



Fall 2018      Volume 22 No. 4

# The Permanente Journal

*A peer-reviewed journal of medical science,  
social science in medicine, and medical humanities*

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**Aloha Wave**  
photograph  
By Sapna Reddy, MD

A beautiful fan wave on the shoreline in Kauai, illuminated by the light of the setting sun.

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

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The authors identified 1,800,948 patients who made 2,326,701 health care encounters eligible for HIV testing before implementation (1/08-6/12) and 1,362,479 eligible encounters after implementation (1/13-6/15). The same-day HIV testing rate increased from 36.7% to 44.1%, a significant increase. The positive test result rate increased from 0.02% to 0.04% ( $p < 0.001$ ). During the postimplementation period, fewer HIV-infected patients had a CD4+ cell count below 200 and/or HIV viral load of 10,000 copies/mL or higher at diagnosis.

- 10 Effect of Meditation on Emotional Intelligence and Perceived Stress in the Workplace: A Randomized Controlled Study.**  
Laurent Valosek; Janice Link, MA; Paul Mills, PhD; Arthur Konrad, PhD; Maxwell Rainforth, PhD; Sanford Nidich, EdD

Of the central office staff at the San Francisco Unified School District, 96 were randomly assigned to either immediate start of the Transcendental Meditation program or to a wait-list control group. There was a significant increase in emotional intelligence total score and a significant decrease in perceived stress in Transcendental Meditation participants (compared with controls), and also a significant increase in general mood, stress management, adaptability, intrapersonal awareness, and reality testing composite scales for emotional intelligence.

- 17 Different Harm and Mortality in Critically Ill Medical vs Surgical Patients: Retrospective Analysis of Variation in Adverse Events in Different Intensive Care Units.**  
Ko Un Park, MD; Michael Eichenhorn, MD; Bruno DiGiovine, MD; Jennifer Ritz, RN; Jack Jordan; Ilan Rubinfeld, MD, MBA

Three years of data were accessed from the Henry Ford Health System No Harm Campaign in Detroit, MI. Harm was defined as any unintended physical injury resulting from medical care. The study included 19,844 patients (7483 were surgical). The overall mortality was 7.8% ( $n = 1554$ ). More surgical patients experienced harm than did nonsurgical patients (2923 [39.1%] vs 2798 [22.6%]). Surgical patients were less likely to die (6.2% vs 8.8%). Surgical patients were more likely to experience harm (procedure related) but had lower mortalities vs other harmed patients.

- 21 Contraception after Abortion and Risk of Repeated Unintended Pregnancy among Health Plan Members.**  
**CME** Debbie Postlethwaite, RNP, MPH; Justine Lee, MD; Maqdooda Merchant, MSc, MA; Amy Alabaster, MPH; Tina Raine-Bennett, MD, MPH

A retrospective cohort study was conducted using a randomized proportional sample of women aged 15 to 44 years having abortions in Kaiser Permanente Northern California (KPNC). Women having abortions from contracted facilities were significantly less likely to initiate long-acting reversible contraception (LARC). Women initiating short-acting or no contraception were significantly more likely to have an unintended pregnancy within 12 months of the abortion than those initiating LARC. KPNC now provides reimbursement for LARC in all outside abortion contracts, internalized more abortions in KPNC facilities, and strengthened clinical recommendations for immediate, elective postabortion contraception, especially LARC.

- 28 Urate-Lowering Therapy in Moderate to Severe Chronic Kidney Disease.**  
**CME** Gerald Levy, MD, MBA; Jiaxiao M Shi, PhD; T Craig Cheatham, PharmD, MS; Nazia Rashid, PharmD, MS

Hyperuricemia is an independent risk factor for progression of kidney disease. This was a retrospective epidemiologic cohort study conducted over 8 years of 12,751 patients; 2690 patients received urate-lowering therapy (ULT) during follow-up and 10,061 did not. Patients who achieve an American College of Rheumatology target serum Uric Acid below 6 mg/dL during ULT have higher rates of estimated glomerular filtration rate improvement, especially in chronic kidney disease Stages 2 and 3.

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Alyssa Finger, Mark Harris; Emily Nishimura; Hyo-Chun Yoon, MD, PhD

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**40 Clostridium Difficile-Associated Infection in Trauma Patients: Development of the Clostridium Difficile Influencing Factors (CDIF) Score.**

Efstathios Karamanos, MD; Arielle Hodari Gupta, MD; Cletus Nor Stanton, MD; Adnan Mohamed, MD; Joe H Patton, MD, FACS; Nathan Schmoekel, DO

All trauma patients admitted to a Level I trauma center from 2001 to 2014 were retrospectively reviewed. Of 11,016 patients identified, 50 patients with *Clostridium difficile*-associated infection (CDAI) were matched to 150 patients without CDAI. Patients in whom CDAI developed had significantly higher mortality (12% vs 4%), need for mechanical ventilation (57% vs 23%), and mean hospital length of stay (15.3 days vs 2.1). In trauma patients, CDAI results in significant morbidity and mortality. The *C difficile* influencing factor score is a useful tool in identifying patients at increased risk of CDAI.

**46 Developing Community-Based Primary Health Care for Complex and Vulnerable Populations in the Vancouver Coastal Health Region: HealthConnection Clinic.**

Ali Rafik Shukor, MBIotech, MSc; Sandra Edelman, MA; Dean Brown, MD; Cheryl Rivard, MA

Designing, delivering, and evaluating high-performing primary health care services for complex and vulnerable subpopulations are challenging endeavors. The HealthConnection Clinic, a public primary care center located in Metropolitan Vancouver's North Shore (British Columbia, Canada) provided valuable insights to development of the Building Blocks' foundational elements, particularly engaged leadership, empanelment, and data-driven improvement. The study highlighted the key enablers, achievements, challenges, and barriers related to operationalizing each Building Block.

**SPECIAL REPORTS****55 Cognitive Behavioral Therapy with Heart Rate Variability Biofeedback for Adults with Persistent Noncombat-Related Posttraumatic Stress Disorder.**

Shawn R Criswell, MA, PhD, LPC; Richard Sherman, MS, PhD; Stanley Krippner, MS, PhD

The authors tested the effectiveness of a mental health therapy designed to reduce noncombat-related persistent posttraumatic stress disorder (PTSD) symptoms in 30 adult outpatients with a diagnosis of PTSD. The study had 2 components: The quality improvement project that performed the treatment within a standard care environment, and a retrospective medical chart review process that analyzed the results. The study findings suggest that this intervention is an effective treatment for helping adult patients, including those with a history of childhood abuse, remit their PTSD diagnosis.

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Ruth Madievsky, PharmD

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Stories and poems with illustrations 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.

**75 FLK.**

Monique Canonico, DO

Cody had been expelled from preschool for biting and for consistently resisting all authority. He picked fights with kids in the neighborhood who were twice his size. He made no eye contact, but he was transfixed by the stuffed Kermit the Frog puppet I had on my office shelf. After listening to the mother's complete story, I asked, "What seems to be the one thing he's good at?" "Well," his mother said, "he's strong, brave, and independent, and he's got street smarts you wouldn't expect from a 5-year-old boy."

**76 Patient as Healer.**

June Pham, MD

My first patient was a Christian minister who was never able enough to control his type 2 diabetes. Quickly into the visit, after the usual questions and answers and advice, he asked me what had changed in my life. I told him and tears came to my eyes.

**77 DNR.**

Felicitas Livaudais, MD

As an intern at Charity Hospital, I was responsible for night call duties. There was a woman on our service with cancer. One night the patient went into agonal breaths. They called me, the intern, so I sat with her daughter as she listened to her mother's raspy breaths until they became less, more quiet, then nothing. They held hands the whole time.

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Scott Abramson, MD

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- 68 **Evidence-Based Medicine and Bioethics: Implications for Health Care Organizations, Clinicians, and Patients.**

Erin G Stone, MD, MA, FACP

This article discusses the deontologic and utilitarian aspects of evidence-based medicine (EBM) and assesses EBM according to 4 bioethical principles: Respect for autonomy, beneficence, nonmaleficence, and justice. Strong ethical arguments support EBM as the best approach to patient care. However, practitioners and health care organizations must be aware that each principle involves complex issues that challenge EBM's ethical values.

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- 74 **Sensory Inattention.**  
Nandini Bakshi, MD

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reacting to beeps and codes

- 78 **To Pace or Not To Pace?  
A Narrative Review of VIP Syndrome.**  
Ching Soong Khoo, MD, MRCP (UK)

The term VIP (very important person) syndrome was introduced by Dr Walter Weintraub in 1964. Managing VIPs poses a great challenge to health care practitioners. A VIP, by definition, is a person given special privileges in view of his or her status or wealth. Examples of VIPs include royalty, politicians, celebrities, corporate leaders, and wealthy individuals. In my very humble opinion, medical personnel or their relatives have increasingly become VIPs for special treatment.

# ADDITIONAL ONLINE

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## ORIGINAL RESEARCH &amp; CONTRIBUTIONS

# Effect of an Electronic Alert on Targeted HIV Testing Among High-Risk Populations

Rulin C Hechter, PhD, MS, MD; Zoe Bider-Canfield, MPH; William Towner, MD

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<https://doi.org/10.7812/TPP/18-015>**ABSTRACT**

**Context:** Screening for HIV infection in medical settings remains suboptimal.

**Objective:** To examine the real-world effectiveness of an electronic clinician alert on the same-day HIV testing rate and early diagnosis in high-risk populations.

**Design:** We identified Kaiser Permanente Southern California Health Plan members aged 14 years or older who received tests for sexually transmitted infections.

**Main Outcome Measures:** Encounter-based same-day HIV testing rate, positive test result rate, and CD4<sup>+</sup> cell count and HIV viral load at diagnosis.

**Results:** We identified 1,800,948 patients who made 2,326,701 health care encounters eligible for HIV testing before implementation (January 1, 2008 - June 30, 2012) and 1,362,479 eligible encounters after implementation (January 1, 2013 - June 30, 2015). The same-day HIV testing rate increased from 36.7% to 44.1% (standardized mean difference = 0.15, significant difference). The alert was associated with a moderate difference and statistically significant increase in the HIV testing rate (adjusted odds ratio = 1.17, 95% confidence interval = 1.16-1.18). The positive test result rate increased from 0.02% to 0.04% ( $p < 0.001$ ). During the postimplementation period, fewer HIV-infected patients had a CD4<sup>+</sup> cell count below 200 and/or an HIV viral load of 10,000 copies/mL or higher at diagnosis.

**Conclusion:** Implementation of a targeted electronic alert embedded in the electronic medical record improved same-day HIV screening rate and positive test result rates among patients receiving tests for sexually transmitted infections in a large health organization. This intervention has potential for facilitating frequent screening and early identification of HIV infection in high-risk populations.

**INTRODUCTION**

Early diagnosis of HIV infection improves personal and public health outcomes. Clinical trial data have indicated that the early initiation of antiretroviral therapy (ART) reduces rates of clinical events and leads to a sustained decrease in linked HIV Type 1 (HIV-1) infections in sexual partners on the basis of phylogenetic analysis of HIV-1 polymerase region sequences.<sup>1,2</sup> Furthermore, persons aware of their HIV infection tend to be less likely to engage in risky sexual behaviors than do unaware persons.<sup>3,4</sup> In 2006, to foster earlier detection of HIV infection

and to identify and link persons with unrecognized HIV infection to clinical and prevention services, the Centers for Disease Control and Prevention (CDC) recommended routine opt-out HIV screening of persons aged 13 to 64 years in all health care settings except in communities where the prevalence of undiagnosed HIV infection is documented at less than 0.1%, and that persons at high risk of HIV infection should be screened for HIV at least annually.<sup>5</sup>

Despite the widespread availability of HIV testing, an estimated 13% of persons living with HIV were unaware of their infection in 2012,<sup>6</sup> and many have a diagnosis of advanced HIV disease (AIDS). There are missed opportunities for HIV testing among high-risk populations in various medical care settings. A study using data from the 2009 National Hospital Ambulatory Medical Care Survey estimated that the HIV testing rate in US Emergency Departments (EDs) in all 50 states and the District of Columbia was very low (about 2.3%) among persons for whom targeted testing was indicated (ie, sexually transmitted diseases, sexual abuse, or pregnancy).<sup>7</sup> Another study, using the data of the National Survey of Family Growth, reported that the rate of annual HIV testing was low for men with a sexual risk of HIV infection (range = 23.9%-41.7% during 2008-2010), and little improvement took place from 2002 to 2006-2010<sup>8</sup> after the 2006 CDC recommendations for HIV testing among high-risk populations.<sup>5</sup> Persons with indication of unsafe sexual activities who seek care and tests for sexually transmitted infections (STIs) are at particularly high risk of HIV infection through unprotected sexual activities. Because sexual contact accounts for most new HIV diagnoses in the US,<sup>9</sup> targeted HIV screening during STI health care encounters presents an opportunity for early identification of HIV infection and timely linkage to HIV specialty care.

As an integrated health care system, Kaiser Permanente (KP) Southern California (KPSC), uses an electronic health record (EHR; Epic Systems Corp, Verona, WI) that captures laboratory, pharmacy, and diagnostic data for members of KPSC. Such a system enables clinical decision support (CDS) tools to be created that would assist practitioners in ordering clinically appropriate HIV tests via a series of prompts. We conducted a retrospective cohort study to 1) examine the real-world effectiveness of a CDS tool embedded in an EHR of a large health care organization on the same-day HIV testing rate among patients seeking care for STIs; 2) study correlates of receiving

a same-day HIV test and determine whether the associations differ during preimplementation vs postimplementation; and 3) examine the impact of the CDS tool on HIV positivity rates and early identification of HIV infection.

## METHODS

### Study Setting

KPSC is the largest Region of KP, a large managed care organization in the US. This Region serves more than 4 million Health Plan members in Southern California. Members of KP are insured through prepaid health plans and receive integrated primary and specialty care. Members of KPSC are very similar to the general population in California regarding age, sex, and race/ethnicity, with only slight underrepresentation of those in very low and very high income and education categories.<sup>10</sup> Electronic reminders and alerts are widely used in KPSC's comprehensive EHR system as a CDS tool to assist clinicians in identifying high-risk patients and in closing care gaps. The electronic reminders and alerts use comprehensive prespecified algorithms based on certain inclusion and exclusion criteria to identify eligible patients through the EHR system and provide real-time support to clinicians' decision making at the point of care. A best practice alert (BPA) is a "hard-stop" CDS tool, which pops up on the computer screen when a clinician opens a patient's chart or signs off on an order, and the clinician needs to either act on the alert or dismiss the alert before s/he can close the patient's electronic chart.

### Electronic Best Practice Alert for HIV testing

To increase opt-out HIV testing among high-risk populations, KPSC launched an HIV/STI Screening and Immunizations BPA in October 2012. The BPA was embedded in the EHR system to remind clinicians to order HIV/STI screening tests for patients aged 14 years or older when ordering tests for syphilis, chlamydia, gonorrhea, hepatitis B surface antigen, or hepatitis C antibody, if HIV or AIDS status was unknown or there were no recent results for an HIV screening test. Specifically, if a test for gonorrhea/chlamydia, hepatitis B surface antigen, or hepatitis C antibody screening were ordered for a patient whose HIV infection status is unknown, and there was no HIV test result documented within the last 30 days, the alert would fire when the clinician signs the order for an STI test. Because patients receiving syphilis treatment often undergo frequent syphilis tests for antibody titers to monitor syphilis treatment efficacy, the alert was not designed to fire at every subsequent follow-up syphilis test. For patients who received a syphilis test order, the alert would fire if there was no HIV test result documented within the last 365 days. The BPA prompted the physician to order an HIV screening test and other relevant STI tests, along with a list of recommended vaccines on the basis of the patient's age and history of vaccination (eg, human papillomavirus and hepatitis B vaccines). Links for ordering the HIV/STI tests and vaccines were embedded in the BPA screen to facilitate the orders.

