes. Given the increased popularity of mobile apps in health care, we sought to develop and implement a mobile app at our medical center that would provide appropriate, cost-effective imaging guidelines based on evidence-centered medicine. The aim is to deliver high-value health care by reducing health care waste and increasing patient safety through improved imaging appropriateness.

**Methods:** We used Guidebook.com as a platform to develop a mobile app called iMAGING APPropriateness App (iAPP), an easy-to-use

application that provides high-value imaging recommendations based on health practitioner-encountered symptoms and diagnoses. iAPP uses validated and evidenced-based literature such as the Canadian Computed Tomography Head Injury Rules, the Pediatric Emergency Care Applied Research Network (PECARN) criteria, the HEART (history, ECG [electrocardiogram], age, risk factors, troponin) Pathway, and Choosing Wisely. The iAPP was made available as a clinical resource across the medical center in 2018. Practitioners were able to access the iAPP at the patient's bedside to determine whether an imaging study needed to be ordered. We compared imaging utilization 3 months before and after implementation. We used the Healthcare Effectiveness Data and Information Set (HEDIS) low back imaging metric as a quality measure.

**Results:** Three months after implementation, iAPP was accessed 825 times by 114 unique health care providers. The average session duration was 33 seconds. Overall imaging utilization decreased from 40.75 (relative value units x order volume per 1000 members) to 35.63 (relative value units x order volume per 1000 members), a 12.6% reduction. HEDIS quality low back imaging metric improved from 90% to 90.7% compliance.

**Discussion:** iAPP, a mobile app based on evidenced-based imaging algorithms and guidelines, was successfully designed, developed, and implemented at our medical center. Health care practitioners were receptive to using this new technology. Leveraging health information technology using a mobile app for imaging guidelines resulted in a reduction in overall imaging utilization and improvement in a HEDIS quality metric.

*From Northwest and Southern California*

### 42. Using Human-Centered Design to Expand Telehealth Into the Hospital and Continuum

**Reema Shah MPH; Estee Neuwirth, PhD; Lan Nguyen; Carissa Lim; George Go, MD; Tamara Hillstrom; Dan Huynh, MD; Margaret Pierce; Colette Lundahl; David Miura; Lisa Arellanes**

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**Background:** As technology advances, telehealth provides a unique opportunity to meet the needs of members, care teams, and caregivers outside the traditional health care delivery setting. Compared with ambulatory arenas, telehealth in inpatient care and for posthospitalization care is limited, and the number of transitions, staff interactions, and acuity of patients causes additional complexities when designing a telehealth solution. Using human-centered design provides the opportunity to design a solution that can meet member, staff, and clinician needs while addressing the complexity of the setting.

**Methods:** Administrative and physician leadership in the hospital and continuum in Southern California and the Northwest were first interviewed to understand where there were opportunities for improvement in the hospital and continuum and how telehealth may be used to solve those gaps. After the interviews were synthesized, leadership, members, and caregivers then met to prioritize opportunities for further understanding and eventual design. Both Regions selected engaging family and caregivers of Medicare members through telehealth. Further ethnographic interviews, observations, and codesign sessions were held with Medicare members, caregivers, clinicians, and staff to develop solution concepts to better engage families and caregivers.

**Results:** Several distinct insights emerged: 1) caregivers felt overwhelmed by their new role and found it difficult to find the right

resources; 2) there are often multiple caregivers with different caregiving roles; 3) caregivers and patients do not feel equipped to manage patient medications; 4) caregivers, especially remote caregivers who were not by the patient's side in the hospital, often felt unprepared for discharge; and 5) caregivers and patients want a way to be able to connect to their care team for unexpected events postdischarge. These insights led to the design of an ecosystem of telehealth solutions that involves video, texting, and telephone capabilities to better connect members, caregivers, and the care team.

**Discussion:** Using human-centered design allowed for concepts to surface that may not have been considered if frontline staff, members, and caregivers were not involved in the design process. The next steps of this work are piloting in the Southern California and Northwest Regions. Because the solution is technology-focused, feasibility and cost must be considered throughout the design process and can be limitations to executing a design for which the technology is not available. Leaders play an important role in defining how a given solution can be made feasible in the short-term.

*From Northwest*

#### 43. Home Health Virtual Complexivist Physician Program: Leveraging Increased Scope of Care at a Crucial Time

Alicia Ahn, MD; Sandra Barton, MD; Binitha X Surendran, MBA, MS

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**Background:** The Home Health Virtual Complexivist Physician program was launched in 2014 as a grassroots effort by an innovative physician who saw a need to provide physician-level care to supplement the home-health visit. After 4 years of piloting workflows, the program now offers 3 virtual physicians who act as the temporary primary care physician for patients while they are receiving home-health services. These physicians take calls from field clinicians (nurses, therapists, and social workers) at the time of the home visit.

**Methods:** Kaiser Permanente members receiving home-health services from a Kaiser Permanente agency ( $n = 500$ ) and multiple contracted agencies ( $n = 500$ ) establish "Doctor of the Day" consultation line staffed by physicians to take calls from home-health nurses, therapists, and social workers when in the home. The program is primarily conducted using telephone calls but also uses a telemedicine resource ("telemdx") that enables 1-way radio and 2-way voice and is operated via cellular service, and thus is not dependent on home Internet or WiFi access. The physician can capture still photos from video and upload them to the patient chart. Metrics included hospital admission rates at 14 and 30 days, patient experience, home-health field clinician experience, and costs.

**Results:** Qualitative results include improved clinician experience. These field clinicians appreciate having a physician call at the time of the visit. The results identify improved timeliness, effectiveness, efficiency, and patient care experience as benefits of the program. The office-based primary care practitioners are appreciative of the care and coordination provided by the virtual physician team. The post-acute (skilled nursing facility) providers appreciate the opportunity to provide "warm hand off" to the home-health team for particularly complicated patients. Quantitative results show a sustained reduction in 14- and 30-day hospital admission and readmission rates from before the program was fully staffed (2013-2015) to full staffing (2016-2018). These data

are limited to the Kaiser Permanente home-health agency patients; we have not collected data from our contracted agencies at this time.

**Discussion:** The virtual physician service provides a unique opportunity to identify problems before they escalate. For patients who require transfer to acute care, the physician notifies the Emergency Department with warm handoff. Field clinicians appreciate physician consultation and teaching and can deliver more effective, patient-centered home-health care. Patients appreciate the opportunity to collaborate on a plan that meets their needs and wants. This often means a trial of "care at home" in which the physician will order services such as mobile imaging, phlebotomy, oxygen, and medications, and will arrange visits on a more frequent basis. Future innovations might include investigating a dedicated clinical nurse navigator to provide proactive outreach.

*From Northern California*

#### 44. Improving Patient Safety Via Information Transparency and Performance-Improvement Infrastructure

Asia Plahar, MS, RN; Kathy Ricossa, MS, RN

DOI: <https://doi.org/10.7812/TPP/19-039-44>

**Background:** The Kaiser Permanente Santa Clara Medical Center created a performance-improvement infrastructure focusing on total harm reduction, which is a composite of the following measures: Central line-associated blood stream infection, hospital-acquired pneumonia, catheter-associated urinary tract infection, *Clostridium difficile*, falls, hospital-acquired pressure injury, and safety events. A transformational shift began in March 2016 when an infrastructure was created as a strategic plan to address total harm using a multidisciplinary team collaboration, evidence-based best practices, and performance-improvement methodology. In July 2017, this project of creating a data transparency system for total harm outcome and process measures was implemented.

**Methods:** The Total Harm Scorecard is composed of patient safety outcome and process measures. Outcome data are updated in real time and process-measures data are collected via rounding on patients daily. Outcome and process-measure data are visible through scorecards and control charts for medical center and departments. The Total Harm Scorecard is reviewed daily at the patient progression hub and managers report harm-reduction strategies in real time. The Total Harm Scorecard link is accessible to the entire medical center. The Total Harm Scorecard and department-level action plans are presented to the medical center's Quality Oversight Committees, which report to the Medical Executive Committee.

**Results:** In 2017, the Kaiser Permanente Santa Clara Medical Center achieved a 30% reduction in patient total harm, an 8.8% reduction in the rate of patients acquiring a nosocomial infection; 78 patients' lives were protected, 729 hospital days were avoided, and there was \$1,526,928 in savings.

**Discussion:** The performance-improvement infrastructure and total harm data visibility has improved the safety of our patients and protected 78 patients from harm in 2017 at our medical center. The performance-improvement infrastructure and total harm data visibility system was created as a strategic plan to reduce patient harm. As the result, 78 patients' lives were protected and harm was reduced by 30% in 2017. This total harm reduction transformational model can be generalized to other health care systems nationally and internationally. ❖



## REVIEW ARTICLE

# Pain Management Associated with Total Joint Arthroplasty: A Primer

Michelle J Lespasio, DNP, JD, ANP<sup>1</sup>; AJ Guarino, PhD<sup>2</sup>; Nipun Sodhi<sup>3</sup>; Michael A Mont, MD<sup>3</sup>

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<https://doi.org/10.7812/TPP/18-169>**ABSTRACT**

This primer presents a synopsis of pain management strategies associated with total joint arthroplasty. Patients considering total joint arthroplasty often experience moderate to severe pain, which places them at risk of opioid abuse or addiction. Currently, the best practice strategies involve the development of individualized multimodal perioperative approaches to pain management. These practices include prescribing opioids at their lowest dose and for the shortest duration necessary to control symptoms, with close monitoring of common adverse effects. Implementing these practices is essential to battling the ongoing opioid crisis in the US.

**INTRODUCTION**

The intent of this article is to deliver a concise introduction to pain management in total joint arthroplasty (TJA) in the midst of the ongoing opioid crisis in the US. The goals are to provide the reader with a synopsis of the current understanding of the opioid crisis and discuss its implications for pain management in patients with end-stage osteoarthritis who undergo TJA, most notably total knee arthroplasty (TKA) and/or total hip arthroplasty (THA). The effects of opiate pain management education on clinical outcomes and patient satisfaction are also described. Please see the Sidebar: Advance Organizer Quiz to Retrieve, Use, and Organize the Materials Presented.

**THE OPIOID OVERDOSE CRISIS**

The US is experiencing the worst overdose epidemic in history, with prescription drug abuse as the leading cause of accidental death.<sup>1</sup> In 2015 alone, there were 52,404 lethal drug overdoses, of which almost 40% were related to legal prescription pain relievers.<sup>2</sup> Between 1999 and 2010, there was a 340% increase in prescription opioid-related fatalities.<sup>3</sup>

The Centers for Disease Control and Prevention (CDC) has designated opioid overdose prevention as one of the leading public health issues that requires prompt attention by the medical community and public.<sup>2</sup>

According to the CDC, a major cause of the overdose epidemic is that opioids (eg, oxycodone, hydrocodone, and methadone) are overprescribed.<sup>1</sup> In 2012, there were 259 million opioid prescriptions—as many prescriptions as there were adults in the US at that time. In 2016, more than 66 opioid prescriptions were issued for every 100 people.<sup>4</sup> While controversial, it has been reported that although the US makes up less than 5% of the global population, it consumes nearly 80% of the global opioid supply.<sup>5,6</sup> A spiraling increase in opioid prescriptions in the US is believed to be the most important factor leading to lethal opioid drug overdoses. Studies document that the opioid crisis primarily originates from the misuse of opioid prescriptions.<sup>7</sup> Opioid prescriptions, obtained either directly from or indirectly through prescribers, are linked to long-term opioid therapy and a major risk of opioid misuse and addiction.<sup>7</sup>

The proportion of elderly patients being prescribed opioids at least once for management of osteoarthritis increased from 31% in 2003 to 40% in 2009.<sup>8</sup> Although osteoarthritis is frequently considered to be a disease of the elderly, the median age at diagnosis of knee osteoarthritis is 55 years, leaving a considerable number of years for patients to live with osteoarthritis and to have the potential to become addicted to prescription opioids.<sup>7</sup> In some patients undergoing TJA, postoperative pain management with opioids may serve as a trigger for long-term opioid use and addiction.<sup>9,10</sup>

In the face of serious risks and the absence of evidence concerning the long-term effectiveness of prescription opioids, there was a dramatic increase before 2013

in the acceptance and use of prescription opioids for surgical pain management.<sup>1</sup> Noteworthy is that despite the increase in use of prescription opioids, there has not been a corresponding change in pain reduction reported by Americans.<sup>1</sup> Now, however, there is close scrutiny in the US on prescribing opioids to patients because of the adverse consequences associated with long-term use and dependence.

**WHAT ARE OPIOIDS?**

Opioids are drugs that interact with specific receptors in the central nervous system to relieve pain.<sup>11</sup> Beyond their direct mechanism of action to control pain, opioids are also known to activate the reward pathway by producing a euphoric sensation that helps patients overcome pain.<sup>4</sup> It is this euphoria that addicted individuals seek.<sup>12,13</sup> Opiates are a subclass of opioids and include the commonly abused drugs morphine, codeine, and oxycodone.<sup>14</sup>

**WHAT IS ADDICTION?**

According to the American Psychiatric Association, *addiction* is a complex condition, a brain disease that is manifested by compulsive substance use despite harmful consequence.<sup>15</sup> People with addiction (severe substance use disorder) have an intense focus on using a certain substance or substances, such as alcohol or drugs, to the point that it takes over their lives.<sup>16</sup> They keep using alcohol or a drug even when they know it will cause problems.<sup>15</sup>

**Author Affiliations**<sup>1</sup> Boston Medical Center, MA<sup>2</sup> The Fullbright Specialist Program, Washington, DC<sup>3</sup> Lenox Hill Hospital, Northwell Health, New York, NY**Corresponding Author**Michelle J Lespasio, DNP, JD, ANP ([michelle.lespasio@bmc.org](mailto:michelle.lespasio@bmc.org))

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## ADDICTION TO OPIOIDS

Symptoms of opioid addiction include intense urges for the drug, taking increasing amounts of the drug, and stealing or illegally obtaining opioids not prescribed. To address the potential for addiction with opioid use, the CDC has recommended preventive approaches for use by clinicians when prescribing opioids to patients. Because the risk of long-term opioid use increases with each additional day the drug is supplied,<sup>15</sup> one approach to reduce the risk of dependence and addiction is by limiting the supply of prescription opioids. This notion of limiting prescription opioids is supported by the CDC, which reported that the risk of long-term opioid use increased 125% between patients with at least 1 day of opioid therapy and those with more than 8 days.<sup>1,17</sup>

### Opioid Withdrawal

Once a patient ceases taking opioid medication, s/he may experience unpleasant withdrawal symptoms (see Sidebar:

Common Symptoms of Opioid Withdrawal),<sup>14</sup> causing his/her return to opioid medication to avoid the withdrawal symptoms. As a result, addiction may develop.

### Risk Factors for Misuse of Prescription Opioids

Certain factors increase the risk of the misuse of prescription opioids leading to persistent use. *Persistent opioid use* is defined as having any number of opioid prescriptions or dosing at least 90 days continuously, or use of opioid prescriptions for 120 nonconsecutive days.<sup>18</sup> Examples of certain factors that increase the risk of persistent use are the patient's sex and age.<sup>19</sup> Women may become dependent on prescription pain relievers more quickly than men because women are more likely to have chronic pain, be prescribed prescription pain relievers, be given higher doses, and use them for a longer period of time than do men.<sup>20</sup> It is estimated that between 1999 and 2010, approximately 48,000

women died of prescription pain reliever overdoses.<sup>20</sup> The CDC reported in 2015 that approximately 276,000 adolescents (12-17 years old) were current nonmedical users of pain relievers, with 122,000 having an addiction to prescription pain relievers.<sup>17</sup> Although the prescriptions for opioids among adolescents and young adults has nearly doubled from 1994 to 2007, most adolescent addicts receive their drugs from friends or relatives.<sup>17</sup> There is some evidence that younger patients, particularly teenagers ages 15 to 19 years, but even as early as 13 years, and young adults in their early twenties, are at a higher risk of persistent opioid use in the general surgical population<sup>21</sup> and that younger patients in their teens use higher opioid amounts perioperatively.<sup>22</sup>

Among surgical patients, female sex; age older than 50 years; and preoperative history of drug abuse, alcohol abuse, depression, benzodiazepine use, or antidepressant use are associated with chronic opioid use.<sup>23</sup> In one study, being female was associated with a 40% higher risk of long-term opioid use after surgery, and specifically after THA surgery.<sup>19</sup>

Patients, including elderly individuals, who are prescribed opioids recommended for treatment of osteoarthritis before TJA, are at increased risk of exposure to opioids for a longer time.<sup>18</sup> Elderly patients often experience other adverse effects from taking opioids, including dizziness and sedation, which increases their risks of falls and fractures.<sup>24</sup>

Use of opioids persistently for 4 months or longer before TJA is a strong predictor of persistent use of opioids after the surgery.<sup>25</sup> Patients known to be taking opioids for other comorbid painful conditions, including back pain and diabetes mellitus, are more likely to be exposed to opioids for longer periods, increasing their chance of experiencing potentially dangerous opioid-related adverse effects.<sup>19</sup> One such adverse effect includes the development of tolerance to an opioid which refers to a decreased response from the drug at the same dosage previously prescribed.<sup>26</sup> Another adverse effect to long-term opioid use is hyperalgesia, which is an abnormally heightened sensitivity to pain.<sup>26</sup> Patients with depression and preoperative use of

### Advance Organizer Quiz to Retrieve, Use, and Organize the Materials Presented

Please answer true or false to the following items:

- 1. Prescribing opioids for acute postoperative pain management is associated with a greater likelihood of long-term opioid use.**  
True. Strategies to assess risk of overuse and overdose before prescribing opioids are advised.
- 2. The rise in prescription opioids among Americans corresponds with a corresponding reduction in pain control.**  
False. Best practices include prescribing opioids at their lowest dose and for the shortest duration necessary to control symptoms, with close monitoring of common side effects.
- 3. Americans who are 18 to 25 years of age have been associated with an increased risk of opiate abuse/misuse.**  
True. There is some evidence that younger patients in their teens and early twenties (ages 13-21) are at a higher risk of persistent opioid use in the general surgical population<sup>20</sup> and that younger patients use higher opioid amounts perioperatively.
- 4. Women may become dependent on prescription pain relievers more quickly than do men.**  
True. Women may become dependent on prescription pain relievers more quickly than men because women are more likely to have chronic pain, be prescribed prescription pain relievers, be given higher doses, and use them for a longer period of time than do men.
- 5. Opioid prescription is recommended for only short-term use in patients with severe joint pain awaiting total joint arthroplasty (TJA).**  
True. Prescription opioids (eg, morphine, codeine, and oxycodone) for patients with chronic joint pain and dysfunction with end-stage osteoarthritis who are awaiting TJA show restricted gains and are not encouraged.
- 6. The optimal strategy for pain management associated with total joint replacement consists of individualized multimodal therapy.**  
True. The optimal strategy for postoperative pain control consists of identifying risk factors for persistent opiate use among patients and using these indicators to stratify risk preoperatively.
- 7. Orthopedic physicians are the most common health care prescribers of opioids before and after TJA.**  
False. Primary care practitioners prescribe more opioids before and after TJA than orthopedic physicians.