### Study Population

We identified KPSC Health Plan members who were age 14 years or older and who received at least 1 test for the

aforementioned STIs targeted by the BPA at a health care encounter during the preimplementation (January 1, 2008 - June 30, 2012) and postimplementation (January 1, 2013 - June 30, 2015) periods. Data from a 6-month washout period around the roll-out of the BPA (ie, July 2012 - December 2012) were excluded from the analysis. We then determined whether an individual was eligible for an HIV test at each health care encounter according to the BPA criteria. Only the eligible encounters were included in the study sample as the index encounters for analyses. An individual could have multiple index encounters during the study period until s/he either received an HIV-positive test result or disenrolled from the Health Plan, whichever came first.

### Outcome Measures

We calculated the encounter-based same-day HIV testing rate, defined by the proportion of the encounters with an HIV test performed on the same day among the STI test encounters when an HIV test was indicated according to the BPA criteria (ie, the index encounter). The same-day HIV testing rate was calculated for the study sample during the pre- and postimplementation periods separately and by age group (14-17, 18-24, 25-39, 40-49,  $\geq 50$  years) at the encounter. Sex, race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, Asian/Pacific Islander, multiple/other, unknown), insurance type (commercial, Medicaid), type of STI test or tests received at the encounter, and history of previous HIV tests were also captured. Among those who received a same-day HIV test, we calculated the encounter-based HIV-positive test result rate during pre- and postimplementation periods (ie, proportion of positive HIV tests among all encounters with a same-day HIV test). To evaluate the impact of the BPA on early identification of HIV infection, we also calculated the proportion of patients with a baseline CD4<sup>+</sup> cell count less than 200 cells/mm<sup>3</sup> (an indication for severely impaired immune function and AIDS) or CD4<sup>+</sup> cell count below 350 cells/mm<sup>3</sup> (clinical indication for ART initiation), and patients with a detectable HIV viral load ( $\geq 200$  copies/mL) or a very high viral load ( $\geq 100,000$  copies/mL) at or immediately after the positive HIV test result, during the pre- and postimplementation periods, respectively. The study protocol was reviewed and approved by the KPSC institutional review board with a waiver of requirement for informed consent.

### Statistical Analysis

We conducted  $\chi^2$  tests to compare the distribution of sex, age (at the first index encounter), and race/ethnicity among the individuals who were eligible for an HIV test during the pre- and postimplementation periods. Because a significance test of p value based on a very large sample may make a very small difference appear statistically significant, we calculated the standardized mean difference (SMD) of the same-day HIV testing rates during the pre- and postimplementation periods. An SMD with an absolute value  $< 0.1$  is considered negligible, an absolute value  $> 0.2$  is considered statistically significant, and an absolute value between 0.1 and 0.2 is considered as a moderate difference.<sup>11-13</sup>

Logistic regression modeling using generalized estimating equations was conducted to estimate the adjusted effects of the BPA implementation on receiving a same-day HIV test at the index encounters (adjusted odds ratio [OR]; and 95% confidence interval [CI]), controlling for patient demographics, type of STI test, Medicaid status, history of previous HIV tests, clinician race/ethnicity, and Medical Centers in the multivariable models. We conducted separate multivariable analyses to evaluate whether those associations differed before and after implementation. To account for potential correlation within individuals (about 44% of the patients had more than 1 index encounter during the study period), we employed Poisson regression models using generalized estimating equations to adjust for intraperson correlation. We conducted  $\chi^2$  tests to compare the proportion of patients with a baseline CD4<sup>+</sup> cell count below 200 or less than 350 cells/mm<sup>3</sup> and patients with

a baseline HIV viral load of at least 200 copies/mL or 100,000 copies/mL or more during the pre- and postimplementation periods. All analyses were performed using SAS Version 9.3 software (SAS Institute, Cary, NC).

## RESULTS

We identified 1,800,948 unique patients who made 2,326,701 index health care encounters at which the patients were eligible for an HIV test according to the BPA criteria during the preimplementation period (January 1, 2008 - June 30, 2012) and 1,362,479 index health care encounters during the postimplementation period (January 1, 2013 - June 30, 2015). Among those, 371,678 patients (20.6%) had index encounters during both pre- and postimplementation periods. There were 153,688 patients (11.9%) in the preimplementation period and 84,212 patients (9.5%) in the postimplementation period who had multiple index encounters. Most of the study population were female and Hispanic or white. The distribution of sex, age, race/ethnicity, and proportion of patients with Medicaid coverage was similar during the pre- and postimplementation periods (SMD < 0.1; Table 1).

The same-day HIV testing rate increased from 36.7% to 44.1% (SMD = 0.15, moderate difference) in the overall cohort after the BPA implementation (Table 2). The increase was observed across all patient sex and race/ethnicity groups, whereas the same-day HIV testing rates varied by different medical centers (statistically significant). The magnitude of the increase was significant among males (SMD = 0.27), Asian/Pacific Islanders (SMD = 0.20), patients who received care from a Hispanic clinician (SMD = 0.26), and those who received a syphilis test (SMD = 0.38) at the index health care encounter. The same-day HIV testing rate remained similar among patients younger than age 25 years old, whereas the rate increased by more than 10% in patients older than age 25 years. The increase was more prominent in the patients who had only 1 index encounter, rising from 36.8% to 48.1%, and among those who received care from a Hispanic clinician (up by 12.8%, SMD = 0.26). Although the baseline same-day HIV testing rate was much higher before the BPA implementation among those who had multiple index encounters, the same-day HIV testing rate remained stable among those patients after the implementation (66.9% vs 69.8%).

We found that implementation of the BPA was associated with a moderate and statistically significant increase in the same-day HIV testing rate (adjusted OR = 1.17, 95% CI = 1.16 - 1.18, Table 3). Other factors associated with a greater likelihood of receiving a same-day HIV test included male sex (adjusted OR = 1.52, 95% CI = 1.51 - 1.54), being a minority (black: adjusted OR = 1.27, 95% CI = 1.25 - 1.29; Hispanic: adjusted OR = 1.08, 95% CI = 1.07 - 1.09; multiple/other races: adjusted OR = 1.11, 95% CI = 1.08 - 1.14 vs white), and received care from a clinician of Hispanic ethnicity (adjusted OR = 1.14, 95% CI = 1.13 - 1.16 vs white race), after adjusting for medical centers. Eligible patients who received an STI test in the Infectious Disease Department were more likely to receive HIV testing than those in primary care (crude OR = 2.13,

**Table 1. Demographics of patients who received at least 1 STI test at a health care encounter and were eligible for HIV testing per best practices alert criteria**

Characteristic	Preimplementation (January 1, 2008 - June 30, 2012), no. (%)	Postimplementation (January 1, 2013 - June 30, 2015), no. (%)	SMD <sup>a</sup>
Total <sup>b</sup>	1,287,187 (100)	885,439 (100)	
<b>Age,<sup>c</sup> y</b>			
14-17	82,631 (6.4)	40,262 (4.5)	-0.08
18-24	255,209 (19.8)	205,224 (23.2)	0.08
25-39	464,086 (36.1)	334,923 (37.8)	0.04
40-49	205,916 (16)	123,893 (14)	-0.06
≥ 50	279,345 (21.7)	181,137 (20.5)	-0.03
<b>Sex<sup>d</sup></b>			
Female	873,214 (67.8)	610,083 (68.9)	0.02
Male	413,961 (32.2)	275,342 (31.1)	-0.02
<b>Race/ethnicity<sup>e</sup></b>			
White	386,830 (30.1)	262,171 (29.6)	-0.01
Black	140,667 (10.9)	99,529 (11.2)	0.01
Hispanic	508,898 (39.5)	386,830 (43.7)	0.08
Asian/Pacific Islander	123,190 (9.6)	90,395 (10.2)	0.02
Multiple/other	27,438 (2.1)	19,548 (2.2)	0.01
Unknown	100,164 (7.8)	26,966 (3.0)	-0.21
<b>Medicaid</b>			
No	1,235,025 (95.9)	830,375 (93.8)	-0.1
Yes	52,162 (4.1)	55,064 (6.2)	0.1

<sup>a</sup> Standardized mean difference with an absolute value less than 0.1 is considered negligible.

<sup>b</sup> A total of 371,678 patients (20.4%) had eligible encounters in both pre- and postimplementation periods. The total number of unique patients across the 2 periods was 1,800,948.

<sup>c</sup> Age was calculated at the date of the first STI test performed during each period if there were multiple eligible encounters during pre- and/or postimplementation periods of the HIV screening best practices alert.

<sup>d</sup> Numbers may not total to 100% because some patients reported "other" for sex (n = 12 in preimplementation and n = 14 in postimplementation period).

<sup>e</sup> May not total to 100% because of rounding.

SMD = standardized mean difference; STI = sexually transmitted infection.



95% CI = 1.98 - 2.29), but the estimate of an adjusted OR could not be obtained in the multivariable model because of a model convergence issue caused by many encounters with the care setting uncoded. Compared with patients who were age 25 to 39 years at the encounter, patients of other age groups were less likely to receive a same-day HIV test (statistically significant). Patients with Medicaid coverage were slightly less likely to receive a same-day HIV test (adjusted OR = 0.91, 95% CI = 0.90 - 0.92). Compared with patients who were tested for multiple types of STI infections at the index encounter, those who received a single STI test were less likely to receive a same-day HIV test (Table 3). Patients with a history of previous HIV tests were more likely to receive a same-day HIV test at the index encounter (adjusted OR = 1.93, 95% CI = 1.91 - 1.94).

Results of separate multivariable analyses in the pre- and postimplementation periods indicated that associations between the patient and clinician characteristics and the likelihood of

receiving a same-day HIV test were similar across time. The likelihood of the same-day HIV testing increased after the BPA implementation among patients who were age 40 to 49 years (preimplementation: OR = 0.44, 95% CI = 0.43 - 0.45; postimplementation: OR = 0.61, 95% CI = 0.59-0.62) and those age 50 years or older (preimplementation: OR = 0.18, 95% CI = 0.18-0.19; postimplementation: OR = 0.33, 95% CI = 0.32-0.34), compared with those age 25 to 39 years.

Among the 854,925 and 600,719 HIV tests performed among the study sample during the pre- and postimplementation periods, 141 patients and 245 patients tested HIV positive, respectively, resulting in an encounter-based HIV positive test result rate of 0.02% and 0.04% respectively ( $p < 0.001$ ). During the postimplementation period, fewer patients who tested HIV positive had a baseline CD4<sup>+</sup> cell count below 200 cells/mm<sup>3</sup> (ie, meets AIDS definition) or less than 350 cells/mm<sup>3</sup>, and fewer patients had a detectable ( $\geq 200$  copies/mL) or very high ( $\geq 100,000$  copies/mL) baseline HIV viral load ( $p < 0.05$ , Table 4).

**Table 2. Same-day HIV testing rate among patients who received at least one STI test at a health care encounter and were eligible for HIV testing per best practices alert criteria**

Characteristic	Preimplementation, no. (%)		Postimplementation, no. (%)		Comparison of same-day testing rates	
	Encounters	Same-day HIV testing rate	Encounters (%)	Same-day HIV testing rate	Percentage difference in testing rate	SMD <sup>a</sup>
Overall	2,326,701	854,925 (36.7)	1,362,479	600,719 (44.1)	7.4	0.15
<b>Age, y</b>						
14-17	120,202 (5.2)	38,589 (32.1)	53,837 (4.0)	17,362 (32.2)	0.1	0.00
18-24	571,344 (24.6)	202,960 (35.5)	390,830 (28.7)	134,890 (34.5)	-1.0	-0.02
25-39	922,518 (39.6)	414,585 (44.9)	524,312 (38.5)	291,833 (55.7)	10.7	<b>0.22</b>
40-49	328,484 (14.1)	112,478 (34.2)	169,005 (12.4)	77,596 (45.9)	11.7	<b>0.24</b>
$\geq 50$	384,153 (16.5)	86,313 (22.5)	224,495 (16.5)	79,038 (35.2)	12.7	<b>0.28</b>
<b>Sex</b>						
Female	1,756,883 (75.5)	570,861 (32.5)	1,010,998 (74.2)	379,388 (37.5)	5.0	0.11
Male	569,800 (24.5)	284,060 (49.9)	351,464 (25.8)	221,324 (63.0)	13.1	<b>0.27</b>
<b>Race/ethnicity</b>						
White	654,557 (28.1)	219,858 (33.6)	381,606 (28.0)	163,285 (42.8)	9.2	0.19
Black	311,829 (13.4)	120,972 (38.8)	177,553 (13.0)	79,372 (44.7)	5.9	0.12
Hispanic	963,686 (41.4)	363,454 (37.7)	610,018 (44.8)	267,660 (43.9)	6.2	0.13
Asian/Pacific Islander	207,999 (8.9)	74,476 (35.8)	127,686 (9.4)	58,316 (45.7)	9.9	<b>0.20</b>
Multiple/Other	51,507 (2.2)	20,967 (40.7)	29,623 (2.2)	14,218 (48.0)	7.3	0.15
Unknown	137,123 (5.9)	55,198 (40.3)	35,993 (2.6)	17,868 (49.6)	9.3	0.19
<b>Medicaid</b>						
No	2,202,827 (94.7)	811,549 (36.8)	1,257,111 (92.3)	559,712 (44.5)	7.7	0.16
Yes	123,874 (5.3)	43,376 (35.0)	105,368 (7.7)	41,007 (38.9)	3.9	0.08
<b>STI test type</b>						
Multiple STI tests	571,754 (24.6)	544,693 (95.3)	448,446 (32.9)	439,275 (98.0)	2.7	0.15
Chlamydia and gonorrhea	1,144,970 (49.2)	99,540 (8.7)	633,727 (46.5)	58,265 (9.2)	0.5	0.02
Hepatitis B and C	402,077 (17.3)	143,835 (35.8)	205,210 (15.1)	65,274 (31.8)	-4.0	-0.08
Syphilis	207,900 (8.9)	66,857 (32.2)	75,096 (5.5)	37,905 (50.5)	18.3	<b>0.38</b>
<b>HIV test history</b>						
No	1,574,507 (67.7)	548,606 (34.8)	729,061 (53.5)	303,515 (41.6)	6.8	0.14
Yes	752,194 (32.3)	306,319 (40.7)	633,418 (46.5)	297,204 (46.9)	6.2	0.13

<sup>a</sup> Boldface = statistically significant difference.

CI = confidence interval; SMD = standardized mean difference; STI = sexually transmitted infection.