hypnotic agents are at increased risk of persistently using opioids after surgery.<sup>19</sup> Similarly, patients subject to postoperative surgical management with opioids increase their potential for long-term use of opioids, increasing their chance of developing opioid-related adverse effects, including tolerance and hyperalgesia.<sup>19,27</sup>

Patients with end-stage osteoarthritis of the knee and hip who are awaiting TJA are in their own category of increased risk of opioid overprescription<sup>24</sup> and present their own risks for misuse. This occurs primarily because of the nature of severe pain experienced by patients with end-stage osteoarthritis and the perceived lack of efficacy of nonpharmacologic and other pharmacologic interventions in alleviating pain, improving function, and/or providing a sustainable quality of life. This perceived lack of efficacy of other therapeutic options is believed to account for the use of opioid prescriptions.<sup>24</sup> Studies show, however, that opioids offer limited benefit for management of osteoarthritis pain and are generally not advised.<sup>27</sup> It is recommended that opioid prescription, if necessary, be considered only for short-term use (less than a week) in patients with severe pain awaiting TJA. The potential for serious adverse effects, including the potential for drug misuse, abuse, addiction, and withdrawal symptoms, outweigh the perceived advantages of long-term use of opioids.<sup>26</sup> Most prescribers of opioids for patients before and after TJA are not orthopedic physicians.<sup>28</sup> Therefore, coordination of prescription opioids among health care practitioners is essential to improve narcotic pain management in patients with osteoarthritis undergoing TJA.<sup>28</sup>

Identification of risk factors that contribute to suboptimal clinical outcomes (including pain relief and successful restoration of joint function) after TJA is essential to achieve the objectives of eliminating the opioid crisis.<sup>29,30</sup> For some patients, pain relief after TJA is suboptimal, and their pain can be challenging to manage. Prolonged use of opioid pain medication in this group of patients has been found to be ineffective and to increase their risk of long-term opioid use. According to 1 study, approximately 20% of patients undergoing TKA and

about 10% of patients undergoing THA reported persistent or recurrent pain in the year after the surgery.<sup>31,32</sup> Another study investigated the relationship of prolonged use of opioid medication as a possible indicator of early THA failure.<sup>33</sup> Results indicated that persistent postoperative use of opioids from 3 months to 1 year after surgery was associated with higher risk of revision THA and may be an early indicator of potential THA surgical failures.<sup>33,34</sup>

### OPIOIDS AND TOTAL JOINT ARTHROPLASTY

When nonsurgical treatment options fail, surgical options, such as TJA, may be the only feasible alternative to manage a patient's moderate to severe pain. The objectives for performing TJA are to correct a deformity and/or restore function to an affected joint, and for many patients, to relieve substantial pain commonly derived from osteoarthritis, a substantial influencing factor associated with TJA.<sup>29</sup> TJA can be performed just about anywhere on the body where there is a joint. Before the surgical option of TJA is considered, nonsurgical interventions, including physical therapy, corticosteroid injections, and nonopioid pain medication, are preferred and often required for pain management associated with joint pain and dysfunction. In conjunction with physical therapy and corticosteroid

injections (which can be done in the office setting), nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen in safe doses are the preferred agents of choice.<sup>35</sup> Use of proton-pump inhibitors to counteract the effects of gastrointestinal ulcer disease and bleeding associated with NSAIDs is recommended.

Prescription opioids (eg, morphine, codeine, and oxycodone) for patients with chronic joint pain and dysfunction with end-stage osteoarthritis who are awaiting TJA show restricted gains and are not encouraged.<sup>14</sup> Observational studies have demonstrated that for patients planning to undergo total joint replacement, those receiving opioids preoperatively experience less pain relief until several years after surgery compared with those who did not use opioids preoperatively.<sup>36</sup> In addition, preoperative use of opioids independently predicted opioid requirement postoperatively and is associated with prolonged hospital stay, greater risks of inpatient hospital complications, and early revision surgery.<sup>36-38</sup> Thus, the rate of successful pain management among patients after TJA is unpredictable, and preoperative use of opioids may be a modifiable risk factor for poor outcomes.<sup>24</sup>

There is evidence suggesting that patients undergoing TKA are more likely to require opioid refills than those undergoing THA.<sup>30</sup> One review showed that the patients undergoing TKA were twice as

#### Common Symptoms of Opioid Withdrawal<sup>13</sup>

##### Early symptoms of opioid withdrawal.

Typically begin in the first 24 hours after you stop using the drug:

- restlessness
- anxiety
- lacrimation (eyes tearing up)
- runny nose
- excessive sweating
- insomnia
- yawning very often
- muscle aches and bone pain

##### Later symptoms of opioid withdrawal, which can be more intense.

Begin after the first day or so:

- diarrhea
- abdominal cramping
- goose bumps on the skin
- nausea and vomiting
- dilated pupils and possibly blurry vision
- rapid heartbeat
- high blood pressure

likely to require refills of opioid prescriptions and were prescribed a greater total morphine equivalent dose for a longer time postoperatively.<sup>30</sup> Additionally, TKA patients with a comorbidity or who were being treated for anxiety or depression were more likely to require a refill.<sup>30</sup>

### Mechanism of Postoperative Pain

Postoperative pain results from inflammation caused by tissue trauma (ie, surgical incision, dissection, burns) or direct nerve injury (ie, nerve transection, stretching, or compression). The patient senses pain through the afferent pain pathway, which is the target of various pharmacologic agents.<sup>7</sup> Use of direct numbing agents (eg, lidocaine) or drugs that diminish the local hormonal response to injury (NSAIDs, such as aspirin or ibuprofen) can be used to block pain receptor activity, thereby decreasing pain receptor activation.<sup>10</sup>

### Factors to Consider in Postoperative Pain Management

A primary goal of pain management associated with TJA is patient comfort with a smooth transition from hospital care to home. When formulating a plan for postoperative pain control, use of regional or local analgesic techniques for certain procedures (ie, nerve blocks, patient-controlled analgesia pumps) or having patients take preoperative oral pain medication is recommended before a procedure. In addition, consideration of individual patient factors, such as age, history of long-term opioid use, and comorbidities, may affect the choice of analgesic options.<sup>32,39</sup> Elderly patients may be more sensitive to the effects of opioid pain medication, and the type of medication and doses should be adjusted accordingly. Patients with long-term use of opioids may require a varied and multimodal approach for optimization of postoperative pain control. Those in whom tolerance to opioids has developed may show no acute effects after use of the drug at a dose typical for that patient but may show signs of opioid withdrawal after surgery.<sup>14</sup> Patients with obstructive sleep apnea may be more prone to adverse effects of sedatives and opioids, requiring either dose modification or avoidance of these medications.<sup>10,40</sup> Therefore, specific

**Table 1. Example of opioid taper plan after total joint arthroplasty<sup>a</sup>**

Date	Day	Maximum amount <sup>b</sup>	Amount taken
	1	10 tablets	
	2	8 tablets	
	3	7 tablets	
	4	6 tablets	
	5	5 tablets	
	6	4 tablets	
	7	4 tablets	
	8	3 tablets	
	9	3 tablets	
	10	2 tablets	
	11	2 tablets	
	12	2 tablets	
	13	2 tablets	
	14	2 tablets	

<sup>a</sup> Personal communication: Chen EY, Betancourt L, Li L, Trucks E, Tornetta P. BMC Patient Safety Week 2017. Standardized, Patient-specific Opioid Prescribing after Inpatient Orthopedic Surgery. October 18, 2017. Poster. Department of Orthopedic Surgery, Boston Medical Center, Boston, MA, 2017, unpublished data.

<sup>b</sup> The opiate pain control plan is based on a calculated amount of a narcotic medication that the patient is taking at the time of discharge from the hospital.

individualized approaches to optimal opioid prescribing should be carefully planned preoperatively for patients requiring postoperative pain medication.

### Goals of Postoperative Pain Management in Total Joint Arthroplasty

Goals of postoperative acute pain management in patients undergoing TJA include relief of pain and suffering, achieving early mobilization postoperatively, reducing hospital length of stay, and achieving patient satisfaction. Prescription opioids should be prescribed at the lowest dose and shortest duration necessary to control symptoms, and close monitoring of adverse effects is advised. Use of prescription opioids should be avoided or limited whenever possible, especially in older adult and elderly populations, or in patients with a prior history of opioid abuse.<sup>11,40</sup> Mild to moderate pain can be expected in patients after TJA. Because of this expected pain, patients who undergo TJA generally require a prescription for higher-dose opiate pain medication for several days after surgery. Current practices recommend an opioid taper plan on hospital discharge (Table 1) and open communication with patients undergoing TJA. At one academic medical center, a specific goal is to ensure that all opioid prescriptions at the point of discharge on the surgical services meet

best practice. Best practice is defined as prescribing less than 90 morphine milligram equivalents per day, to specify the total number of days of the prescription, and not to exceed 7 days unless there is clinical justification for an extended course within the patient's medical chart (Eric L Smith, MD, personal communication, 2018 Oct 16).<sup>a</sup>

### Recommendations

Prescribing opioids for acute pain is associated with a greater likelihood of long-term opioid use,<sup>41</sup> and a greater amount of initial opioid exposure (ie, greater higher total dose) is associated with higher risks of both long-term use and overdose.<sup>41</sup> Thus, opioids should be prescribed only when necessary, at the lowest effective dose, and for the shortest duration necessary. To help monitor opioid use and potentially prevent overprescribing, prescription-monitoring programs available in the US and other countries can be used to identify patients prescribed opioid medications by multiple practitioners. In fact, regulations in some US states require clinicians to review this online resource before starting an opioid prescription for a patient.<sup>42</sup> It is important to keep in mind when prescribing opioid medication that no single or simple change in prescribing behavior

can be expected to alleviate all risks while properly managing pain.<sup>43</sup>

It is important to evaluate patients for tolerance to opioid pain medication before prescribing the drug.<sup>14</sup> Tolerance, the decreased response from a drug at the same dosage previously prescribed, can be concerning because patients then need to use a greater amount of the drug to receive the same therapeutic effect.<sup>14</sup> As mentioned earlier, by taking increased doses, especially for longer durations, patients are at a greater risk of addiction, medication adverse effects, or even death caused by overdose. In assessing for tolerance, physicians should ask patients whether they have been using increasing doses of pain medication to get the same effect. If so, a tolerance has likely developed, and that patient is more likely to experience withdrawal symptoms if s/he abruptly stops using the opioid. Patients who have recently consumed an opioid and are tolerant to its effects may not show obvious signs of intoxication or withdrawal. Any patient in whom opioid tolerance is identified before surgery should receive a specific plan for postoperative pain management and be followed-up closely after surgery by his/her primary care practitioner and/or a pain management specialist.