**DISCUSSION**

Our findings suggest that implementing a targeted electronic alert embedded in a comprehensive EHR system of a large health care organization has a moderate and statistically significant effect

**Table 3. Factors associated with receiving same-day HIV testing among patients who received at least 1 STI test at a health care encounter and were eligible for HIV testing per BPA criteria**

Factor	Crude OR (95% CI)	Adjusted OR (95% CI)
<b>BPA implementation</b>		
Preimplementation	Reference	Reference
Postimplementation	1.36 (1.35-1.36)	1.17 (1.16-1.18)
<b>Age, y</b>		
25-39	Reference	Reference
14-17	0.50 (0.49-0.50)	0.84 (0.82-0.85)
18-24	0.57 (0.57-0.58)	0.91 (0.91-0.92)
40-49	0.64 (0.64-0.65)	0.45 (0.45-0.46)
≥ 50	0.39 (0.38-0.39)	0.21 (0.21-0.22)
<b>Sex</b>		
Female	Reference	Reference
Male	2.30 (2.29-2.32)	1.52 (1.51-1.54)
<b>Patient race/ethnicity</b>		
White	Reference	Reference
Asian/Pacific Islander	0.88 (0.87-0.89)	0.88 (0.87-0.89)
Black	1.27 (1.25-1.29)	1.27 (1.25-1.29)
Hispanic	1.08 (1.07-1.09)	1.08 (1.07-1.09)
Multiple/other	1.11 (1.08-1.14)	1.11 (1.08-1.14)
Unknown	0.99 (0.97-1.01)	0.99 (0.97-1.01)
<b>Medicaid</b>		
No	Reference	Reference
Yes	0.90 (0.89-0.91)	0.91 (0.9-0.92)
<b>Provider race/ethnicity</b>		
White	Reference	Reference
Asian	1.08 (1.08-1.09)	0.88 (0.87-0.89)
Black	0.72 (0.71-0.73)	0.77 (0.76-0.79)
Hispanic	1.25 (1.24-1.26)	1.14 (1.13-1.16)
Other/missing	0.97 (0.96-0.98)	0.96 (0.94-0.98)
<b>Provider specialty</b>		
Family medicine	Reference	Reference
Infectious disease	2.13 (1.98-2.29)	NA <sup>a</sup>
Unknown	0.75 (0.74-0.75)	NA <sup>a</sup>
Other	0.82 (0.82-0.83)	NA <sup>a</sup>
<b>STI test category</b>		
Multiple STIs	Reference	Reference
Chlamydia and gonorrhea	0 (0-0)	0 (0-0)
Hepatitis B and C	0.02 (0.02-0.02)	0.03 (0.03-0.03)
Syphilis	0.03 (0.03-0.03)	0.04 (0.04-0.05)
<b>HIV testing history</b>		
No	Reference	Reference
Yes	1.14 (1.13-1.15)	1.93 (1.91-1.94)

<sup>a</sup> Multivariable model did not converge. BPA = best practices alert; CI = confidence interval; NA = not applicable; OR = odds ratio; STI = sexually transmitted infection.

on the same-day HIV testing rate among patients who received an STI test. Late diagnosis and poor HIV/AIDS prognosis affect racial/ethnic minorities (ie, blacks and Hispanics) and older adults (ie, aged ≥ 50 years) disproportionately. Although the overall increase in the same-day HIV testing was moderate (adjusted OR = 1.17), we observed a greater increase in patients age 50 years and older (by 12.7%) after implementing the BPA, suggesting that this CDS tool has potential to address HIV testing disparity among high-risk older adults.

Our findings support that an evidence-based, targeted HIV screening CDS tool improved HIV testing rate among patients who received an STI test and increased the positivity rate of HIV testing (from 0.02% to 0.04%), which suggests that this approach also improved efficiency of HIV screening. Late presentation for treatment is associated with higher early mortality rates, higher direct health care costs, and poor retention in care.<sup>14-16</sup> On the basis of evidence from clinical trials<sup>17,18</sup> and recent observational studies<sup>19-21</sup> showing that earlier use of ART results in better clinical outcomes for people living with HIV compared with delayed treatment and better prevention of HIV transmission, the World Health Organization recommends that ART should be initiated in everyone living with HIV at any CD4<sup>+</sup> cell count.<sup>22</sup> Although the median CD4<sup>+</sup> cell count at the time of ART initiation is increasing, it remains lower than 350 cells/mm<sup>3</sup> in many settings, including in high-income countries. We hypothesized that the implementation of the BPA would likely facilitate early identification of HIV infection because it promotes frequent HIV testing among high-risk populations. Our findings supported our initial hypotheses because we observed fewer patients had a CD4<sup>+</sup> cell count below 200 cells/mm<sup>3</sup> or less than 350 cells/mm<sup>3</sup> or a very high HIV viral load (> 100,000 copies/mL) at the diagnosis during the postimplementation period.

**Table 4. Baseline CD4<sup>+</sup> count and HIV viral load among patients with a positive test result during pre- and postimplementation periods**

Measure	Preimplementation	Postimplementation	p value
<b>CD4<sup>+</sup> counts, no. (%)</b>			
Number of patients	135	236	
Median no. of counts (Q1, Q3)	364 (184, 567)	539 (384, 771)	< 0.0001
< 200 cells/mm <sup>3</sup>	37 (27.4)	23 (9.8)	0.0001
≥ 200 cells/mm <sup>3</sup>	98 (72.6)	213 (90.3)	
< 350 cells/mm <sup>3</sup>	64 (47.4)	54 (22.9)	0.0001
≥ 350 cells/mm <sup>3</sup>	71 (52.6)	182 (77.1)	
<b>Viral load, no. (%)</b>			
Number of patients	134	239	
Median no. of copies (Q1, Q3)	32,898 (8981, 126,254)	75 (0, 56,205)	< 0.0001
< 200 copies/mL	6 (4.5)	125 (52.3)	0.0001
≥ 200 copies/mL	128 (95.5)	114 (47.7)	
< 100,000 copies/mL	97 (72.4)	196 (82.0)	0.0299
≥ 100,000 copies/mL	37 (27.6)	43 (18.0)	

Q1 = 25th percentile; Q3 =75th percentile.

This study took advantage of a comprehensive EHR system of an integrated, large health care organization to examine the real-world effectiveness of an embedded electronic alert on the same-day HIV cotest rate targeting patients at increased risk of HIV infection. However, there are certain limitations in this study. We did not collect data on the reason for patients receiving an order for STIs test on the index date. A certain percentage of the patients may have received the STI tests as a routine screening; for instance, the CDC recommends annual chlamydia screening of all sexually active females younger than age 25 years. Clinicians might have chosen not to order a same-day HIV screening test for those persons who received routine STI screening if they did not present with STI symptoms. About 76% of the study population were women age 18 to 24 years, and 59% of these women received a same-day HIV test during the study period, higher than the overall same-day HIV testing rate. Therefore, routine STI screening practice among women age 18 to 24 years seemed unlikely to have influenced the effect of the BPA. In addition, we did not collect data on whether there were other clinician and patient education programs to enhance the awareness of HIV testing that might have influenced HIV screening practice during our study period.

## CONCLUSION

There are missed opportunities in health care settings in early identification of HIV infection. This targeted, clinician-level, systematic intervention has shown potential of facilitating frequent screening and early identification of HIV infection in high-risk populations in ambulatory care settings. ❖

## Disclosure Statement

The author(s) have no conflicts of interest to disclose. Dr Hechter, Ms Bider-Canfield, and Dr Towner are employed by Kaiser Permanente Southern California Department of Research and Evaluation and have received internal funding to conduct this study. The study sponsor had no role in study design, data collection, analysis, interpretation, writing of the report, or decision to submit for publication.

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# Effect of Meditation on Emotional Intelligence and Perceived Stress in the Workplace: A Randomized Controlled Study

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## ABSTRACT

**Context:** Research highlights the role of emotional intelligence and perceived stress as important factors associated with mental and physical health and organizational effectiveness.

**Objective:** To determine whether a mind-body technique, the Transcendental Meditation<sup>a</sup> (TM) program, delivered in the context of a workplace wellness program, could significantly decrease perceived stress and improve emotional intelligence in government employees.

**Design:** Ninety-six central-office staff at the San Francisco Unified School District were randomly assigned to either an immediate start of the TM program or to a wait-list control group.

**Main Outcome Measures:** The Bar-On Emotional Quotient Inventory and the Perceived Stress Scale were administered at baseline and at 4-month posttest.

**Results:** Findings indicate a significant increase in emotional intelligence total score ( $p < 0.003$ ) and a significant decrease in perceived stress ( $p < 0.02$ ) in TM participants compared with controls. A significant increase in general mood, stress management, adaptability, intrapersonal awareness, and reality testing composite scales for emotional intelligence were observed ( $p < 0.05$ ); a significant increase was not observed in the interpersonal scale. Compliance with meditation practice was high (93%). Because of the sex composition in this study, results are most generalizable to female employees.

**Conclusion:** The TM program was effective as a workplace wellness program to improve emotional intelligence and reduce perceived stress in employees.

## INTRODUCTION

According to the World Health Organization, psychological stress is one of the most common occupational health problems affecting workers worldwide.<sup>1</sup> Psychological stress, including perceived stress, adversely affects organizational commitment, work engagement, and productivity, as well as contributes to poor mental and physical health.<sup>2-4</sup>

Emotional intelligence has gained considerable attention in the workplace because of its positive association with mental and physical health and with social-emotional competencies.<sup>5,6</sup> Emotional intelligence refers to the ability to perceive emotions in oneself and others, and to understand, regulate, and use such information in productive ways toward

successful environmental adaptation and problem solving.<sup>7-9</sup>

Study findings indicate that emotional intelligence has a moderating effect on psychological well-being and mental health.<sup>10,11</sup> It is further linked to organizational effectiveness, social-emotional competencies such as the ability to manage stress, organizational awareness, and self-confidence associated with work productivity and effective leadership.<sup>12-19</sup>

Recent developments in neurocognition reveal that decisions and actions cannot be undertaken without engaging both the emotional and thought-processing areas of the brain.<sup>20</sup> Research on decision making and brain functioning supports the notion that emotional-social intelligence is distinctly different from

cognitive intelligence.<sup>7,20</sup> Emotional intelligence can be developed over time through training programs, coaching, and psychosocial therapy.<sup>13,18-21</sup> Emotional intelligence is also associated with better recovery from work-related stressors and better mental health in clinical populations.<sup>22,23</sup>

The impact of self-development and mind-body programs such as the practice of meditation has been studied in the fields of health and management. One such program that has received wide attention is the Transcendental Meditation<sup>a</sup> (TM) program, a neuropsychological technique for mind-body integration. This traditional form of meditation is generally described in the research literature as an automatic self-transcending technique for brain integration.<sup>24,25</sup>

Research on TM has shown that practitioners of TM achieve a high level of brain integration both during and after practice.<sup>26,27</sup> Practice of the TM technique shows increased electroencephalographic alpha coherence and synchrony, especially in the frontal area of the brain, responsible for cognition related to emotional self-awareness and stability.<sup>24,27-29</sup> In randomized controlled research, increased structural and functional connectivity between brain areas and decreased reactivity to stress are observed in those practicing the TM technique compared with controls.<sup>26</sup>

Other randomized controlled trials of TM have found significant reductions in perceived stress in employees,<sup>30</sup> patients with chronic illness,<sup>31,32</sup> and young adults.<sup>33</sup> Meta-analyses on the TM program have indicated increased

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self-actualization and decreased anxiety, factors associated with emotional intelligence and perceived stress.<sup>34-37</sup>

On the basis of prior research, a randomized controlled study was conducted to evaluate the effects of the TM program on emotional intelligence and perceived stress in administrators and staff. It was hypothesized that there would be a significant decrease in perceived stress and an increase in emotional intelligence resulting from TM practice compared with controls during a 4-month intervention period.

## METHODS

### Participants

Approval was given on August 31, 2009, by the institutional review board of Maharishi University of Management, Fairfield, IA, before the start of the study. Participants of the study were recruited from Fall 2009 through Spring 2010 from administrators and staff working in the central offices of the San Francisco Unified School District who were interested in being part of a workplace wellness program. Interested participants were asked to attend an informational meeting to learn about the wellness project. Those who wanted to join were then scheduled for baseline testing. Ninety-six supervisors and administrative staff completed written informed consent, followed by baseline testing, and were then randomly assigned to either an immediate start of the TM program ( $n = 48$ ) or a delayed-start wait-list control group ( $n = 48$ ; Figure 1).

Group allocation was concealed by an off-site member of the research group, using a computer-generated random number sequence (SPSS 2009, IBM Corp, Armonk, NY). The off-site member assigned the participant to treatment and notified the study coordinator, who informed the participant of his/her allocation. Participants completed psychological measures via the Internet. Final statistical analyses were conducted with blinding to group assignments. Senior investigators and the study statistician were blinded throughout the study.

Inclusion criteria included age 18 years or older, being an employee of the San Francisco Unified School District, attendance at an informational meeting on

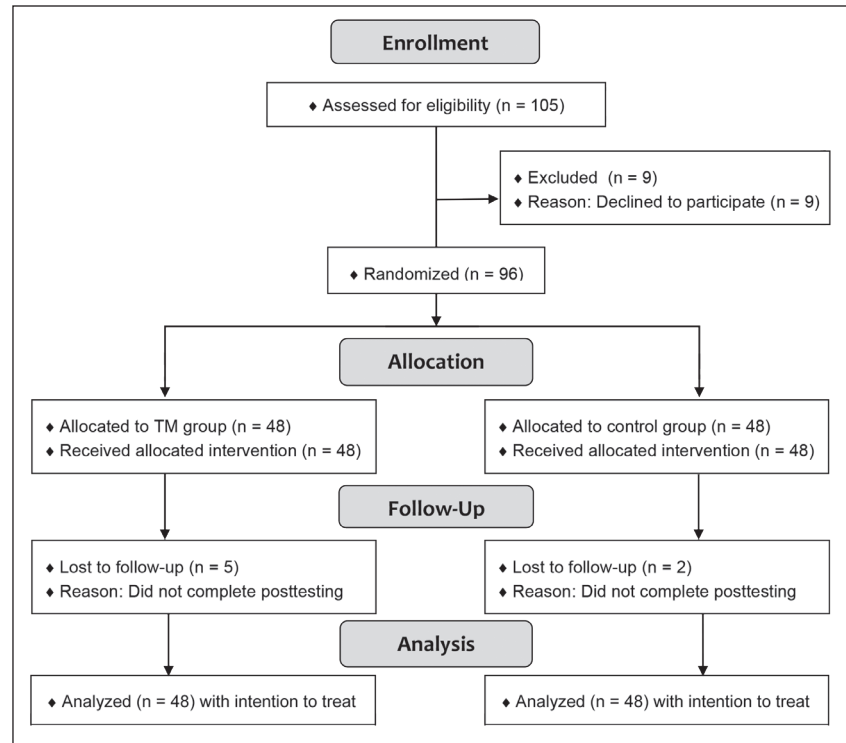


Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram of study enrollment. TM = Transcendental Meditation.

the TM program, and willingness to be randomly assigned to either active treatment or the control group. Exclusion criteria included having already learned TM.

### Interventions

#### Transcendental Meditation Program

The TM technique is a simple, natural, effortless technique that allows the mind to experience a state of “restful alertness” associated with a more integrated style of brain functioning.<sup>29,36</sup> Four certified instructors taught TM to the study participants using standardized procedures for teaching.<sup>38,39</sup>

After initial introductory and preparatory lectures and a brief personal interview with the teacher, participants attended an individual personal instruction session, followed by group meetings to verify the correctness of practice and to provide additional knowledge about the practice. The personal instruction and follow-up group meetings were held during 4 consecutive days (about 90 minutes each day). Participants were instructed to practice their meditation program at home, sitting

comfortably with their eyes closed, twice a day for 20 minutes each session, for the duration of the project (4 months). Follow-up group sessions were offered 2 times each month during the 4-month intervention to review experiences, verify the correctness of practice, and support participants’ regular home practice.

#### Control Group

Members of the control group served as wait-list controls and were eligible to learn the TM technique after completion of the four-month study. Both the control and TM group participants continued with their usual daily work routines during the study.

### Outcome Measures

The Emotional Quotient Inventory (EQ-i, Multi-Health Systems Inc, Toronto, Ontario, Canada) is a widely used measure of emotional intelligence that evaluates a broad range of noncognitive, social-emotional skills, influencing one’s ability to positively cope with environmental demands and pressures.<sup>20,40</sup> The EQ-i has a total Emotional Quotient (EQ) score

and 6 composite scales (intrapersonal, interpersonal, stress management, adaptability, reality testing, and general mood) with 14 subscales. Scale scores indicate the degree of effectiveness in understanding oneself, relating well to people, and adapting to and coping with one's immediate surroundings.<sup>7,20,40</sup> The Cronbach  $\alpha$  for the total EQ scale is 0.97, the composite scales range from 0.88 to 0.93, and subscales are all above 0.77.<sup>40</sup>

The Perceived Stress Scale (PSS, 14-item version) measures the degree to which situations in one's life are appraised as stressful. The Cronbach  $\alpha$  is reported to be 0.85. The PSS shows good discriminative validity with meditation.<sup>41</sup>

### Procedures

All participants were tested at baseline, after giving written informed consent and before the start of meditation training, and were then randomly assigned to either the TM program or wait-list control groups. Participants were then posttested 4 months later, at the end of the intervention period. Each participant took the EQ-i and PSS online. The EQ-i was scored by Multi-Health Systems, the publisher of the EQ-i. The total EQ, composite, and subscale scores for each participant were then electronically transmitted to the research staff for inclusion in the study database. The PSS was scored by the study statistician.