Pain control regimens should be designed to meet the needs of each individual patient, taking into account the patient's age; medical, psychological, and physical conditions; levels of fear or anxiety; personal preference regarding undergoing surgery; and tolerance and response to therapeutic agents.

The optimal strategy for postoperative pain control consists of identifying the risk factors for persistent opiate use among patients and using these indicators to stratify risk preoperatively. This approach to pain management can help target patient groups for multimodal therapy to minimize the needs for opioid pain medication.<sup>10</sup> Clinicians should develop an individualized approach to pain management for patients undergoing TJA. Use of both nonopioid and opioid

medications to target central mechanisms involved in the perception of pain, each acting at different sites of the pain pathway, may reduce a patient's dependence on a single medication and, more importantly, may reduce or eliminate the need for opioids.<sup>10,14</sup> Synergy between opioid and nonopioid medications reduces both the overall opioid dose and unwanted opioid-related adverse effects.

## CONCLUSION

The general approach for effective perioperative pain management involves prescribing opioids only when necessary, at the lowest effective dose, and for the shortest duration necessary.<sup>17</sup> With attention across the country now on the opioid crisis, judicious safe prescribing practices are actively advocated and required to avoid risks of opiate overuse and overdose and to help prevent opioid-related tragedies.

The general approach recommended for effective postoperative pain control in TJA starts early in the surgical process and involves an individualized multimodal approach to patient care. Risk stratification and identification of risk factors for persistent use are advised. Reducing the dependence on a single opioid medication and targeting central mechanisms involved in the perception of pain can minimize the use of opioids and avoid overuse. Coordination of opioid prescriptions among health care practitioners is recommended, as is improved communication with patients on expectations of narcotic use both preoperatively and postoperatively. Strategies to assess the risk of overuse and overdose before prescribing opioids are advised. One strategy is to use statewide electronic prescription drug monitoring programs that allow clinicians to identify patients prescribed opioid medications by multiple practitioners. Being cognizant of the signs and symptoms of dependence, tolerance, addiction, and overdose is essential knowledge before the implementation of any surgical pain management plan. Prevention through avoidance of

overprescription of opiate medication is key to solving the opioid crisis. ❖

<sup>a</sup> Personal communication: Eric L Smith, MD, Chief, Division of Arthroplasty, Associate Professor of Orthopaedic Surgery, Opioid Prescribing for Acute Pain, Boston Medical Center, Boston, MA, October 16, 2018, unpublished data.

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## Intent

Poisons and medicines are oftentimes the same substances given with different intents.

— Peter Mere Latham, MD, 1789-1875, British physician and medical educator, physician extraordinary to Queen Victoria

# Acute Convulsive Seizures: When is It Too Early to Treat?

Omar Hussein, MD<sup>1</sup>

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## ABSTRACT

Acute convulsive seizures are overwhelming events that require immediate attention from clinicians and practitioners, especially when witnessed in a hospital setting. Adequate management of inpatient-witnessed seizures lies in understanding the time-related pathophysiologic stages of the seizure. The anatomical location of the seizure origin is as important as seizure stage but might not be easy to determine in the acute setting, especially if the seizure is nonfocal. Although investigating and treating the cause of a seizure has high priority, understanding the interplay between the pathophysiologic responses and the various bodily responses are crucial in treatment. This interplay has interesting dynamics that change within minutes. Knowing such dynamics allows clinicians and practitioners to choose their best treatment options in the best time interval when a seizure occurs in an acute care facility. Our commentary provides an overview of such dynamics and how they can change the misconceptions that many clinicians and practitioners have in dealing with an acute convulsive seizure.

## INTRODUCTION

Acute convulsive seizures occur at least once in about 10% of the population younger than age 85 years.<sup>1</sup> These seizures are frequently seen in most health care facilities. They can occur in a hospital's Emergency Department, postoperative recovery room, Intensive Care Unit, inpatient wards, and rehabilitation ward, as well as outpatient clinics and nursing homes. Most community hospitals do not have dedicated inpatient wards for patients with seizures, and some do not even have a dedicated neurology ward. Even some university medical centers and their affiliated hospitals do not have a dedicated neurology ward. Thus, the first responders to seizures are frequently neither a neurologist nor a neurologist in training. The main target of this article is to educate these clinicians and practitioners.

## TYPES OF SEIZURE

A clinical convulsive seizure is defined as rhythmic convulsions that last less than 5 minutes. It can be partial (affecting one limb or one side of the body and/or the face) or generalized (affecting the whole body). In partial seizures, consciousness is usually preserved unless they are partial complex seizures. In generalized seizures, consciousness is always impaired unless they are psychogenic nonepileptic seizures.<sup>1</sup> Although a single limb convulsion is the most common presentation of a partial seizure, generalized seizures

can appear in several forms from the start or can become generalized from a focal seizure.

Tonic-clonic seizures are the most common presentation of generalized seizures in adults. They start with a tonic phase in which the limbs appear to spastically contract toward the body, followed by their extension and rhythmic jerking. Tonic generalized seizures consist of constant muscle contraction. Clonic generalized seizures consist of constant rhythmic jerking from the start. Myoclonic seizures are usually composed of a group of muscles or the entire body jerking, jumping, or flinging out in a sudden unpredictable way. Atonic seizures usually present as episodes of a sudden fall or collapse caused by sudden loss of muscle tone. This type of seizure is usually confused with cardiac arrhythmias and other pathologies. It is usually suspected after a cardiac cause is ruled out.

Finally, absence seizures are a type of generalized seizure that usually starts in childhood but can continue in adulthood. This seizure type is composed of a sudden stare with unresponsiveness. It can be accompanied with blinking or a slight head turn. It might be confused with a partial complex seizure except that the latter is usually preceded by an aura and accompanied by automatisms.<sup>2</sup> Once the seizure duration passes 5 minutes, or convulsions recur within a 5-minute period without return of consciousness, it is called

convulsive status epilepticus (whether partial or generalized) according to the currently operational newer guidelines.<sup>3,4</sup>

## TREATMENT

Early administration of benzodiazepines has been well established as the first treatment option for termination of status epilepticus before internalization of the  $\gamma$ -aminobutyric acid (GABA) A receptors (where benzodiazepines act) in the brain.<sup>5,6</sup> Among some clinicians, there is a misconception that the algorithm of treatment of seizures starts by administering benzodiazepines and escalates to antiepileptic medications such as phenytoin, valproate, phenobarbital, and levetiracetam, ending with sedation and anesthesia. Although this statement is correct for the treatment of status epilepticus, it is incorrect for the treatment of acute convulsive seizures. Treatment of acute convulsive seizures (less than 5-minute duration) starts with supportive care, protecting the airway, and assisting breathing during the seizure. Benzodiazepines should not be given that early except in certain specific conditions. One such situation is when there are numerous and frequent short epileptic seizures with consciousness regained in-between (does not meet criteria of status epilepticus) and especially when there is a known severe underlying epileptic syndrome.<sup>2</sup> This faulty practice might occur for many reasons. One is that the patient might be hypertensive or hypotensive, tachycardic or bradycardic, tachypneic or brachypneic, and in some occasions hypoxic. Although these symptoms are concerning and should be monitored carefully because of the possibility of severe complications such as

### Author Affiliations

<sup>1</sup> Department of Neurology—Division of Neurocritical Care and Neurophysiology, the Ohio State University Wexner Medical Center, Columbus

### Corresponding Author

Omar Hussein, MD ([omar.hussein@osumc.edu](mailto:omar.hussein@osumc.edu))

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sudden unexpected death in epilepsy,<sup>7,8</sup> the symptoms should not be overwhelmingly managed. Another reason for inappropriate treatment is the dramatic appearance of the patient, which creates a panic situation around him/her. Last but not least is that everyone is expecting the clinician or practitioner to do a heroic measure that matches the dramatic situation when actually the less we do, the better the outcome will likely be. To understand this clearly, we must look at the different stages of a seizure on the physiologic, cellular, and synaptic levels. It is also important to know when the different subtypes of GABA receptor are regulated during a seizure and correlate it with the time when dysfunction of the blood-brain barrier (BBB) occurs.<sup>9</sup>

**LOCATION OF THE EPILEPTIC FOCUS AND THE AUTONOMIC RESPONSE**

The location of the epileptic focus in the brain might determine the autonomic response from a seizure. The more common is a sympathetic overstimulation. Less commonly, a parasympathetic overstimulation or a mixed overstimulation occurs. Studies have shown that sympathetic overstimulation usually occurs if the right insular cortex is involved, especially the rostral part of it. Similar response occurs if the thalamus or the ventromedial hypothalamus, or both, are involved. If parasympathetic overstimulation is observed, several locations have been identified. These are the left insular cortex, especially the caudal part of it; the cingulate gyrus; the prefrontal cortex; the lateral hypothalamus; or the preoptic hypothalamic area. Involvement of the amygdala usually produces variable responses. Meanwhile, if several foci are involved, they create a nonselective activation, which ends up with either an oscillatory pattern or a dominating pattern. Finally, several cardiovascular and cardiorespiratory reflexes might also interact in determining the dominating pattern.<sup>10</sup>

**STAGES OF A SEIZURE**

**Very Early Stage/Nonstatus Seizures —Less than 5 Minutes**

At the very early stages of a seizure (first 5 minutes), peripherally, there is more commonly an increased sympathetic activity within the body. Nonetheless, a

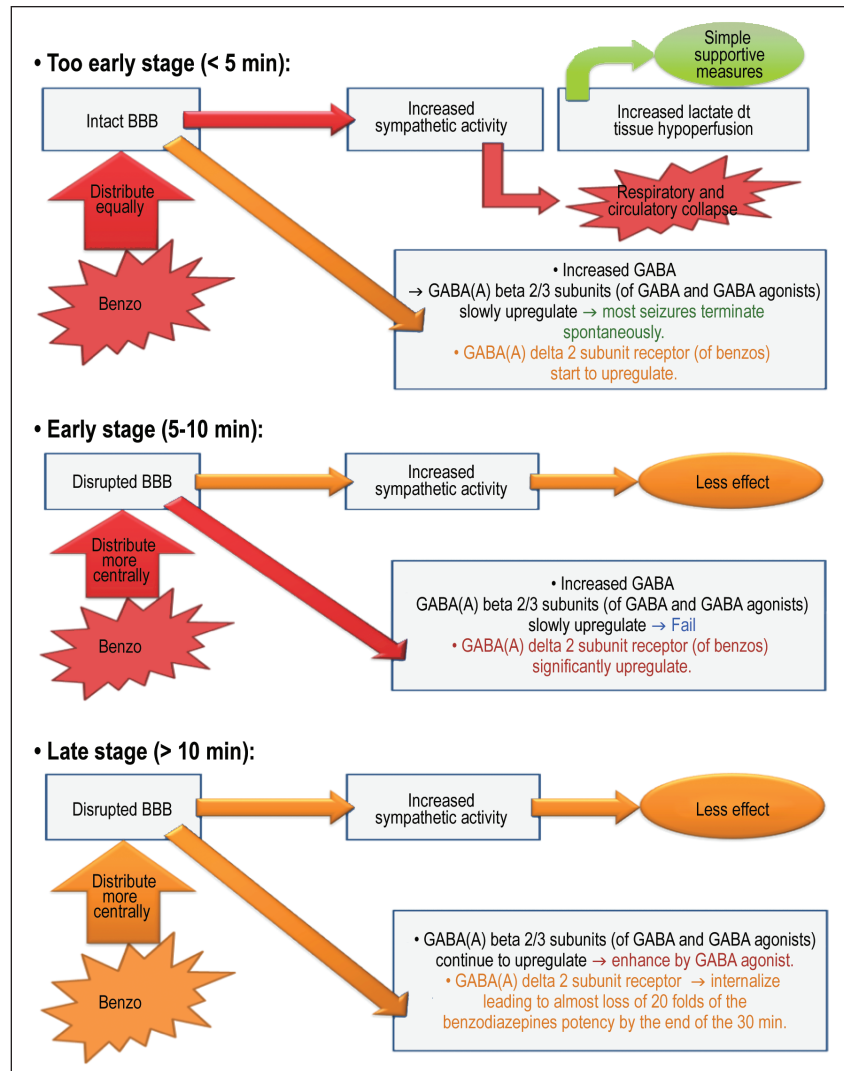


Figure 1. Effect of benzodiazepines on different pathophysiologic pathways of seizure as time progresses.<sup>a</sup>  
<sup>a</sup> Red pathway = more potent drug effect; orange pathway = lack of or less potent effect; and light green pathway = supportive measures only are indicated.  
 BBB = blood-brain barrier; benzo = benzodiazepine; dt = due to; GABA =  $\gamma$ -aminobutyric acid.

dominating response from the parasympathetic system is less common but possible. At the cellular level, the brain increases the production of GABA neuroinhibitor, which is usually sufficient to inhibit the seizure (self-limiting). At the synaptic level, the GABA A- $\delta_2$  subunit receptor (binding site for benzodiazepines) start to upregulate while the GABA A- $\beta_{2/3}$  subunits (binding site for GABA and GABA agonists) also start to upregulate but at a slower rate (Figure 1).

Despite this upregulation, the risk of administering benzodiazepines at this very early stage might outweigh the benefit.

This is because the BBB is still intact, and thus benzodiazepines are equally distributed peripherally and centrally.<sup>11</sup> On the other hand, at this stage there might be 2 main reasons for hypoxemia. The first is directly from the seizure itself, likely from collapse of the airway during or after the seizure without an adequate support given. There is also an increasing peripheral acidosis secondary to lactate production, which leads to tissue hypoperfusion and hypoxemia. The second reason is potential oversedation produced by benzodiazepines. Although some can blame the respiratory collapse on the seizure itself, the



addition of benzodiazepines certainly does not help the respiratory status, and intubation is imminent if the patient was already compromised from the seizure. Although a benzodiazepine might act centrally to stop the seizure, this medication acts in equal effect peripherally because of the intact BBB. This can lead to suppression of the increased sympathetic activity that is usually required to maintain the bodily demands during a seizure and thus leads to respiratory and circulatory compromise. Less commonly but equally harmful, it might add to the cardiocirculatory depression when a parasympathetic response is dominating. Both mechanisms frequently end up with intubation of the patient and the need for vasopressors.

In summary, benzodiazepines given for a seizure before 5 minutes have elapsed might be effective to abort a seizure but are more harmful because they suppress the associated autonomic response and aggravate the cardiorespiratory compromise produced by a seizure (Table 1). This leads us to a potentially counteracting statement: Too early administration of benzodiazepines is accompanied with more complications than benefits.

#### Early Stage/Early Status Epilepticus—5 to 10 Minutes

After 5 minutes, many conditions change because the BBB starts to be compromised, allowing more benzodiazepine effect centrally than peripherally.

Of course, this is also augmented by the higher level of GABA A- $\delta_2$  subunit receptors (Figure 1).<sup>11-13</sup> Benzodiazepines given for a seizure after 5 minutes have elapsed might be effective to abort a seizure and prevent the potentially profound adverse effects of a prolonged seizure (Table 1).

#### Intermediate Stage/Late Status Epilepticus—10 to 30 Minutes

After 10 minutes, because of the continuous production of GABA as the patient continues to have a seizure, the GABA A- $\delta_2$  subunits start to internalize, leading to loss of almost 20-fold of the benzodiazepine's potency by the end of 30 minutes (Figure 1).<sup>11-13</sup> Thus, benzodiazepines given for a seizure continuing for more than 10 minutes might be less effective to abort a seizure. However, benzodiazepines remain the most effective and most feasible treatment in this period and should always be the first choice in treatment (Table 1).

#### Late Stage/Refractory Status Epilepticus—More Than 30 Minutes

After 30 minutes, upregulation of the *N*-methyl-D-aspartate (NMDA) and  $\alpha$ -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (AMPA) receptors occurs, along with decreased production of the inhibitory neurotransmitters and overproduction of the pro-seizure neurotransmitters (Figure 1). These changes are mostly responsible for the refractory state.

This state is certainly much less responsive to benzodiazepines. Therefore, benzodiazepines given for a seizure continuing for more than 30 minutes might be significantly less effective to abort a seizure. Other alternatives (eg, ketamine and propofol) should be considered after benzodiazepines have been tried and failed (Table 1).

#### Very Late Stage/Super-refractory Status Epilepticus—24 hours or longer

After 24 to 48 hours of attempts at seizure suppression, a lack of response despite aggressive sedation, or a seizure recurrence within 24 hours of weaning the patient from the sedation, is defined as lack of seizure suppression and called super-refractory status epilepticus. Multiple hypotheses have been proposed for this state, but the etiology remains undetermined. Reversal of GABA properties owing to changes in extracellular ionic environment, cell death secondary to excitotoxicity, and mitochondrial malfunction have all been suggested as etiologic factors.<sup>14</sup> Super-refractory status epilepticus is extremely challenging to treat and has high mortality rates. Expert consultation for other advanced therapies should always be considered in such a scenario (Table 1).

## DISCUSSION

These seizure stage timelines are surely not strict cutoffs, and certainly interindividual and intraindividual variability are possible. However, it is helpful clinically

**Table 1. Comparison of different stages of seizure**

Seizure or treatment characteristic	Acute convulsive seizure	Early status epilepticus	Late status epilepticus	Refractory status epilepticus	Super-refractory status epilepticus
Time from seizure onset	< 5 min	5-10 min	10-30 min	≥ 30 min	≥ 24 hours
Role of BZD	Too early	Early	Intermediate	Late	Too late
BBB disruption	-	+	++	+++	++++
Neurotransmitter upregulation	GABA	GABA	GABA	Glutamate, AMPA	Dysregulation
Receptor upregulation	++GABA A $\beta$ , +GABA A $\delta$	+++GABA A $\beta$ , ++GABA A $\delta$	+GABA A $\beta$ , +++GABA A $\delta$	NMDA, AMPA, ++GABA A $\delta$	Dysregulation
BZD control of seizures	++	+++	+	+/-	-
Other sedatives	Not needed	May or may not give propofol and/or phenobarbital	Propofol and/or phenobarbital	Ketamine, propofol, and/or pentobarbital	Pentobarbital and advanced management
Prominent clinical effect of BZD	With or without cardiorespiratory collapse	Seizure control	Less effective seizure control	With or without seizure control	Usually ineffective

AMPA =  $\alpha$ -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid; BBB = blood-brain barrier; BZD = benzodiazepines; GABA =  $\gamma$ -aminobutyric acid; NMDA = *N*-Methyl-D-aspartate; - = none; + = mild; ++ = moderate; +++ = substantial; ++++ = very substantial.

to put the stages into an approximate time frame that clinicians and practitioners can follow easily, in the hope for better outcomes. Nonetheless, the types of seizure are different, and involvement of the autonomic system is variable from 1 seizure to another. Thus, it is always helpful to take into account the type of seizure if possible. For example, a patient with an autonomic seizure characterized with high sympathetic or parasympathetic outflow might drastically decompensate after a single dose of benzodiazepine. On the other hand, a patient with a seizure with less or no autonomic involvement might be more tolerant to a certain dose of benzodiazepine even if administered early.<sup>6</sup> Thus, although early use of benzodiazepines is highly recommended for termination of status epilepticus, too early use of benzodiazepines for seizure termination (less than 5 minutes) might not be encouraged because of the liability for severe adverse effects in this period. The brain is usually able to self-suppress a seizure in this very early period, and all the patient needs is simple supportive measures and certainly a search for the cause of the seizure. The use of other antiepileptic treatments depends on the clinical scenario.