### Statistical Analysis

The sample size was determined using statistical power calculation software (G\*Power 3.1.3, available at [www.gpower.hhu.de/en.html](http://www.gpower.hhu.de/en.html)). We based the sample size on previous studies,<sup>30,40</sup> which reported effect sizes for TM vs control groups on outcome measures similar to our study: Experiential intelligence as measured by the Constructive Thinking Inventory ( $\delta = 0.62$ ) and the PSS ( $\delta = 0.94$ ). The power calculation showed that a sample size of 48 per group would provide at least 90% power to detect treatment effects similar to those reported in these previous studies, assuming a 2-sided test for between-group differences at the 0.05 significance level.

The main outcomes of the study were the total EQ and perceived stress scores.

Secondary outcomes were the EQ composite scales—intrapersonal, interpersonal, stress management, adaptability, reality testing, and general mood. Data were analyzed using repeated-measures analysis of variance according to the intention-to-treat principle; all randomized participants were included. Missing data were imputed using the software programs SAS PROC MI (SAS Institute Inc, Cary, NC), a multiple imputation using the Markov Chain Monte Carlo method, and SAS PROC MIANALYZE. Alpha was set at 0.05, 2-tailed, for the primary outcomes and at 0.01, 2-tailed, for the secondary outcome scales. Additional secondary analyses were conducted for the subscales (comprising the 6 main scales), with the  $\alpha$  level set at 0.01, 2-tailed. Effect sizes

(Cohen  $\delta$ ) were computed for the PSS and total EQ and composite scales, using the difference in mean change scores divided by pooled standard deviation. Effect sizes are: Small ( $\delta = 0.20$ ), medium ( $\delta = 0.50$ ), and large ( $\delta = 0.80$ ).

## RESULTS

### Baseline Data

Table 1 shows the baseline characteristics of the study participants. The average age was 45.5 years (standard deviation = 10 years), and 83% of the participants were women. There were no statistically significant differences between groups at baseline in age, sex composition, race/ethnicity, administrator/staff status, baseline emotional intelligence, and perceived stress.

**Table 1. Baseline characteristics by group**

Variable	Control (n = 48)	Transcendental Meditation (n = 48)	p value
Age, y, mean (SD)	45.5 (9.4)	45.5 (11.0)	0.992
Female sex, no. (%)	40 (83)	40 (83)	0.999
Administrator vs staff, no. (%)	40 (83)	37 (77)	0.442
Race/ethnicity, no. (%)			
White (non-Hispanic)	18 (38)	16 (33)	0.937
African American	5 (10)	5 (10)	
Asian American	12 (25)	12 (25)	
Hispanic	11 (23)	14 (29)	
Other	2 (4)	1 (2)	
Emotional intelligence total score, mean (SD)	97.2 (15.4)	96.7 (15.4)	0.879
Perceived Stress Scale, mean (SD)	22.9 (7.4)	23.3 (7.6)	0.766

SD = standard deviation.

**Table 2. Pretest and posttest scores for Perceived Stress Scale (PSS) and Emotional Quotient (EQ) total and major scales by group<sup>a</sup>**

Variable	Control (n = 48)		Transcendental Meditation (n = 48)		p value	Effect size <sup>c</sup>
	Pretest	Posttest <sup>b</sup>	Pretest	Posttest <sup>b</sup>		
PSS	22.9 (7.4)	22.2 (8.1)	23.4 (7.6)	18.8 (7.1)	0.015	-0.51
EQ total	97.2 (15.4)	96.6 (16.0)	96.7 (15.4)	101.8 (14.2)	0.003	0.37
EQ composite scales						
Intrapersonal	96.6 (16.2)	96.7 (16.3)	96.9 (16.1)	102.2 (15.4)	0.004	0.33
Interpersonal	100.1 (15.1)	100.6 (12.4)	100.2 (16.0)	101.7 (12.6)	0.613	0.07
Stress management	98.9 (14.8)	98.9 (15.2)	98.8 (12.4)	103.7 (12.4)	0.022	0.36
Adaptability	97.1 (15.8)	96.6 (16.1)	96.4 (14.8)	100.0 (12.4)	0.033	0.27
Reality testing	100.8 (15.2)	100.3 (16.8)	99.3 (14.4)	102.8 (14.0)	0.035	0.27
General mood	94.8 (14.5)	92.8 (16.3)	94.7 (13.7)	99.9 (13.3)	0.001	0.51

<sup>a</sup> Data are presented as mean (standard deviation).

<sup>b</sup> Based on intention-to-treat analysis.

<sup>c</sup> Cohen  $\delta$ .

EQ total = emotional intelligence total score.

### Pretest-Posttest Change

Intention-to-treat analysis indicated a significant improvement in total EQ score in those practicing TM compared with controls:  $F(1,94) = 5.95, p < 0.02$ . A significant decrease in perceived stress owing to the TM treatment compared with controls was also found:  $F(1,94) = 9.12, p < 0.003$ ; Table 2.

Multivariate analysis of variance showed significant improvement in the composite scales comprising the total EQ score (Wilks  $\lambda = 0.835, p = 0.009$ ). Univariate tests showed significant effects for intrapersonal [ $F(1,94) = 8.29, p = 0.004$ ]; stress management [ $F(1,94) = 5.29, p < 0.03$ ]; adaptability [ $F(1,94) = 4.54, p < 0.04$ ]; reality testing [ $F(1,94) = 4.45, p < 0.04$ ]; and general mood [ $F(1,94) = 11.42, p = 0.001$ ] composite scores during the 4-month intervention period. Table 2 shows the pretest and posttest scores by group for total EQ and the composite EQ scores.

The largest effect sizes for the main scales in the study were for perceived stress ( $\delta = -0.51$ ) and EQ general mood

composite score ( $\delta = 0.51$ ). The effect size for the total emotional intelligence main scale was  $\delta = 0.37$ .

Table 3 shows the post hoc findings for each of the emotional intelligence subscales comprising the composite scores. The largest effect sizes were for happiness ( $\delta = 0.49$ ) and stress tolerance ( $\delta = 0.45$ ).

Further analyses of both EQ total score and perceived stress showed no significant group by sex interaction ( $p = 0.21$  and  $p = 0.79$ , respectively, on the dependent variables perceived stress and total EQ score). Thus, there was no evidence that the treatments varied significantly by sex subgroups. In a separate analysis, the group by administrator/staff status interaction also showed no significant effects ( $p = 0.97$  and  $p = 0.25$ , respectively, on the dependent variables perceived stress and total EQ score). Hence, there was no evidence that the treatments varied significantly by administrator/staff status.

Overall, change in perceived stress inversely correlated with change in total EQ ( $r = -0.613, p < 0.01$ ).

### Compliance

Regularity in TM practice was defined as home practice of the TM program of at least once a day, on average, by self-report at posttest. Compliance with the meditation program was high, with 93% of participants meeting the criteria for study practice regularity. A dose response was observed, with those meditating more regularly scoring lower on perceived stress ( $r = -0.33, p = 0.032$ ) and higher on total EQ ( $r = 0.28, p = 0.067$ ) at posttest. No adverse events were reported for either group.

**The findings on perceived stress are consistent with prior randomized controlled studies showing decreased psychological distress and burnout because of TM practice.**

### DISCUSSION

The results of this study suggest beneficial effects of the TM program on perceived stress and emotional intelligence in workplace administrators and staff. The findings on perceived stress are consistent with prior randomized controlled studies showing decreased psychological distress and burnout because of TM practice.<sup>30</sup> The findings on increased emotional intelligence are consistent with previous research on TM showing improved constructive thinking and emotional and behavioral coping ability.<sup>33,39</sup> The present study advances this prior research by demonstrating such beneficial effects in the context of the workplace. Prior studies demonstrate an inverse relationship between perceived stress and emotional intelligence, thus supporting the importance of reducing stress in the workplace.<sup>42</sup>

Prior research on TM found reduced psychological and physiologic response to stress factors, including decreased sympathetic nervous system and hypothalamic-pituitary-adrenal axis overactivation, and reductions in elevated cortisol levels.<sup>43,44</sup> Research also showed a more coherent and integrated style of brain functioning, evidenced by electroencephalographic imaging associated with lower stress reactivity.<sup>26</sup> These physiologic factors owing to TM practice may provide possible

**Table 3. Pretest and posttest scores for Emotional Quotient (EQ) subscales by group<sup>a</sup>**

Variable	Control (n = 48)		Transcendental Meditation (n = 48)		p value	Effect size <sup>c</sup>
	Pretest	Posttest <sup>b</sup>	Pretest	Posttest <sup>b</sup>		
<b>Intrapersonal subscales</b>						
Self-regard	94.8 (15.5)	94.9 (14.9)	96.0 (15.0)	101.1 (13.6)	0.004	0.33
Emotional self-awareness	102.6 (14.7)	101.3 (15.0)	100.5 (17.2)	103.8 (14.4)	0.031	0.29
Assertiveness	96.3 (15.7)	96.9 (16.3)	95.1 (16.2)	99.4 (16.2)	0.082	0.23
Independence	97.5 (15.6)	98.7 (17.5)	101.6 (14.3)	103.1 (14.4)	0.919	0.01
Self-actualization	96.2 (16.0)	96.1 (16.1)	95.4 (15.9)	101.2 (15.2)	0.003	0.37
<b>Interpersonal subscales</b>						
Empathy	103.3 (13.6)	102.6 (12.3)	100.0 (14.2)	101.2 (13.8)	0.314	0.14
Social responsibility	102.3 (11.9)	101.6 (10.3)	100.6 (12.2)	100.1 (12.1)	0.929	0.02
Interpersonal relationships	101.5 (13.4)	98.5 (15.1)	100.3 (14.9)	102.4 (13.8)	0.034	0.37
<b>Stress management subscales</b>						
Stress tolerance	92.7 (16.6)	91.7 (19.6)	95.5 (14.6)	101.5 (14.0)	0.006	0.45
Impulse control	105.8 (15.2)	106.6 (12.2)	102.3 (13.0)	105.2 (12.7)	0.267	0.15
<b>Reality testing subscales</b>						
Flexibility	97.1 (16.2)	95.0 (15.4)	98.7 (13.2)	99.4 (12.1)	0.203	0.19
Problem solving	94.4 (16.2)	95.6 (14.4)	92.4 (16.2)	97.1 (13.7)	0.157	0.21
<b>General mood subscales</b>						
Optimism	94.1 (15.5)	92.9 (17.8)	94.0 (14.2)	98.5 (14.1)	0.006	0.38
Happiness	96.7 (15.0)	94.9 (15.7)	96.7 (13.9)	101.9 (13.0)	0.006	0.49

<sup>a</sup> Data are presented as mean (standard deviation).

<sup>b</sup> Based on intention-to-treat analysis.

<sup>c</sup> Cohen  $\delta$ .

mechanisms for the results found in this study on decreased perceived stress and increased emotional competencies. However, further direct research is needed.

Recent research highlights the importance of emotional intelligence as a predictor of important work-related factors such as stress management, job performance, negotiation, leadership, emotional labor, trust, and work-family conflict.<sup>45-50</sup> Emotional intelligence further adds incremental predictive validity beyond general mental abilities and the Five-Factor Model of Personality regarding job performance.<sup>51</sup>

### Strengths and Limitations

The study presented was a randomized controlled trial of 96 administrators and staff working in the same organizational setting. One major advantage of a wait-list control is that all participants can eventually receive the intervention. This, in turn, can facilitate both recruitment and retention. Use of an active control group with matched treatment sessions and daily home practice would have helped control for time and attention factors. Other possible confounders such as participant expectations, treatment preference, and possible social support influence could be addressed using an active control group. All participants were tested under the same conditions, using self-administered, Internet-based measures although sole use of self-report measures for study outcomes is a possible limiting factor. Future workplace studies should consider adding supervisor and colleague rating scales for emotional intelligence and workplace behaviors. Because of the sex composition of the San Francisco Unified School District administrators and staff in their central offices, the findings are most generalizable to female administrators.

Future research is encouraged to use a larger-designed, multisite study, with a more active control group in additional workplace settings. Future studies also may want to have an equal balance of male and female participants to more adequately evaluate the effects of meditation on sex. In addition, a measure of job performance may be useful to determine relationships between mental health factors (eg, emotional intelligence and perceived stress) and job performance.

### CONCLUSION

The results of this study indicate decreased perceived stress and improved emotional intelligence in administrators and staff associated with practice of TM. Total EQ and stress management, general mood, intrapersonal, adaptability, and reality testing composite scales of the EQ-i were found to significantly improve in the TM group compared with controls. These results have implications for organizations interested in improving the mental health and social-emotional competencies of employees. ❖

\* Transcendental Meditation and TM are service marks registered in the US patent and trademark office, licensed to Maharishi Foundation USA, a nonprofit 501(c)(3), and used under sublicense.

### Disclosure Statement

*The author(s) have no conflicts of interest to disclose. None of the study funders played any role in the design of the study, in the collection, analysis, or interpretation of data, in the writing of the report, or in the decision to submit the report for publication.*

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### Authors' Contributions

*Laurent Valosek; Sanford Nidich, EdD; and Janice Link, MA, participated in the study design, supervision of the study, and drafting and critical review of the final manuscript. Arthur Konrad, PhD, participated in the management of data, and critical review of the manuscript. Paul Mills, PhD, participated in the critical review of the final manuscript. Maxwell Rainforth, PhD, participated in the analysis of data and critical review of the manuscript. All authors have given final approval to the manuscript.*

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Keywords: behavioral medicine, emotional intelligence, integrative medicine, mind-body therapies, perceived stress, spiritual medicine, stress, Transcendental Meditation

## Spirits and Health

I find my spirits and my health affect each other reciprocally—that is to say, everything that decomposes my mind produces a correspondent disorder in my body; and my bodily complaints are remarkably mitigated by those considerations that dissipate the clouds of mental chagrin.

— Tobias Smollett, 1721-1771, Scottish poet and author



**Innocence of Daydreaming**  
colored-pencil drawing  
**Michelle Nguyen**

This drawing was done completely with colored pencils. The artist began drawing in 2015 as a way to release and reveal difficult emotions. Art remains a valuable tool for her, and now she hopes to inspire and comfort others through her work.

Ms Nguyen is an X-ray Technician at Health Scan Imaging in Temecula, CA. More of her artwork can be seen in this issue of *The Permanente Journal*.

# Different Harm and Mortality in Critically Ill Medical vs Surgical Patients: Retrospective Analysis of Variation in Adverse Events in Different Intensive Care Units

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## ABSTRACT

**Background:** Institutional harm reduction campaigns are essential in improving safe practice in critical care. Our institution embarked on an aggressive project to measure harm. We hypothesized that critically ill surgical patients were at increased risk of harm compared with medical intensive care patients.

**Methods:** Three years of administrative data for patients with at least 1 Intensive Care Unit day at an urban tertiary care center were assembled. Data were accessed from the Henry Ford Health System No Harm Campaign in Detroit, MI. *Harm* was defined as any unintended physical injury resulting from medical care. Patients were deemed surgical if they had at least 1 procedure in the operating room. Univariate analysis was used to compare surgical patients with nonsurgical. Logistic regression was used for risk adjustment in predicting harm and death.