## CONCLUSION

Acute convulsive seizures that do not meet the criteria for status epilepticus should be managed conservatively as most of these seizures are self-limiting. Autonomic involvement with seizures is not

very well understood and to the best of our knowledge is variable. Early inhibition of seizures with benzodiazepines can affect the overstimulated autonomic system and therefore can have drastic effects on the cardiorespiratory system. Thus, clinicians and practitioners should be cautious with administering benzodiazepines too early in the seizure course. Further research is needed to clarify the role of benzodiazepines in disrupting the autonomic balance during acute convulsive seizures. ❖

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## The Falling Sickness

Cassius: But soft, I pray you: What, did Caesar swoond?

Casca: He fell down in the market-place, and foamed at mouth, and was speechless.

Brutus: 'Tis very like: He hath the falling sickness.

— *Julius Caesar*, act I, scene ii; William Shakespeare, 1564-1616, English poet, playwright, and actor

# Disrupting Physician Clinical Practice Peer Review

Rajesh Swaroop, MD

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## ABSTRACT

The goal of physician peer review has been to assess and improve the quality of care by individual physicians. Unfortunately, this enshrined piece of medical practice suffers from deep flaws that hamper the achievement of assessment and improvement. This institution is in serious need of disruption, both for the safety of patients and for the wellness of practicing physicians. This commentary describes the inherent flaws of physician practice review and how physicians and health care organizations can address them.

## INTRODUCTION

Peer review of physician clinical practice has existed in essentially the same form for more than 100 years.<sup>1</sup> The laudable goal of peer review has been to assess and improve the quality of care by individual physicians. Maintaining a program of peer review of physician clinical practice is also a requirement for continued hospital accreditation by The Joint Commission. Unfortunately, this enshrined piece of medical practice suffers from deep flaws that hamper the achievement of assessment and improvement.<sup>2</sup> This institution is in serious need of disruption, both for the safety of patients and the wellness of practicing physicians.

The current state of physician clinical practice review could be called the deliberative framework. In my institution, cases involving an instance of care provided by an individual physician are referred by physicians, nurses, or risk managers, or from patient complaints about quality of care. The case is then prescreened by a nurse quality coordinator and ultimately reviewed in detail by a physician trained in peer review or a peer-review body consisting of a group of physicians trained in peer review. The final written review is attested by the physician chief of service as to a lack of bias. If an opportunity to improve care is

identified, the physician being reviewed is notified. If the opportunity is determined to meet a threshold of potential “significant patient harm,” the reviewed physician can be required to complete a structured plan of performance improvement. The reviewed physician’s privilege of continued practice can be placed at risk if s/he does not satisfactorily complete performance improvement plans.

In theory, the mechanism of physician practice review is an unbiased thorough review of care by peer physicians to uphold maintenance of quality standards.

## INHERENT FLAWS OF PHYSICIAN PRACTICE REVIEW

The flaws inherent to physician practice review are many, but some deserve special recognition.

### Lack of Resources and Existence of Bias

A thorough physician practice review requires time, energy, and structure. There are many health care systems where reviews are not supported with adequate resources.

A problematic issue is the existence of bias. Bias encompasses many concerns, which include financial bias, work group bias, cognitive bias, and sex-based/racial/sexual-orientation discrimination. In health care systems where physicians are competing for market share, there is an inherent financial conflict for competing physicians to review each other.<sup>1</sup> Because it is extremely difficult to preserve absolute anonymity in peer review, peer reviewers may legitimately consider how an unfavorable review may affect their ongoing relationship with a reviewed physician who is in their work group. Literature on cognitive bias suggests that hindsight bias and availability bias are common, among other cognitive errors.<sup>3,4</sup> Finally, a lack of heterogeneity in peer-review bodies can lead to groupthink, resulting in the “in” group members receiving more lenient scores compared with those

who are perceived as being “outsiders.”<sup>5</sup> Homogeneous groups, unfortunately, also frequently lack the insight to know about their own biases, which are frequently unconscious and unintentional.

### Misinterpretation or Misuses of Peer Review

Another concern is the co-opting of peer review as a proxy for managing people. The primary aim of peer review is assessing and improving quality of care. However, lack of emotional intelligence and group cooperation by an individual physician can trigger reviews, forcing the peer-review process to deal with issues that are fundamentally not about the quality of care provided. Similarly, complaints from patients about cost, service, or access to care may be unfortunately triaged into the peer-review process, again forcing peer review to deal with issues that are not primarily about quality of care provided.

The misinterpretation of physician peer review as being a justice system is another fundamental problem. Leaders, reviewed physicians, physicians performing peer review, and Quality Department staff may perceive their activities as being part of a system of justice. This is an unfortunate view because, unlike law, there are many situations in health care in which the standard of care is unclear or evolving. A justice-based approach also triggers defensiveness on the part of reviewed physicians, which impedes the ability to learn. It also drives the system into being focused on individuals, although much more frequently there are underlying important systemic and workflow issues. Valiant attempts at creating a more logical approach have included development of just culture algorithms,

#### Author Affiliations

<sup>1</sup> Orange County Medical Center, Irvine, CA

#### Corresponding Author

Rajesh Swaroop, MD ([raj.x.swaroop@kp.org](mailto:raj.x.swaroop@kp.org))

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to clearly indicate when to hold individuals vs systems accountable. However, the widespread use of just culture algorithms has not yet been achieved. The unfortunate result of these issues is that many frontline physicians view peer review as a fundamentally unfair justice system—and on the basis of their worldview that is an accurate assessment.

## DISRUPTING PEER REVIEW

The first step to disrupting peer review is to bring it back to the original intention of assessing and improving care. Taking conscious steps to address the inherent flaws is necessary. Finally, adding the modern interpretation of care delivery from a team of health care providers rather than from an individual physician fills out the model of the disruptive framework.

A crucial theme in the disruptive approach is to place culture first. An organization that actively supports a healthy culture of learning should view peer review as an important tool to achieve its aims.

Relentless attention on the aim of learning is necessary to reassert the psychological safety of the physician learners. This also brings back peer review to its original intention. For any case that proceeds to the peer review process, it is critical to ask and receive a learning point that can be broadly shared. It is also important for psychological safety to transparently share those learning points. There may be medicolegal concerns, but regulators would look favorably on this practice. Any shared learnings should be deidentified with names of physicians and patients removed.

## ADDRESSING FLAWS

In large health care organizations, financial bias is generally not a concern because financial motivations are in alignment. Health care systems that have competitor physician groups could consider having equal representation of groups on peer-review committees.

Work group bias can be concerning. A steadfast attention to learning as the primary driver of peer review can make this easier. It is encouraged to have the physician leaders model vulnerability in speaking about cases from which they learned. It is

essential to have this behavior inculcated at multiple levels, including by Medical Directors, Department Chiefs, Division Chiefs, and so on. A true learning organization would see that learning opportunities accrue for all of us, and recognizing them is a privilege, not a punishment.

Cognitive bias may be inescapable, but the first step is awareness. A commonly occurring form of cognitive bias is hindsight bias, that is, scoring cases on the basis of outcomes rather than actions. When cases are presented for group discussion and scoring, hindsight bias can be mitigated by avoiding disclosure of patient outcome when feasible. Focus should be placed on the actions of the physicians and the accepted standards of care.

Availability bias is the habit of using the ease of retrieving an example from one's memory as a judgment of the frequency of an event.<sup>6</sup> This can be mitigated by referencing scientific literature for objective prevalence and incidence data rather than relying on the memory of individual peer reviewers.

Unconscious sex-based/racial/sexual-orientation bias is best overcome by having a diverse group of physician reviewers. This includes creating roughly proportional representation of minority groups, reviewers of both sexes, and those with varied work experiences.

Although difficult, having clear distinction between quality issues and human resources issues is essential for preserving the intention of the physician case review process. This often may require discussion with physician leaders for appropriate triage. There is a blurred line between quality of care provided and overall human interaction, so a reasonable aim is to have a consistent practice of when cases are referred to peer review.

## A NEW AGE OF ENGAGEMENT

In the current state of the deliberative framework of peer review, an extraordinary amount of energy and attention goes toward assessing care and scoring the cases. Although important, this is not the fundamental goal of the disruptive framework. Rather, the fundamental goal is to improve care.

Most improvement requires managing systems and processes, rather than singling out individual errors. The Plan-Do-Study-Act cycle is well established as a mechanism for improving processes. In addition, many key performance improvement initiatives for health care systems and processes require strong physician leaders. Therefore, the energy shift from physician peer reviewers should be from deliberating scores to engaging in active performance improvement on the issues identified. Peer reviewers in the modern era should see their role much more broadly than reviewing cases. It is time for those physicians to emerge from the conference room and into the clinics and hospital wards. Their passion and energy should be dedicated to leading teams toward better outcomes. ♦

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## ■ NARRATIVE MEDICINE

This is a story and illustration from the upcoming book *100 Little Stories of Big Moments* published by The Permanente Press.