**Results:** The study included 19,844 patients, of whom 7483 (37.7%) were surgical. The overall mortality was 7.8% (n = 1554). More surgical patients experienced harm than did nonsurgical patients (2923 [39.1%] vs 2798 [22.6%], odds ratio [OR] = 2.2, p < 0.001). Surgical patients were less likely to die (6.2% vs 8.8%, p < 0.001). Surgical patients were more likely to experience harm (OR = 2.1) but had lower mortalities (OR = 0.45) vs other harmed patients (OR = 3.8; all p < 0.001).

**Conclusion:** Most harm in surgically critically ill patients is procedure related. Preliminary data show that harm is associated with death, yet both surgical and African American patients experience more harm with a lower mortality rate.

## INTRODUCTION

The 1999 Institute of Medicine report, *To Err is Human*, led to an intense focus on reducing harm at health care organizations throughout the US.<sup>1</sup> One of the report's main conclusions was that most medical errors occur not from individual recklessness or the actions of a particular group. More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. Much like in Reason's Swiss Cheese model of accident causation, used

in aviation safety, mistakes can best be prevented by designing the health system so that it is harder for people to do something wrong and easier for them to do it right.<sup>2</sup>

Thus, institutional harm reduction campaigns have become essential in our improvement of safe practice in critical care. Our institution embarked on an aggressive project to measure harm in our patients, called the No Harm Campaign.<sup>3</sup> The No Harm Campaign uses initiatives such as Michigan Health & Hospital Association's Keystone Center for Patient Safety and Quality initiatives in Detroit, MI, the Institute for Healthcare Improvement's "Saving 100,000 Lives" and "5 Million Lives" campaigns' evidence-based interventions, and the American College of Surgeons' National Surgical Quality Improvement Program to build an infrastructure for systemwide harm reduction efforts. One of the key objectives of this campaign was to build an error management system that begins with accurate harm measurements. To achieve this objective, we defined 27 major types of harm in 6 broad categories.

Many studies have demonstrated that to improve patient safety, different methods other than voluntary adverse event (AE) reporting systems are required.<sup>4</sup> Depending on the method of record review and identification of AEs, there is a wide range of reported AEs in the literature. In the Intensive Care Unit (ICU), it has been reported that approximately 20% of patients experience an AE.<sup>5</sup> The most common AEs involve procedural complications, nosocomial infections, and adverse drug events. Almost 20% of ICU patients who died during or shortly after ICU care experienced AEs. Despite the impact of AEs on mortality and morbidity, there is no comprehensive set of harm measures for US hospitals.

Because the ICU is traditionally the unit with the highest mortality in the hospital and a likely site of medical error given the complexity of care,<sup>6-8</sup> we studied the patterns of harm in critically ill patients. We hypothesized that critically ill surgical patients were at more risk of harm compared with medical intensive care patients. To test this hypothesis, we used the No Harm Campaign data, which uses a variety of sources to capture the various types of AEs in the health care setting.

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**METHODS**

With the approval of the institutional review board, 3 years of administrative data from 2009 through 2011 at a single urban tertiary care center were collected. Patients with at least 1 ICU day were included in the study. The hospital is a Level 1 trauma center and tertiary care academic center with 802 beds, which includes 168 ICU beds with dedicated intensivists. The medical ICU and coronary care unit have a closed-unit attending model with hospital-based intensivists and cardiologists assuming primary patient responsibility.<sup>4</sup> The surgical ICU, cardiothoracic ICU, and neurologic ICU have an open ICU model with the surgical team assuming primary patient responsibility with a mandatory intensivist consultation. If the primary team in the neurologic ICU is not the neurosurgery team but the neurology team, then it is a closed unit.

**Data Collection**

Harm data was accessed from the Henry Ford Health System No Harm Campaign. According to this campaign, *harm* is defined as “any unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment) that requires additional monitoring, treatment, or hospitalization or that results in death. Such injury is considered harm whether or not it is considered preventable, resulted from a medical error, or occurred within a hospital.”<sup>3</sup> Patients were deemed surgical if they had at least 1 procedure in the operating room. A *surgical patient*, for the purposes of the study, was defined not by the patient’s location or primary care team but by the presence of a procedure performed in the operating room. This was to capture the harms that are unique to surgical patients.

The No Harm Campaign groups harm into the following categories: Infection related, medication related, procedure related, care delivery harm (falls and pressure ulcers), employee

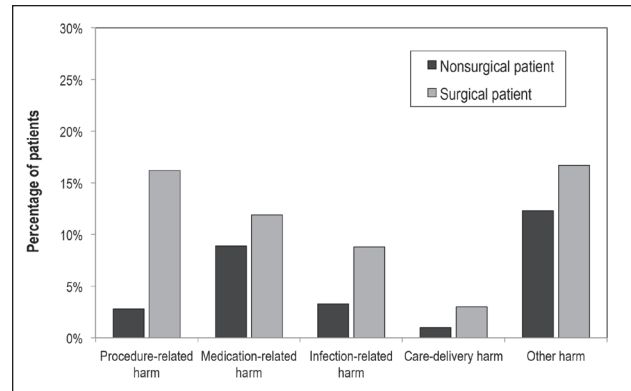


Figure 1. Different categories of harm in nonsurgical and surgical patients. Percentage was calculated by dividing number of nonsurgical or surgical patients harmed by total number of nonsurgical or surgical patients.

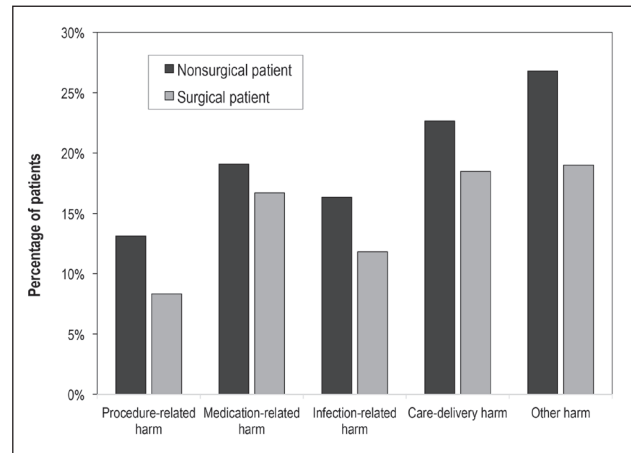


Figure 2. Mortality in surgical and nonsurgical patients who experienced various categories of harm. Percentage was calculated by dividing number of patients with harm who died by total number of patients who experienced that harm.

Table 1. Characteristics of study patients	
Characteristic	Number
Study group totals	
All patients	19,844
Nonsurgical	12,361
Surgical	7483
Mean age, years	
All patients (25th-75th percentile)	52.5 (41-70)
Nonsurgical	48.7
Surgical	58.8
Mean Elixhauser score	
All patients (range)	5.88 (0-10)
Nonsurgical	5.63
Surgical	6.29
Mean ICU stay, days	
All patients (range)	4.79 (1-249)
Nonsurgical	3.78
Surgical	6.46

ICU = intensive care unit.

harm, and other harm (health care-acquired acute renal failure, code blue alert, deep vein thrombosis, and obstetrics harm). Infection-related harm data (ie, bloodstream infection, ventilator-associated pneumonia, urinary tract infection, *Clostridium difficile*, surgical site infection, and sepsis) were collected from chart review by the hospital’s Infection Control Surveillance Committee or from administrative data, including coded data (ie, International Classification of Disease, Ninth Revision [ICD-9] Codes 599.0 and 996.64 for urinary tract infection). *Surgical site infection* was defined as a surgical wound infection (purulent drainage, organism isolated from aseptic culture from incision, symptoms of infection, incision opened by surgeon because of concern for infection) that occurred within 30 days after a procedure. *Medication-related harm* (blood glucose level < 40 mg/dL, international normalized ratio < 5, narcotics) was defined as ICD-9 code beginning with the E code related to medication. *Procedure-related harm* was defined as ICD-9 Codes E998.0 to E999.99 or ICD-9 codes related to procedures (ie, coded complications, procedural harm recorded in the National

Surgical Quality Improvement Program, and pneumothorax). *Patient falls* were defined as ICD-9 Codes E880.9 to E884.6 related to falls, and pressure ulcer data were obtained from nursing skin audits. *Acute renal failure harm* was defined as ICD-9 codes beginning with 584. *Code blue alert events* were defined as all patients with recorded blue alert with documented zero pulse, shock delivery, or epinephrine administration. Venous thromboembolism events were based on ICD-9 Codes 415, 451, and 453. Employee-related harm, which includes needle-sticks and job-related musculoskeletal back injuries, was excluded from the analysis to focus on harms to patients.

### Statistical Analysis

Univariate analysis was used to compare surgical patients with nonsurgical using the occurrence of various harms grouped by category. Logistic regression was used to attempt risk adjustment in predicting a harm event and in predicting death. Elixhauser scores were calculated for each group. The Elixhauser Comorbidity Index is a single score that summarizes a patient's disease burden on the basis of 30 comorbidities from administrative data. This score has been tested in previous studies to adequately predict hospital mortality.<sup>9</sup> Statistical analysis was performed using statistical software (SPSS Version 21, IBM Corp, Armonk, NY).

### RESULTS

A total of 19,844 patients met eligibility criteria, with 7483 surgical patients (37.7%) and 12,361 (62.3%) nonsurgical patients. Operative procedures included all surgical specialties, including general, cardiothoracic, vascular, otolaryngology, transplant, neurosurgery, urology, and orthopedic surgery. The mean age of the patients was 52.5 years. The mean length of stay in the hospital was 9.26 days. There were no statistically significant differences in age, length of stay in the ICU, ventilator days, or Elixhauser score between the surgical and nonsurgical groups (Table 1). The overall mortality was 7.8% (n = 1554), and the overall harm rate was 28.8% (n = 5721).

In general, more surgical patients experienced harm than did nonsurgical patients (2923 [39.1%] vs 2798 [22.6%], odds ratio = 2.2, p < 0.001). Across all harm categories, surgical patients experienced more harm than did nonsurgical patients (Figure 1). Not surprisingly, procedure-related harm was one of the most common types of harm for surgical patients.

Overall, patients were more likely to die if they experienced harm: 912 patients with harm who died (57.7%) vs 642 without harm who died (41.3%). Interestingly, harmed surgical patients had decreased mortality (6.2% vs 8.8%, p < .001), and this was also true when stratified by harm (Figure 2, Table 2). Regression analysis showed that among harmed patients, the risk of mortality in nonsurgical patients was higher than in surgical patients (relative risk = 1.7, confidence interval = 1.49-1.92, p < 0.001). Even among the 14,123 patients who experienced no harm, the mortality rate among the surgical patients was lower than in the nonsurgical patients (113 [2.5%] vs 529 [5.5%], p < 0.001). Regardless of the type of patient, the "other harm" category was the most common harm type among those who died.

**Table 2. Risk of experiencing a specific type of harm in surgical versus nonsurgical patients who died<sup>a</sup>**

Category of harm	Odds ratio	95% Confidence interval
Procedure-related harm	6.5	4.51-9.47
Medication-related harm	2	1.58-2.59
Infection-related harm	3.2	2.24-4.49
Care delivery-related harm	3.6	2.19-5.84
Other harm	1.8	1.44-2.23
Total harm	2.9	2.27-3.68

<sup>a</sup> All p < 0.001.

**Table 3. Multivariate logistic regression predicting harm**

Variable	Odds ratio	95% Confidence interval	p value
Male sex	1.0	0.93-1.06	< 0.001
African American	1.2	1.12-1.28	0.915
Elixhauser score	1.06	1.059-1.070	< 0.001
Surgical patient	2.2	2.08-2.37	< 0.001

**Table 4. Multivariate logistic regression predicting mortality**

Variable	Odds ratio	95% Confidence interval	p value
Male sex	1.2	1.08-1.34	< 0.001
African American	0.88	0.79-0.98	0.02
Elixhauser score	1.1	1.08-1.10	< 0.001
Surgical patient	0.5	0.41-0.53	< 0.001
Harmed	3.8	3.40-1.25	< 0.001

Surgical patients were more than twice as likely to experience harm than nonsurgical patients, and there was a trend toward greater harm in African Americans (odds ratio = 1.2, p = 0.915; Table 3). Interestingly, multivariate logistic regression analysis showed that surgical and African American patients had the lowest odds of a fatal outcome (Table 4).

### DISCUSSION

Our study demonstrates the high rate of AEs in the ICU and its association with mortality. In general, those who were harmed were 3.8 times more likely to die. We report an overall harm of 28.8%. The sensitivity of the No Harm Campaign to capture an AE regardless of preventability likely contributed to the higher rate of AEs in our study compared with the literature.

Although procedure-related harm was one of the most common types of harm for surgical patients, across all the harm categories, surgical patients experienced more harm than did nonsurgical patients. Previous study findings have shown that intrahospital transport of the patient for diagnostic studies or surgical intervention outside the ICU is associated with a higher rate of adverse drug events.<sup>10</sup> Furthermore, the difference in ICU models may have also contributed to the difference in the rate of harm.<sup>11,12</sup> For instance, Ghorra et al<sup>12</sup> reported a decrease in overall complication and mortality rates in a closed unit vs an open ICU.

Our study results show that patients undergoing surgery experience fewer fatal outcomes. Even though the surgical patients were more likely to experience harm, they were less likely to die.

The way we defined a patient as surgical may be a contributing factor to this result. A surgical patient was not defined by the patient's location or primary care team but by the presence of a trip to the operating room. Only those who received a surgical intervention outside the ICU were categorized as a surgical patient. Thus, even those with a surgical problem under the care of the surgical ICU but who were too sick to receive an operation were grouped as a nonsurgical patient. Furthermore, most of the surgical patients were those undergoing surgical interventions who were postoperatively admitted to the ICU. Elective surgical patients would have undergone perioperative risk assessment and been deemed to have adequate functional reserve to endure the operation.

There are several limitations of our study. First, this is a single-institution study from an urban care center. Although the data were collected prospectively, the analysis was retrospective. Additionally, we did not collect data regarding the reason for admission to the ICU. Furthermore, the actual contribution of harm to the patient's mortality was unclear because we did not grade the severity of the harm.

## CONCLUSION

The No Harm Campaign at the Henry Ford Health System offers a comprehensive method of measuring the diverse types of health care-related harm. Our study shows that harm is associated with mortality. Although surgical patients experienced more harm than nonsurgical patients did, harmed surgical patients had a lower mortality rate than harmed nonsurgical patients. The next step is to identify ways to reduce the harms that were identified. ❖

## Disclosure Statement

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

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Keywords: adult therapy, care management, complications, guidelines, intensive care

## Care

Care more particularly for the individual patient than for the special features of the disease.

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

## ORIGINAL RESEARCH &amp; CONTRIBUTIONS

# Contraception after Abortion and Risk of Repeated Unintended Pregnancy among Health Plan Members

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## ABSTRACT

**Context:** Optimizing access to effective contraception at the time of abortion can reduce repeated unintended pregnancies.

**Objective:** To assess contraception initiation and repeated unintended pregnancies among women receiving abortions in Kaiser Permanente Northern California (KPNC) facilities and through outside contracted facilities.

**Design:** A retrospective cohort study was conducted using a randomized proportional sample of women aged 15 to 44 years having abortions in KPNC, to determine contraception initiation within 90 days. Demographic and clinical characteristics (age, race/ethnicity, gravidity, parity, contraceptive method initiated, and pregnancies within 12 months) were collected from electronic health records. Descriptive statistics,  $\chi^2$  tests, *t*-tests, and logistic regression models assessed predictors of long-acting reversible contraception (LARC) initiation and having another unintended pregnancy within 12 months of abortion.