Most of the stories and poems were written by clinicians in 15 minutes in writing workshops about meaningful moments in their work and life of practicing medicine. Professional artists were asked to create a visual representation of the story.

# The Elderly Couple

William Lynes, MD<sup>1</sup>

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The Smiths were here again, dressed so nicely and polite as always—Tom’s hat and Maggie’s dress just so. Tom helped her with her walker, and yet obviously his walker was present as well. Maggie didn’t remember my name—she always knew me before—her dementia, just worse. Tom’s PSA had doubled since his last visit. He looked so gaunt; his weight dropped another 10 pounds. He wouldn’t take the pain medicine—could not help Maggie if he did. We talked as usual; they, as always, asked about my family, about my problems. Leaving with an appointment in a month, his disease was unremitting. I knew that he wouldn’t be back again. ❖

### How to Cite this Article

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*The story “The Elderly Couple” was originally published in leaflet, 2018;5(2). Available from: <http://leaflet.thepermanenteppress.org/2012-09-07-07-54-29/volume5-issue2/item/the-elderly-couple>.*

Accompanying artwork:  
**The Elderly Couple**  
by Damien Webb



### Author Affiliation

<sup>1</sup> Retired, Department of Urology, Riverside Medical Center, CA

### Corresponding Author

William Lynes, MD ([wlynemd@gmail.com](mailto:wlynemd@gmail.com))

### Artist Information

Damien Webb is an Illustrator and Graphic Artist based in Milwaukie, OR. He works in mixed media.

## ■ NARRATIVE MEDICINE

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# Hiding It

Tina Olkowski, MD<sup>1</sup>

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"Always assume the patient is lying," I say as the young medical student finishes his presentation. He tries to maintain a poker face, but there is a perceptible twitch at the side of his mouth. I see this.

I've been an Emergency Department attending for 20 years, and I quickly assess people, noticing these things almost at a subconscious level. Sighing to myself, I retract the ugliness of my statement. I soften it, talking more quietly, drawing

him in: "Or withholding something, hiding it." The student relaxes. Yes, I guess I don't have to say patients are telling purposeful lies. Instructing him, I say, "So in each encounter, I usually ask, 'Is there anything else I should know?'" And then I sit and stare quietly at the patient. You can sometimes get the most extraordinary additional details."

I send him back to the patient's room. A whole 5 minutes later, which is a lifetime in the Emergency Department, he returns smiling. I look at him, so young and eager to please me.

"Well, I asked your question and waited," he gushes. "Turns out, maybe she could be pregnant after all!"

I smile and pass him the lab slip. "She is." ❖



Accompanying artwork:  
**Hiding It**  
by Reid Psaltis

### Author Affiliation

<sup>1</sup> Emergency Department, Moanalua Medical Center, Honolulu, HI

### Corresponding Author

Tina Olkowski, MD ([tina.olkowski@kp.org](mailto:tina.olkowski@kp.org))

### Artist Information

Reid Psaltis lives in Portland, OR, where he makes illustrations, comics, and sculptures about science, nature, and natural history.

This is a story and illustration from the upcoming book *100 Little Stories of Big Moments* published by The Permanente Press.

Most of the stories and poems were written by clinicians in 15 minutes in writing workshops about meaningful moments in their work and life of practicing medicine. Professional artists were asked to create a visual representation of the story.

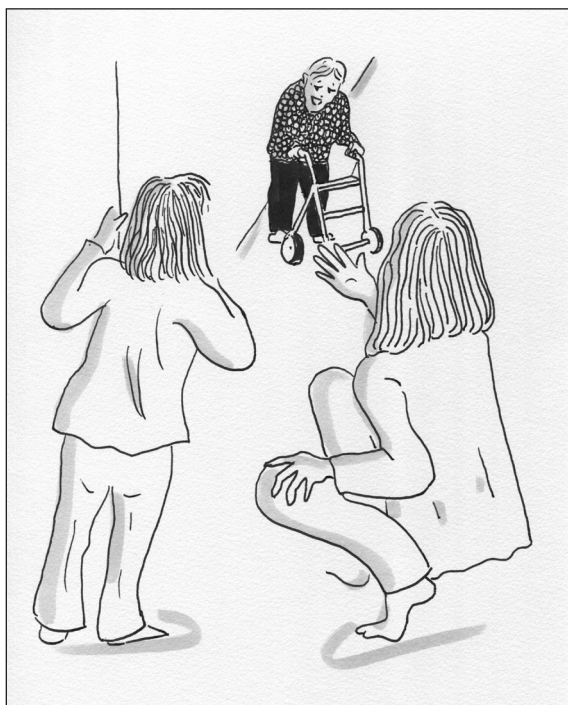
## Stories for My Daughter

Lindsay Mazotti, MD<sup>1,2</sup>

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Accompanying artwork:  
**Stories for My Daughter**  
by Susan MacLeod

Tell me about your patients, she asks  
Before a song, before a kiss, before goodnight  
As a toddler there were fairy-tale endings  
A man came in today and his heart wasn't squeezing very well  
We made it better  
No one ever died

Now there are no more fairy tales  
The man who drinks too much and destroys his liver  
The woman who smokes with lung cancer  
Consequences. Realities.

But I want to share more than a diagnosis with her  
I want her to hear the stories and see the patients as I do  
To glimpse the colors and textures of my daily doctoring fabric

Tell me about your patients, she asks  
A grandmother with pneumonia warmly surrounded by pictures of her  
88 grandchildren  
A 90-year-old widow, with freshly manicured red nails, anxiously clutching  
the latex glove balloon her grandson created  
A 50-year-old man embarking on a month of inpatient chemotherapy  
with bravery and a sweet smile through his tears

I share with her the imagery of the humanness and fragility  
that breaks my heart a little every day  
Sharing gratitude for my patients  
in the stories for my daughter ❖

### How to Cite this Article

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Available from: <http://leaflet.thepermanentepress.org/2012-09-07-07-54-29/volume5-issue2/item/stories-for-my-daughter>.

### Author Affiliation

<sup>1</sup> Department of Hospital Medicine, Kaiser Permanente East Bay, Oakland, CA  
<sup>2</sup> Kaiser Permanente School of Medicine, Pasadena, CA

### Corresponding Author

Lindsay Mazotti, MD ([lindsay.a.mazotti@kp.org](mailto:lindsay.a.mazotti@kp.org))

### Artist Information

Susan MacLeod has been a Freelance Cartoonist, Writer, and Graphic Facilitator in Halifax, Nova Scotia, Canada for the past 7 years. She is currently working on a humorous graphic novel about navigating her mother through 9 years of long-term care.

# Enlightened Aging: Building Resilience for a Long, Active Life

by Eric B Larson, MD, and Joan DeClaire

Review by Arthur Hayward, MBA, MD<sup>1,2</sup>

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Baby boomers are living longer and are healthier than their parents. They are better educated and more interested in health. They are less passive and therefore more inclined to question norms and to individualize solutions. In a 2002 contribution to the *Journal of American Geriatrics*, Eric Larson stated, “Because of this combination of circumstances, healthcare providers may find their patients seeking information about how to age successfully.”<sup>1</sup> He and his cowriter, Joan DeClaire, now offer this information in their excellent book *Enlightened Aging: Building Resilience for a Long, Active Life*.

As Larson is a baby-boomer himself, he is in a very good position to dispense information on aging successfully. After completing a term as chief resident at the University of Washington in the 1970s, he was asked to stay on as medical director for a pioneering geriatric clinic. He has remained there as a primary care physician for 4 decades.<sup>2</sup> Many of his patients passed through late-life and end-of-life phases under his care. He and others interested in clinical research developed a patient registry in 1985 to allow close, sophisticated monitoring of a large sample of their Seattle-area patients.<sup>2</sup> Approaching his patients through the broad lens of a primary care physician, Larson studied all aspects of aging, particularly dementia. He became a widely published expert and teacher in the field.

From analysis of their large patient database, Larson and his collaborators have made hallmark discoveries that include early recognition of the critical association between physical activity and brain and heart health. They described a connection between dementia and anticholinergic drug burden, even for over-the-counter antihistamines. They have shown that even in nondiabetic patients, high blood glucose levels predict subsequent cognitive impairment.

Larson’s years as a primary care physician and medical researcher also enable him to comment on evolving concepts of successful aging and how the public and research scientists define it differently. In successive chapters, he borrows and updates the dominant model developed by Rowe and Kahn in 1997

that posits physical, mental, and social dimensions.<sup>3</sup> In a departure from most researchers, Larson asks older people how they define successful aging, and he sees their view differs markedly from a more scientific formulation that emphasizes longevity and biomechanical function. Old-old people often describe themselves as doing well, when medical scientists’ measurements would indicate they are not.

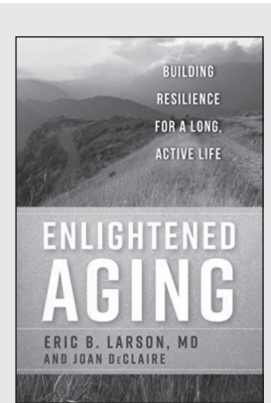
Larson cites studies that counter conventional wisdom, including the widespread notion that old age inevitably brings disappointment. Old-old people, he states, typically self-rate their well-being higher than do their middle-aged children. In one chapter, Larson makes

the case for an activist approach to managing health risks; in the next he shows that through resilience and acceptance, older adults can still remain happy after their abilities begin to diminish.