**Results:** Women having abortions from contracted facilities were significantly less likely to initiate LARC within 90 days compared with those receiving abortions in KPNC facilities (11.99% vs 19.10%,  $p = 0.012$ ). Significant factors associated with 90-day LARC initiation included abortions in KPNC facilities (adjusted odds ratio [aOR] = 1.87,  $p = 0.007$ ) and gravidity of 3 or more. Women initiating short-acting or no contraception were significantly more likely to have an unintended pregnancy within 12 months of the abortion than those initiating LARC (aOR = 3.66,  $p = 0.005$ ; no contraception vs LARC, aOR = 3.75,  $p = 0.005$ ).

**Conclusion:** In response to this study, KPNC now provides reimbursement for LARC in all outside abortion contracts, internalized more abortions in KPNC facilities, and strengthened clinical recommendations for immediate, effective postabortion contraception, especially LARC.

## INTRODUCTION

Annually, 1.2 million women have abortions in the US; half of these women have already had at least 1 prior abortion.<sup>1</sup> One way to help prevent repeated unintended pregnancies is to provide access to highly effective contraception at the time of abortion.<sup>2-8</sup> Because of limited numbers of trained abortion providers and staff, referral to specialty abortion facilities is the predominant model of abortion care in the US.<sup>9,10</sup>

For personal reasons, some women may prefer their abortion care to be provided at facilities outside of their Health Plan. For some women who have their abortions through contracted abortion facilities, coverage or reimbursement for postabortion contraception may or may not be included in the abortion services. Besides coverage or reimbursement, specialty abortion facilities also may have immediate onsite contraception available, especially long-acting reversible contraception (LARC). As a result, some women may not receive contraceptive services from the contracted abortion facilities and on the same day as their abortion. Although referral to contracted specialty abortion facilities provides private and efficient access for many women, it may undermine the continuity of care and timely access to postabortion contraception.

As a large integrated health care system, Kaiser Permanente Northern California (KPNC) delivers emergent and nonemergent health services in its facilities. Abortion services are provided in many KPNC facilities and through preauthorized referrals to outside contracted abortion facilities. Both short-acting contraception and LARC are provided to KPNC Health Plan members as a covered benefit with most insurance plans regardless of whether they receive abortion care in KPNC facilities or from outside contract facilities. However, during this study period (2011-2013), contraception was not covered or reimbursed by KPNC as a part of outside contracted abortion services.

Our main study objective was to assess contraceptive initiation within 90 days of the abortion and to determine the risk of having a repeated unintended pregnancy within 12 months by the women receiving abortion services in KPNC facilities vs those receiving abortion services through outside contracted facilities.

We hypothesized that women having abortions in the KPNC facilities would be more likely to initiate contraception within 90 days, particularly LARC, compared with women having abortions through outside contracted facilities. A secondary hypothesis was that women initiating LARC would be less likely to have a repeated unintended pregnancy within 12 months compared with women initiating a short-acting or no contraceptive method within 90 days of their abortion.

## METHODS

A retrospective cohort study was conducted with a proportional random sample of women aged 15 to 44 years with a medical or

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surgical abortion performed in KPNC facilities or provided by reimbursed contracted abortion facilities between January 2011 and December 2012. Industry standard codes—Current Procedural Terminology, 4th Edition (CPT-4), International Classification of Diseases, Ninth Revision (ICD-9), and Healthcare Common Procedure Coding System (HCPCS)—plus records of administered mifepristone were used to electronically identify the abortions provided in KPNC facilities and through KPNC's authorized outside medical facilities system (AOMS). Women receiving authorized referrals through AOMS have a documented positive pregnancy test, may have had pregnancy-dating ultrasonograms and examinations performed in KPNC, and had confirmed Health Plan coverage for the abortion. The decision to refer women through AOMS or to provide the abortion services in KPNC facilities depends on the facility, access to provide the abortion services in a timely manner, clinician and support staffing mix, and sometimes the woman's preference.

The first abortion identified within the study timeframe was considered the index case. Eligible women were required to have Kaiser Foundation Health Plan membership in the 3 months before and the 12 months after the index abortion as well as a prescription drug benefit in the 3 months after the index abortion. All data obtained from KPNC electronic databases were validated by review of the electronic health records. The Kaiser Foundation Research Institute's institutional review board approved this retrospective cohort study with waiver of consent and authorization.

### Data Collection

The patient's age at index abortion, race/ethnicity, and prescribed or administered method of contraception within 90 days of abortion were electronically extracted. The 90-day period to assess initiation of contraception after the abortion was chosen to allow adequate time for all subjects to initiate contraception in KPNC regardless of where the abortion services were provided.

Methods of LARC included both the levonorgestrel-releasing and the copper intrauterine contraceptive device (IUD) and the subdermal contraceptive implant. Short-acting reversible methods included depomedroxyprogesterone acetate, oral contraceptive pills, transdermal patch, vaginal ring, and prescribed barrier methods (diaphragm, cervical cap, and condoms). Emergency contraception was considered a short-acting method prescribed if no other methods were prescribed.

Evidence of the first repeated pregnancy within 12 months after the index abortion was electronically identified. For pregnancies for which prenatal care was initiated, self-reported pregnancy intention status was obtained from questions routinely asked at entry to prenatal care: "*At the time that you conceived, did you want to become pregnant?*" (intended vs unintended), "*Did you want to become pregnant but not at this time?*" (mistimed), or "*Did you not want to become pregnant at all?*" (unwanted). If the self-reported pregnancy intention status was reported as mistimed or unwanted, it was defined as unintended. Pregnancies resulting in abortion were considered unintended unless prenatal care was initiated and the pregnancy was self-reported as intended. If the repeated pregnancy resulted in a spontaneous or missed abortion or ectopic

pregnancy, pregnancy intention status was considered unknown unless the pregnancy was self-reported as intended at entry to prenatal care before termination.

During the study, 57% of the abortions were performed in KPNC facilities and 43% through outside contracted facilities. To calculate the sample size to test the first hypothesis, we estimated that 5% of women receiving abortions through outside contracted abortion facilities and 10% to 15% receiving abortions in KPNC facilities would initiate LARC within 90 days of abortion. With use of unequal group sample size and power calculations, a 2-group, continuity-corrected  $\chi^2$  test with a 0.05 two-sided significance level would have 80% power to detect the difference between 10% and 15% LARC initiation in the KPNC facilities, compared with 5% LARC initiation in the outside contracted facilities, with sample sizes of 400 and 300 cases, respectively.

To calculate the sample size to test the secondary hypothesis, we conservatively estimated that approximately 10% of women after abortion would initiate LARC methods. We hypothesized that 30% of women who initiated short-acting or no contraception within 90 days after abortion, and who became pregnant within 12 months, would have an unintended pregnancy, compared with 5% initiating LARC after abortion. Use of a 2-group, continuity-corrected  $\chi^2$  test with a 0.05 two-sided significance level would have 80% power to detect the 25% difference in unintended pregnancies between women initiating LARC within 90 days of abortion and those initiating short-acting contraception or no contraceptive method within 90 days after abortion, with sample sizes of 26 and 228, respectively. Therefore, a proportional random sample of 400 women receiving abortion services in KPNC facilities and 300 women receiving abortions through outside contracted facilities was selected, exceeding the required sample sizes to test both hypotheses.

Electronic medical record review, conducted by 2 gynecologic resident physicians, validated the type of contraception initiated within 90 days of the index abortion and obtained accurate gravidity and parity for the study cohort. These physicians also identified repeated pregnancies within 12 months that were not captured in the electronic-coded data and determined the self-reported pregnancy intention status if available. They also confirmed the repeated pregnancy outcome (prenatal care ongoing, spontaneous abortion, missed abortion, ectopic pregnancy, type of abortion [medical or surgical], fetal demise, or delivery). A total of 690 women with abortions performed in 2011 to 2012 made up the final analytic dataset. Ten women with abortions were excluded because of miscoding because they either did not have an abortion or had an abortion but not within the study period.

### Data Analysis

We used descriptive statistics (frequencies, means, medians, and proportions) to describe the cohort by abortion service group (in KPNC facilities vs outside contracted facilities). Comparisons of the women's demographic and clinical characteristics in the 2 abortion service groups were made using  $\chi^2$  tests for all categorical variables and  $t$ -tests for continuous variables.

Logistic regression models were used to identify predictors of LARC initiation within 90 days of the index abortion and



for having a repeated unintended pregnancy within 12 months. The primary predictor in each model was the abortion service group (in KPNC facilities vs outside contracted facilities). In the model identifying predictors of LARC initiation within 90 days, we controlled for age categorically, race/ethnicity, and gravidity. For the model assessing predictors of having a repeated

unintended pregnancy within 12 months of the index abortion, we controlled for age categorically, race/ethnicity, gravidity, and contraception method initiated after abortion. Pairwise comparisons between LARC vs no method, short-acting vs no method, and LARC vs short-acting were included in this model using contrast statements.

**RESULTS**

There were significant differences in age, race/ethnicity, and gravidity between the 2 abortion service groups (Table 1). The mean age of women receiving abortions in KPNC facilities was significantly older than the women receiving abortions from outside contracted facilities (29.8 vs 26.6,  $p < 0.001$ ; Table 1). A greater proportion of adolescents and black women received abortions by outside contracted facilities. Of 690 abortions, 75% were surgical (80% from contracted facilities, 71% in KPNC facilities) and 25% were medical (20% from contracted facilities, 29% in KPNC facilities). The proportion of women initiating short-acting contraception within 90 days was similar in the 2 abortion service groups (39% vs 43%, respectively,  $p = 0.333$ ), with the pill being the most frequently initiated method in both groups (Table 1, Figure 1).

**Table 1. Demographic and clinical characteristics of women (N = 690) by abortion service**

Characteristic	Contracted facilities (n = 292), no. (%)	KPNC facilities (n = 398), no. (%)	p value	
Mean age, years (median)	26.6 (25.0)	29.8 (30.0)	<b>&lt; 0.001<sup>a</sup></b>	
<b>Age group, years</b>				
15-19	56 (19.18)	35 (8.79)	<b>&lt; 0.001</b>	
20-29	140 (47.95)	154 (38.69)		
30-39	76 (26.03)	176 (44.22)		
≥ 40	20 (6.85)	33 (8.29)		
<b>Race/ethnicity</b>				
Asian	34 (11.64)	87 (21.86)	<b>&lt; 0.001</b>	
Black	79 (27.05)	51 (12.81)		
Hispanic	61 (20.89)	83 (20.85)		
White	88 (30.14)	151 (37.94)		
Other/unknown	30 (10.27)	26 (6.53)		
<b>Gravidity</b>				
1	100 (34.84)	112 (28.21)	<b>0.026</b>	
2	44 (15.33)	91 (22.92)		
≥ 3	143 (49.83)	194 (48.87)		
<b>Parity</b>				
0	139 (48.43)	169 (42.57)	0.47	
1	68 (23.69)	109 (27.46)		
2	51 (17.77)	78 (19.65)		
≥ 3	29 (10.10)	41 (10.33)		
<b>Type of contraception initiated within 90 days</b>				
LARC (vs no LARC)	35 (11.99)	76 (19.10)	<b>0.012</b>	
IUD	30 (10.27)	73 (18.34)		
Implant	5 (1.71)	3 (0.75)	0.333	
Short-acting (vs no short-acting)	114 (39.04)	170 (42.71)		
DMPA	26 (8.90)	29 (7.29)		
Pill	68 (23.29)	100 (25.13)		
Patch	2 (0.68)	3 (0.75)		
Ring	7 (2.40)	11 (2.76)		
Emergency contraception only	7 (2.40)	12 (3.02)		
Condoms (prescribed)	4 (1.37)	15 (3.77)		
No contraception method documented (vs method documented)	143 (48.97)	152 (38.19)		<b>0.005</b>
Repeated unintended pregnancy within 12 months	50 (17.12)	46 (11.62)		<b>0.04</b>

<sup>a</sup> p values for mean age comparisons were calculated using the t-test. All other p values were calculated using  $\chi^2$  tests. Boldface indicates statistical significance. DMPA = depomedroxyprogesterone acetate; IUD = intrauterine contraceptive device; KPNC = Kaiser Permanente Northern California; LARC = long-acting reversible contraception.

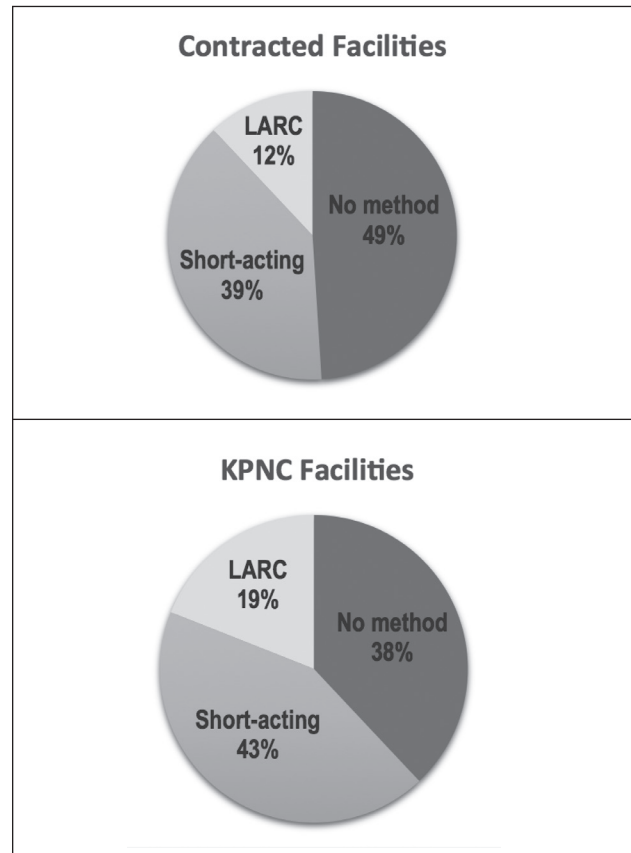


Figure 1. Contraception category initiated within 90 days, by abortion service. KPNC = Kaiser Permanente Northern California; LARC = long-acting reversible contraception.

Overall, LARC was initiated within 90 days of the abortion by 16% of the cohort, which was higher than expected. However, women were significantly less likely to initiate LARC when their abortions were provided through outside contracted facilities

**Table 2. Factors associated with LARC initiation within 90 days of abortion**

Characteristic	Adjusted OR (95% CI) <sup>a</sup>	p value <sup>b</sup>
Abortion service (reference: Provided by contracted facilities)		
Provided by KPNC facilities	1.87 (1.18-2.96)	<b>0.007</b>
Age group (reference: 20-29 years)		
15-19 years	0.77 (0.36-1.66)	0.506
30-39 years	0.58 (0.35-0.94)	<b>0.027</b>
≥ 40 years	0.52 (0.22-1.24)	0.141
Race/ethnicity (reference: White)		
Asian	1.19 (0.66-2.16)	0.563
Black	1.09 (0.59-2.02)	0.779
Hispanic	1.09 (0.61-1.94)	0.771
Unknown/other	0.85 (0.35-2.05)	0.714
Gravidity (reference: 1)		
2	1.71 (0.90-3.26)	0.102
≥ 3	2.23 (1.26-3.95)	<b>0.006</b>

<sup>a</sup> Odds ratios were calculated using the logistic regression model.  
<sup>b</sup> Boldface indicates statistical significance.  
 CI = confidence interval; KPNC = Kaiser Permanente Northern California; LARC = long-acting reversible contraception; OR = odds ratio.

**Table 3. Factors associated with having a repeated unintended pregnancy within 12 months of abortion**

Characteristic	Adjusted OR (95% CI) <sup>a</sup>	p value <sup>b</sup>
Abortion facilities (reference: Provided by KPNC facilities)		
Provided by contracted facilities	1.1 (0.67-1.78)	0.71
Age group (reference: 30-44 years)		
15-19 years	6.56 (2.80-15.34)	<b>&lt; 0.001</b>
20-24 years	4.31 (2.19-8.48)	<b>&lt; 0.001</b>
25-29 years	3.28 (1.74-6.18)	<b>&lt; 0.001</b>
Race/ethnicity (reference: White, non-Hispanic)		
Asian	2.02 (1.01-4.07)	<b>0.048</b>
Black	1.78 (0.93-3.38)	0.08
Hispanic	1.26 (0.65-2.44)	0.49
Unknown/other	0.95 (0.35-2.53)	0.91
Gravidity (reference: 1)		
2	1.25 (0.59-2.66)	0.56
≥ 3	3.60 (1.91-6.78)	<b>&lt; 0.001</b>
Method initiated within 90 days (reference: LARC)		
No method	3.75 (1.50-9.36)	<b>0.005</b>
Short-acting method	3.66 (1.48-9.03)	<b>0.005</b>
No method initiated within 90 days (reference: Short-acting method)	1.03 (0.63-1.66)	0.92

<sup>a</sup> Odds ratios were calculated using the logistic regression model.  
<sup>b</sup> Boldface indicates statistical significance.  
 CI = confidence interval; KPNC = Kaiser Permanente Northern California; LARC = long-acting reversible contraception; OR = odds ratio.

compared with those receiving abortions in the KPNC facilities (11.99% vs 19.10%, p = 0.012; Table 1, Figure 1). When the abortion was performed in KPNC facilities, 70% of the women initiating LARC did so within 14 days and 45% initiated LARC the same day as their abortion. In contrast, only 15% of the women receiving abortions through outside contract facilities who initiated LARC did so within 14 days, and none did so on the same day of their abortion. The most common LARC method initiated in both abortion service groups was the IUD (Table 1).

Controlling for demographic and clinical characteristics, women with abortions provided in KPNC facilities were 87% more likely to initiate LARC within 90 days of abortion compared with women with abortions provided by outside contracted facilities (adjusted odds ratio [aOR] = 1.87, p = 0.007). Women with gravidity of 3 or more were twice as likely to initiate LARC compared with women who were gravida 1 (aOR = 2.23, p = 0.01). Women aged 30 to 39 years were 40% less likely to initiate LARC compared with women aged 20 to 29 (aOR = 0.6, p = 0.03; Table 2).

Nearly 14% of the women (96 of 690) had a repeated unintended pregnancy within 12 months. Women with abortions from outside contracted facilities were significantly more likely to have a repeated unintended pregnancy within 12 months compared with those having abortions in KPNC facilities (17.1% vs 11.6%, p = 0.04; Table 1). After we controlled for all other demographic and clinical predictors, women initiating short-acting contraception (aOR = 3.66, p = 0.005) and women with no prescribed contraception initiated within 90 days of abortion (aOR = 3.75, p = 0.005) were almost 4 times as likely to have a repeated unintended pregnancy within 12 months compared with women initiating LARC (Table 3). There was no statistically significant difference in the odds of women having a repeated unintended pregnancy within 12 months when no method was initiated compared with short-acting contraception initiation (aOR = 1.03, p = 0.92; Table 3).

The younger a woman was, her odds significantly increased of having a repeated unintended pregnancy within 12 months of the abortion (15-19 vs 30-44 years, aOR = 6.56, p < 0.001; 20-24 vs 30-44 years, aOR = 4.31, p < 0.001; 25-29 vs 30-44 years, aOR = 3.28, p < 0.001). Other significant predictors of having a repeated unintended pregnancy included being Asian (reference: white, aOR = 2.02, p = 0.048) and having higher gravidity (≥ 3 vs 1, aOR = 3.59, p < 0.001; Table 3).

**DISCUSSION**

In this study, about 1 in 7 KPNC Health Plan members experienced a repeated unintended pregnancy within 12 months of having an abortion. Women having abortions in KPNC facilities were twice as likely to initiate LARC within 90 days as women having their abortions from contracted facilities. The largest factor associated with the women having a repeated unintended pregnancy within 12 months was no initiation of contraception or initiation of short-acting contraception after abortion, compared with LARC.

This study adds to the existing literature, providing insight on women's postabortion outcomes in the US. A New Zealand

study providing free medical care to all residents reported a repeated abortion rate at 24 months of 9.6%, with repeated abortions being 2 to 4 times higher in women initiating immediate short-acting contraception vs LARC.<sup>8</sup> Two US studies showed significantly lower 12-month pregnancy rates after abortion between immediate and delayed LARC insertion in different Medicaid-reimbursed populations.<sup>11,12</sup>

The difference in LARC initiation by women having abortions in KPNC vs through contracted facilities is likely owing to the lack of reimbursement for LARC as a covered benefit in the abortion service contract, thus requiring a second visit to KPNC to obtain LARC. One US study found that only 32% of women who reported they intended to have an IUD insertion after their abortion actually had the IUD insertion by 6 months after their abortion.<sup>13</sup>

The largest barrier identified was the time needed for the additional visit.<sup>13</sup> Similarly, another study showed more than half of the women who intended to have subdermal contraceptive implant placement immediately after abortion missed their follow-up insertion appointments.<sup>7</sup> Thus, lack of contraceptive reimbursement with outside contracted abortion facilities as well as the discontinuity of care may serve as barriers to initiation of timely and effective postabortion contraception. In KPNC's integrated health care system, most health care services are typically provided internally. Because of limitations in the number of trained abortion service clinicians and support staff in some KPNC facilities, other logistical system issues, and a woman's preference, there is a need for an outside abortion referral system to achieve timely access. Contraceptive services are routinely provided by all KPNC gynecology clinicians, most primary care clinicians, and most of the contracted abortion services. However, contracting abortion services outside KPNC led to the "unbundling" of abortion and contraceptive services, which ideally should be provided together. Because women are more likely to be highly motivated to improve contraceptive use right after an unintended pregnancy, initiation of contraception immediately after abortion is optimal.<sup>14</sup> In addition, studies have shown that 86% of women ovulate within the first month after abortion and can ovulate as soon as 8 days after abortion.<sup>14,15</sup>

In this study, almost half (49%) of the women having abortions from contracted facilities had no prescribed contraception within 90 days after abortion. However, a significant proportion (38%) of women having their abortion in KPNC facilities also had no prescribed contraception. It is likely that women undergoing an abortion may continue contraceptive use patterns after abortion that put them at risk of another unintended pregnancy.<sup>14</sup> Less-than-optimal contraception initiation by women receiving abortions through contracted facilities or from KPNC facilities may reflect missed opportunities to reduce the risk of a repeated unintended pregnancy. In the Contraceptive CHOICE project, women offered a choice of methods immediately after abortion at no cost were more likely to choose LARC (85%) than short-acting contraception, suggesting that higher adoption rates are

possible.<sup>16</sup> In our study, women initiating short-acting contraception after abortion had similar risks for having a repeated unintended pregnancy within 12 months to those initiating no contraceptive method. This is consistent with previous studies showing that women not initiating LARC after abortion were more likely to have a repeated unintended pregnancy.<sup>2,8,11-13,17,18</sup>

This study's limitations included the retrospective observational design and lack of Health Plan information on deductibles, which may have affected affordability of LARC for some women. However, during the study period, more than 80% of women had no deductible applied for outpatient contraception facilities. Variation in deductible amounts under different Health Plans is unlikely to have had a differential effect because deductible amounts were the same regardless of whether the abortion was provided

in KPNC or by outside referral. Women who chose not to disclose their pregnancy to KPNC or did not have abortion coverage in their Health Plan, such as federal employees, were not included in the study cohort.<sup>19</sup> Approximately 5% of KPNC membership is made up of federal employees. History of a previous abortion before the index abortion was also not collected because of underreported documentation in the medical record. In this study, it was not feasible to include all abortions performed during the study period because of the need to perform electronic medical record review to identify gravidity and parity, and to validate type of contraception and repeated unintended pregnancies within 12 months. However, the demographic characteristics (ie, age and race/ethnicity) of the random sample of women that made up the analytic study cohort were similarly distributed by race and ethnicity, with the mean and median ages being the same as in the overall abortion service group.

The study's strengths include the setting in KPNC's demographically diverse population representative of the geographic region.<sup>20</sup> The KPNC system's electronic health records and electronic databases allowed for accurate capture of study variables validated with electronic medical record review.

## CONCLUSION

These study findings resulted in KPNC strengthening clinical recommendations for providing immediate postabortion LARC insertion regardless of the abortion setting, internalizing more abortion services in KPNC facilities, and adding contraception reimbursement, including for LARC, in all outside abortion service contracts. Access to immediate, effective postabortion contraception, especially LARC, as an essential component of abortion care, should be integrated into all abortion care settings. We hope these findings lead to optimization of abortion care in Kaiser Permanente and across all US health plans, including providing immediate access to highly effective contraception. There are plans to study changes in LARC initiation after abortion in KPNC in the future to learn whether strengthened clinical recommendations and contract changes successfully reduce repeated unintended pregnancies. ❖

**... women initiating short-acting contraception after abortion had similar risks for having a repeated unintended pregnancy within 12 months to those initiating no contraceptive method.**

**Disclosure Statement**

Four of the authors (Debbie Postlethwaite, Maqdooda Merchant, Amy Alabaster, and Tina Raine-Bennett) are participating in a US Food and Drug Administration-mandated safety study funded by Bayer Global. The author(s) have no additional conflicts of interest to disclose.

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Keywords: care management, gynecology, health policy, ob/gyn, prevention

**Every Occasion**

Contraceptives should be used on every conceivable occasion.

— Terence Alan “Spike” Milligan, KBE, 1918–2002, British-Irish comedian, writer, poet, playwright, and actor



**Therapy**  
mixed-media sculpture  
**Stephen Bachhuber, MD**

This sculpture is composed of welded scrap steel and a high-intensity light mounted on a wooden base. The artist states, "It represents the radiation therapy I received for cancer treatment in the late 1980s, and the subsequent painful deterioration of my spine."

Dr Bachhuber is a retired Anesthesiologist from the Sunnyside Medical Center in Clackamas, OR. More of his work can be seen in other issues of *The Permanente Journal*.

This photograph of Dr Bachhuber's sculpture was taken by Paul Cunningham, of Paul Cunningham Photography in West Linn, OR.

## ORIGINAL RESEARCH &amp; CONTRIBUTIONS

# Urate-Lowering Therapy in Moderate to Severe Chronic Kidney Disease

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<https://doi.org/10.7812/TPP/17-142>**ABSTRACT**

**Context:** Hyperuricemia is an independent risk factor for progression of kidney disease.

**Objective:** To determine whether lowering serum uric acid level (sUA) to below 6 mg/dL (target) improves mild to moderate chronic kidney disease (CKD) and whether CKD stage influences the benefit of lowering sUA to target.

**Design:** Retrospective epidemiologic cohort study conducted over 8 years. Estimated glomerular filtration rate (eGFR) was required in the 6 months preceding the index date (defined as first occurrence of sUA < 7 mg/dL), and at least 1 sUA and eGFR were required during follow-up. Patients were urate-lowering therapy (ULT) naïve, aged 18 years or older, and had CKD Stages 2 to 4 at baseline. Health Plan enrollment with drug benefit was required. Exclusions included active cancer, dialysis, or other kidney disease.

**Main Outcome Measures:** A 30% decrease or 30% improvement in eGFR from baseline.

**Results:** A total of 12,751 patients met inclusion criteria; 2690 patients received ULT during follow-up and 10,061 did not. Target sUA was achieved in 1118 patients (42%) receiving ULT. A 30% improvement in eGFR was likelier in patients who achieved the target (odds ratio [OR] = 1.78,  $p < 0.001$ ). Pairwise comparison of CKD stages showed a 30% improvement in eGFR in CKD Stage 2 (OR = 2.26,  $p = 0.017$ ) and Stage 3 (OR = 2.23,  $p < 0.001$ ) but not Stage 4 (OR = 1.50,  $p = 0.081$ ).

**Conclusion:** Patients who achieve an American College of Rheumatology target sUA below 6 mg/dL during ULT have higher rates of eGFR improvement, especially in CKD Stages 2 and 3.

**INTRODUCTION**

Gout has a substantial and growing impact on the health and well-being of patients around the world. The 2007 to 2008 National Health and Nutrition Examination Survey of self-reported gout showed a prevalence of 3.9% compared with the 1988 to 1994 estimate of 2.7%.<sup>1,2</sup> An epidemiologic study from British Columbia notes an increase in both the prevalence (2.4%-3.8%) and incidence (1.71-2.89) of gout from 2000 to 2012.<sup>3</sup> This increase in gout comes with substantial costs both to the individual and to the health care system.

Elevated serum uric acid level (sUA), the principal cause of gout, has been shown to be an independent risk factor for progression of kidney disease in both animal and human studies. Large epidemiologic studies from Taiwan<sup>4</sup> and Austria<sup>5</sup> showed

hyperuricemia as an independent risk factor for kidney disease. Studies by Siu et al<sup>6</sup> and Kim and colleagues<sup>7</sup> demonstrated that when sUA is reduced, the progression of kidney disease can be slowed. A 10-year follow-up study of hyperuricemia and glomerular filtration rates (GFRs) from Iseki et al<sup>8</sup> in Okinawa showed that hyperuricemia was a strong independent risk factor for a decline in GFR. Sircar and colleagues,<sup>9</sup> in a 6-month, double-blind study in hyperuricemic patients, randomly assigned to receive urate-lowering therapy (ULT) or placebo demonstrated patients receiving ULT improved their GFR by 3.2 mL/min/1.73 compared with the placebo group, which declined by 4.4 mL/min/1.73m<sup>2</sup> ( $p < 0.05$ ). Hyperuricemia has been shown to also have adverse effects on diabetes<sup>10</sup> and cardiovascular disease<sup>11</sup> and increased overall all-cause mortality.<sup>12</sup>

In a previous study, we demonstrated that in patients who achieved an American College of Rheumatology (ACR) sUA target of less than 6 mg/dL while receiving ULT had a 37% reduction in the risk of their kidney disease worsening, defined as a 30% decrease in GFR from baseline.<sup>13</sup> This current study is designed to determine whether ULT can improve mild to moderate chronic kidney disease (CKD) when patients achieve the ACR target of an sUA below 6 mg/dL (target) and whether baseline CKD stage influences the benefits when the target is attained with ULT.

**METHODS****Setting and Patients**

This retrospective cohort study used the Kaiser Permanente (KP) Southern California (KPSC) electronic medical records and administrative databases from January 1, 2008, through July 31, 2014. KPSC has 15 Medical Centers and 225 medical offices serving more than 4 million members. The first instance of an sUA above 7 mg/dL was defined as the index date, not the first diagnosis of gout. To be eligible for study entry, patients were age 18 years or older on the index date and had 12 months of continuous KPSC membership and pharmacy benefits both before and after the index date. The 1-year follow-up period was selected because previous work showed that GFR changes tended to occur within months of ULT initiation.<sup>13</sup> All study patients were naïve to ULT for at least 1 year before the index date (Figure 1). Patients with mild to moderate renal impairment at baseline (CKD Stages 2, 3, and 4) were included. Those with CKD Stages 1 and 5 as well as patients with human immunodeficiency

virus, active cancer treatment, dialysis, or renal disease including proteinuria and kidney transplant were excluded (Figure 2).

**Outcomes**

Study patients had at least 1 estimated GFR (eGFR) measurement in the 6 months before the index date. All subjects had at least 1 sUA and eGFR laboratory test in the period 3 to 12 months after the index date (follow-up period). We excluded eGFR laboratory values within 90 days of the index date from the analysis because this was not enough time for the beneficial effects of ULT to manifest. Outcomes were defined as either a 30% decrease or a 30% improvement in eGFR from baseline.<sup>7</sup> The eGFR was calculated from the serum creatinine level using the Modification of Diet in Renal Disease (MDRD) calculation.<sup>14</sup>

**Statistical Analysis**

A 30% change in eGFR by ULT status stratified by baseline CKD stage was the primary outcome. Demographic characteristics and comorbidities were categorized and compared between ULT status and CKD stages. The primary outcome of eGFR change was compared between ULT status using  $\chi^2$  test, and a p value of less than 0.05 (2-sided) was considered statistically significant. Among patients receiving ULT, the odds ratios (ORs) and 95% confidence intervals (CIs) were estimated using multinomial logistic models on the treatment outcome (achieving target or not achieving target). The same analysis was used to further stratify patients by CKD stage. All analyses were performed using SAS Version 9.3 (SAS Institute Inc, Cary, NC). The Southern California Permanente Medical Group institutional review board approved this study.