Throughout the book, Larson uses the pronouns “I” (himself) and “you” (the reader), as if advising a patient on measures to promote a long, active life. He introduces his family members and his patients under aliases and relays how their stories shaped and altered his thinking. What comes through to the reader from these accounts is an appreciation for the intimacy and richness of Larson’s relationship with patients, and his humility as an observer and healer. The writing is simple, direct, and free of jargon. Concepts are explained.

The book may have minor shortcomings. It is short, after all, at 234 pages. Previous discussions of successful or healthful aging have been criticized for omitting or minimizing spirituality as an important fourth dimension of aging, and this topic receives small consideration in this book. In addition, because he assigns value to having sufficient financial assets entering old age and recognizes the high costs of care, readers may be disappointed that Larson gives so little attention to the plight of the majority of Americans who lack those assets. Or maybe Larson does address high costs, at least obliquely. He is convinced that many older people are overtested, overdiagnosed, overtreated, and overmedicated. He cites work by Gilbert Welch, a former associate who has published widely on those topics and who supplies the preface for *Enlightened Aging*.<sup>2</sup>

**Old-old people often describe themselves as doing well, when medical scientists’ measurements would indicate they are not.**



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**Author Affiliations**

<sup>1</sup> Emeritus, Department of Geriatrics, Northwest Permanente, Portland, OR

<sup>2</sup> Department of Internal Medicine, Oregon Health and Science University, Portland, OR

**Corresponding Author**

Arthur Hayward, MBA, MD ([arthur.d.hayward@kp.org](mailto:arthur.d.hayward@kp.org))

Keywords: ageing, aging, baby boomers, enlightened ageing, enlightened aging, healthful ageing, healthful aging, successful ageing, successful aging, healthy ageing, healthy aging, late life



Larson points out that much preventive and intensive care in late life confers risk and expense without commensurate benefit.

The final chapter is devoted, appropriately, to end-of-life care. This may be where the content of medical care has changed the most during past decades, and Larson addresses physician-assisted suicide with the sensitivity and humanity that a reader will come to expect after getting to know him during the preceding chapters.

I highly recommend this book for lay readers interested in late-life health and medical care. I also heartily recommend it for health professionals for these reasons: We are a society of aging individuals. The context of medical care has changed substantially through advances in medical technology and through better understanding of how disease affects the old, the old-old, and the dying. Larson has provided updated evidence-based advice for the conversations we will soon have with our aging patients to optimize their health.

And although it is not the main intent of *Enlightened Aging*, the book offers all readers a personal account of how one

dedicated physician-scientist learned about late-life care from his patients and from his Seattle registry cohort, evolved his thinking, and then negotiated his path to a remarkably long career during a time of unprecedented advances in medical care. ❖

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#### Disclosure Statement

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

#### How to Cite this Article

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### Casting Off

In old age  
the mind  
casts off  
rebelliously  
the eagle  
from its crag

— William Carlos Williams, MD, 1883-1963, Puerto-Rican American physician and poet

Spring 2019

# CME Evaluation Program

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## Section A.

### Article 1 (page 13) Clinical Response to Real-Time Patient-Reported Diabetic Peripheral Neuropathy Symptoms

Which of the following were observed following implementation of the diabetic peripheral neuropathy (DPN) screener?

- a. improvements in HbA<sub>1c</sub>
- b. increases in the recording of DPN diagnoses in the electronic health record
- c. decreases of new starts of medications commonly used to treat DPN symptoms
- d. improvements in patient quality of life

Each of the following patient characteristics was associated with lower rates of treatment intensification, except patients:

- a. who were using opioids
- b. who had visited a podiatrist
- c. who had no concurrent pain diagnoses

### Article 2 (page 36) - Sociodemographic Determinants of Health and Well-Being Among Adults Residing in the Combined Kaiser Permanente Regions

Which set of sociodemographic factors were significantly associated with both excellent/very good health and thriving overall in life?

- a. age, race/ethnicity, perceived financial situation, and educational attainment
- b. age, race/ethnicity, and educational attainment
- c. age, race/ethnicity, and perceived financial situation
- d. age, educational attainment, and perceived financial situation

Which of the following statements is true?

- a. differences in excellent/very good health and thriving between low and high levels of perceived financial situation were larger than between low and high levels of education
- b. differences in excellent/very good health and thriving between low and high levels of education were larger than between low and high levels of perceived financial situation
- c. differences in excellent/very good health and thriving were about the same for low vs high levels of education and low vs high perceived financial situation

### Article 3 (page 60) - Progel Use is Not Associated with Decreased Incidence of Postoperative Air Leak after Nonanatomic Lung Surgery

What is the incidence of lung air leak after nonanatomic lung resection? What is the incidence of prolonged air leak?

- a. 10% - 20%, 5% - 10%
- b. 20% - 50%, 10% - 15%
- c. 30% - 60%, 5% - 10%
- d. 40% - 70%, 10% - 15%
- e. 50% - 60%, 10% - 15%

Which of the following statements is true?

- a. a prolonged air leak is one that persists beyond postoperative day 2
- b. staple line oversewing and use of buttressed staples have the equivalent effect on air leak incidence
- c. intraoperative air leaks are usually not clinically significant
- d. intraoperative air leaks typically resolve within a few hours of surgery by apposition of visceral pleura to adjacent visceral pleura
- e. prolonged air leak is associated with increased chest tube duration but not increased length of hospitalization

### Article 4 (page 95) - Pain Management Associated with Total Joint Arthroplasty: A Primer

Which of the following is the underlying cause of the opioid crisis?

- a. patients with long-term chronic pain issues
- b. prescriber prescriptions of opioids
- c. opioid misuse
- d. opioid addiction

Which best-practice strategy supports the safe use of prescribing opioid analgesics?

- a. using a daily total 90-mg morphine equivalent
- b. prescribing extended-release/long-acting opioids for opioid-naïve patients
- c. influencing prescribing behavior through professional mandates
- d. coprescribing short-acting opioids with a second medication to decrease dependence of a single medication

## 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	Objective 1	Objective 2	Objective 3
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
Article 3	5 4 3 2 1 0	5 4 3 2 1 0	5 4 3 2 1 0
Article 4	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)

Name \_\_\_\_\_  
 Physician  Non-Physician

Title \_\_\_\_\_

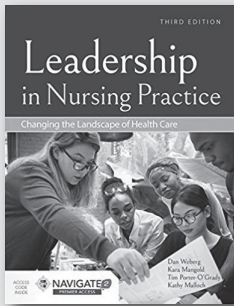
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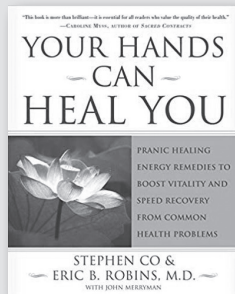
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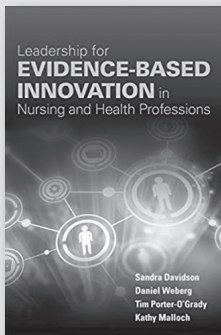


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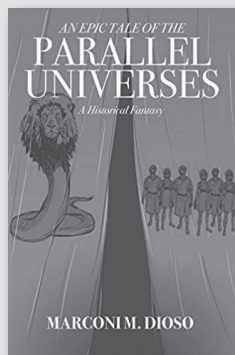
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- Fractional Exhaled Nitric Oxide-Assisted Management of Uncontrolled Persistent Asthma: A Real-World Prospective Observational Study
- Health Status of Young Adults with Insurance Coverage Before and After Affordable Care Act Passage
- Temporal Trends in Mortality Rates among Kaiser Permanente Southern California Health Plan Enrollees, 2001-2016

### REVIEW ARTICLES

- 95 Pain Management Associated with Total Joint Arthroplasty: A Primer
- A Mucinous Cystic Neoplasm Originating from the Gallbladder: A Case Report and Literature Review

### CLINICAL PRACTICE

- 101 Acute Convulsive Seizures:  
When is It Too Early to Treat?

### CASE REPORTS

- A Rare Case of an Abdominal Aneurysm in a Patient with Lymphangioleiomyomatosis: A Case Report
- Scalp Intravenous Catheter Infiltration Leading to Subdural and Intraparenchymal Fluid Collection and Severe Neurologic Sequelae: A Case Report

### IMAGE DIAGNOSIS

- Image Diagnosis: Scapholunate Dissociation

### BOOK REVIEW

- 110 Enlightened Aging: Building Resilience for a Long, Active Life
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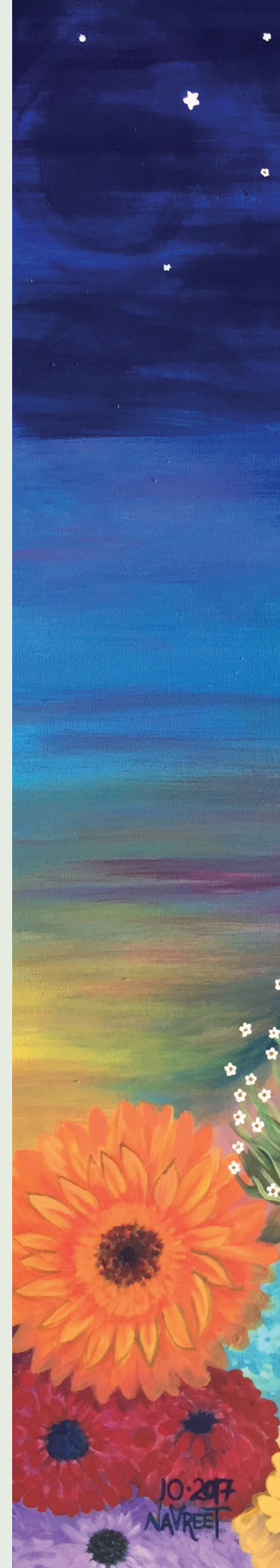
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