**RESULTS**

After inclusion and exclusion criteria were applied to the 133,265 patients with baseline sUA above 7 mg/dL, there were 12,751 remaining who were then analyzed by ULT status (Figure 2). ULT 10,061 did not receive ULT. The racial/ethnic breakdown of the cohort was primarily white but with a large

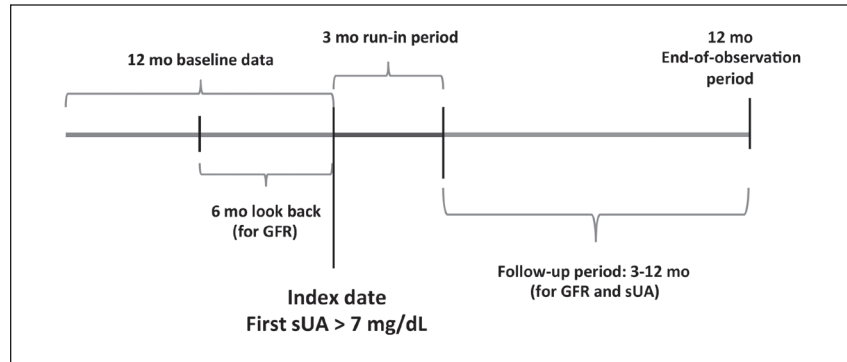


Figure 1. Study timeline.

GFR = glomerular filtration rate (mL/min); sUA = serum uric acid.

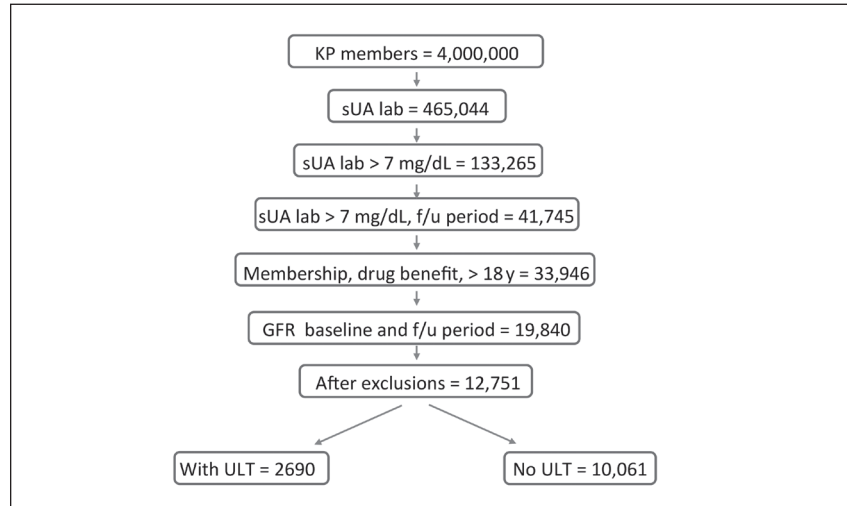


Figure 2. Inclusions and exclusions for study subjects.

f/u = follow-up; GFR = glomerular filtration rate (mL/min); KP = Kaiser Permanente; lab = laboratory value; sUA = serum uric acid; ULT = urate-lowering therapy.

Characteristic	ULT (n = 2690)	No ULT (n = 10,061)	CKD Stage 2 (n = 4343)	CKD Stage 3 (n = 6299)	CKD Stage 4 (n = 2109)
Male sex	63	59	68	59	48
<b>Age, years</b>					
< 50	6	10	16	5	6
50-59	16	19	29	13	12
60-70	32	30	34	31	24
> 70	47	41	22	51	58
<b>Race</b>					
White	53	52	48	54	55
Asian	15	13	17	12	9
Hispanic	17	20	19	18	24
Black	13	13	13	14	11
Other	2	2	3	2	1

<sup>a</sup> Data are presented as percentages. Some percentages may not total to 100 because of rounding. CKD = chronic kidney disease; ULT = urate-lowering therapy.

representation of Asian, Hispanic, and African Americans, mirroring the population of Southern California (Table 1). A younger, higher-percentage male population was seen in CKD Stage 2 compared with CKD Stages 3 and 4. Comorbidities for cardiovascular disease, diabetes, dyslipidemia, hypertension, osteoarthritis, and obesity are shown in Table 2. Rheumatoid arthritis was diagnosed in 2% to 4% of the patients. Allopurinol prescriptions accounted for 97% of the ULT prescriptions, with another 2% of patients receiving febuxostat and 1% receiving probenecid. Table 3 shows the impact of ULT on changes in eGFR. The use of ULT had significant impact on the 30% eGFR improved function (13.16% vs 11.47%,  $p = 0.016$ ) and the 30% eGFR decreased function (6.01% vs 6.10%,  $p = 0.026$ ) compared with the group not receiving ULT.

Table 4 shows the changes in eGFR in patients receiving ULT for the entire cohort and for the individual stages. There were 2690 patients receiving ULT, of which 1118 achieved the target sUA and 1572 did not. Patients at target, with mild to moderate CKD showed improvement (OR = 1.78; 95 CI = 1.42-2.23;  $p = 0.001$ ), compared with patients receiving ULT not at target. Individual CKD Stages 2, 3, and 4 were evaluated for nonprogression of CKD (eGFR decreased by more than 30%) and CKD improvement (eGFR improved by more than 30%). In patients with sUA below 6 mg/dL, eGFR improvement by 30% or more was seen in those with CKD Stage 2 (OR = 2.26; 95% CI = 1.16-4.41;  $p = 0.017$ ) and CKD Stage 3 (OR = 2.23; 95% CI = 1.65-3.00;  $p \leq 0.001$ ), but not in CKD Stage 4 (OR = 1.50; 95% CI = 0.95-2.37;  $p = 0.081$ ).

**DISCUSSION**

Hyperuricemia has been conclusively linked to decline in renal function. Hyperuricemic mouse models demonstrate the underlying pathophysiology responsible for kidney damage with glomerular changes including vascular wall thickening, tubulointerstitial inflammation, fibrosis, and arterial hypertension.<sup>15,16</sup> Hyperuricemia can cause endothelial changes and vascular pathologies leading

to renal insufficiency.<sup>17</sup> Studies using mouse models show that allopurinol has the potential of reversing kidney disease when the sUA is normalized.<sup>16,17</sup> Whereas the guidelines for treating symptomatic

gout are well defined, the treatment of asymptomatic hyperuricemia remains controversial. In human subjects, Obermayr et al<sup>5</sup> showed that risk of incident kidney disease increased with sUA greater

**Table 2. Comorbidities and therapies of study cohort<sup>a</sup>**

Factors	ULT (n = 2690)	No ULT (n = 10,061)	CKD Stage 2 (n = 4343)	CKD Stage 3 (n = 6299)	CKD Stage 4 (n = 2109)
CV-related disease	51	46	32	52	63
Diabetes	50	47	36	51	62
Dyslipidemia	86	85	78	88	91
Hypertension	95	92	85	96	98
Obesity (BMI < 30 kg/m <sup>2</sup> )	48	46	49	45	43
Osteoarthritis	46	42	37	47	43
Rheumatoid arthritis	4	3	2	3	4
Gout diagnosis at index date	47	24	33	30	20
Corticosteroids	52	49	48	50	49
Colchicine	17	9	11	11	9
NSAIDs	82	79	83	80	74
ULT prescription					
Allopurinol	97	NA	29	55	16
Febuxostat	2		7	57	36
Probenecid	1		52	48	0

<sup>a</sup> Data are presented as percentages. Some percentages may not total to 100 because patients had more than 1 comorbidity or treatment. BMI = body mass index; CKD = chronic kidney disease; CV = cardiovascular; NA = not applicable; NSAIDs = nonsteroidal anti-inflammatory drugs; ULT = urate-lowering therapy.

**Table 3. Changes in glomerular filtration rate based on use of urate-lowering therapy (ULT)**

Therapy	Change in glomerular filtration rate			
	Decrease 30%	-30% to +30%	Improve 30%	Total
No ULT (% of row total)	605 (6.01)	8302 (82.52)	1154 (11.47)	10,061
ULT (% of row total)	164 (6.1) <sup>a</sup>	2172 (80.74)	354 (13.16) <sup>b</sup>	2690
Total (% of row total)	769 (6.03)	10,474 (82.14)	1508 (11.83)	12,751

<sup>a</sup>  $p = 0.026$ .  
<sup>b</sup>  $p = 0.016$ .  
 - = decrease; + = increase.

**Table 4. Impact of serum uric acid target by 30% change in glomerular filtration rate**

Category	At target, %	Not at target, %	Difference	Odds ratio (95% CI)	p value
Patients with < 30% decline in glomerular filtration rate					
CKD Stage 2	4.24	5.58	-1.34	0.75 (0.39-1.45)	0.390
CKD Stage 3	3.21	6.29	-3.08	0.49 (0.29-0.83)	0.008
CKD Stage 4	15.0	10.56	4.44	1.49 (0.82-2.72)	0.189
Total	5.0	6.9	-1.9	0.71 (0.51-1.00)	0.048
Patients with < 30% improvement in glomerular filtration rate					
CKD Stage 2	7.06	3.26	3.8	2.26 (1.16-4.41)	0.017
CKD Stage 3	19.87	10.02	9.85	2.23 (1.65-3.00)	< 0.001
CKD Stage 4	30.0	22.18	7.82	1.50 (0.95-2.37)	0.081
Total	17.1	10.4	6.7	1.78 (1.42-2.23)	< 0.001

CI = confidence interval; CKD = chronic kidney disease.



than 8 (OR = 1.74; CI = 1.45–2.09) and was more likely when the sUA is above 9 (OR = 3.12; CI = 2.29–4.25).<sup>5</sup> A study by Uchida and colleagues<sup>18</sup> also showed that hyperuricemia can lead to end-stage renal disease using 3 different propensity scores. Hyperuricemia, independent of gout, has recognized comorbidities of kidney, cardiac, cerebral disease, and an increase in all-cause mortality.<sup>11,12,19</sup> A recent multicenter international review by Sivera et al<sup>20</sup> did not recommend treating asymptomatic hyperuricemia, citing articles that showed no significant differences in GFR, serum creatinine level, or proteinuria. A double-blind, placebo-controlled study by Sircar et al,<sup>9</sup> not included in the review by Sivera and colleagues, showed a significant improvement in GFR with ULT. Our study also shows the potential benefit of normalizing the sUA in hyperuricemic patients with CKD. The beneficial effect is not uniform across the CKD spectrum; patients with CKD Stages 2 and 3 appear to have the greatest benefit when ACR target sUA is reached.

The 2012 ACR guidelines suggest initiation of ULT in the setting of tophi, frequent gout attacks, or CKD Stage 2 or worse.<sup>21</sup> Guideline protocol states that patients should have sUA monitoring every 2 to 5 weeks during ULT initiation and every 6 months after the target sUA is achieved. The recent American College of Physicians recommendation takes a different approach, favoring treating acute attacks over the ACR treat-to-target approach.<sup>22</sup> Compliance issues in gout treatment are substantial as reported by Riedel et al<sup>23</sup> in an allopurinol compliance study; the diagnosis of gout was made in 42.6% of their 9482 study patients, of which 56% of the patients were compliant with their allopurinol regimen during the 2-year follow-up period and 44% were noncompliant. Even with strong evidence for the treatment of gout, it often remains underdiagnosed and undertreated.<sup>24,25</sup>

Untreated or poorly treated gout leads to increases in direct health care costs and indirect costs of absenteeism in the workplace. Actual cost estimates for gout vary widely because of the degree of disease burden and different methods. Patients incur direct costs up to \$25,000,

with higher costs seen in patients with higher sUA and tophi. In addition to the direct costs, indirect costs have a major impact through lost wages.<sup>26</sup> A US study estimated that patients with gout annually missed 4.6 days of work and were less productive at work than were individuals without gout.<sup>27,28</sup> There is a linear relationship between disease burden, as measured by presence of tophi and number of gout flares, and overall health-related quality of life.<sup>29</sup> Wood et al<sup>30</sup> compared patients who were controlled with patients who were inadequately controlled, defined by sUA greater or less than 6 mg/dL, respectively, and counted the number of gout flares over 12 months. Patients whose sUA was under control had better quality of life, better productivity, fewer work absences, and less impairment while working than did patients with inadequate control.

One innovative study from KP Northern California used a protocol-driven pharmacist intervention compared with usual care. The primary measure was each group's ability to achieve the ACR sUA target of 6 mg/dL during a 26-week period.<sup>31</sup> Patients in the intervention group lowered their sUA, on average, by 1.5 mg/dL, with 35% of the patients achieving the ACR target compared with 13% in the control group (risk ratio = 2.8; 95% CI = 1.1–7.1;  $p = 0.03$ ). One conclusion from this study emphasized the importance of periodic contact with the patient. Contact including request for laboratory testing, office visits, phone calls, and letters seemed to improve overall compliance and lessen the risk of adverse consequences of hyperuricemia and gout. Factors contributing to improved control include active management, typically by a rheumatologist, and dose escalation of ULT leading to fewer gout flares.<sup>32</sup>

In this study we extended the work of our first study to examine whether lowering sUA could improve kidney function and whether that improvement was influenced by CKD stage. We did not include “normal” patients with no signs of renal disease (Stage 1 CKD) or those who had “pre-end-stage renal disease” (Stage 5 CKD). We have noted in previous work that the GFR changes with ULT tend to occur within the first

year in patients with more advanced disease, whereas asymptomatic patients would not be expected to show changes for years. In addition, patients with CKD Stage 5 would require only a small change in eGFR to trigger the designation of an outcome. For example, a patient with an eGFR of 15 mL/min would require a change of only 4.5 mL/min, which is well within the daily variation and imprecision of MDRD testing in advanced kidney disease.<sup>33</sup>

This study has several notable strengths. It reflects the real world because the patients are from KPSC's 4.2-million-member enrollment. Furthermore, KPSC's integrated electronic medical system includes clinic notes, hospitalizations, pharmacy, and laboratory data. We used an eGFR change of 30% that is based on the literature<sup>34</sup> and a desire to establish a sufficiently high bar to not overstate the effects of therapy.

Study limitations include characteristics of all epidemiologic studies, including the inability to control laboratory acquisition and compliance issues, making this essentially a usual-care study across our entire population. We “lost” more than 100,000 potential patients because they did not obtain GFR or sUA tests during the follow-up period. Table 2 shows only 47% of the study patients had a gout diagnosis at the index date. The study design used the first incidence of laboratory test of sUA above 7 mg/dL for the diagnosis of gout, rather than the initiation of ULT. This would account for the seemingly low number of patients with gout in the study. Proteinuria is a frequent feature of kidney disease, but because it was not a determinant for therapy, it was not included as a comorbidity factor. Additionally, we were not able to control for use of over-the-counter nonsteroidal anti-inflammatory drugs or differences in diet because these items are generally not contained in the clinical record. It is known from other work that nonsteroidal anti-inflammatory drugs are nearly universally used either by prescription or over the counter.<sup>35,36</sup> Only 3% of the study patients used an ULT other than allopurinol, 2% for febuxostat and 1% for probenecid. There were not sufficient numbers of patients in these subgroups

for separate analysis. As more patients use febuxostat in the future, a study will be needed to see if allopurinol benefit also holds for febuxostat. All patients came from a single medical group, albeit a very large one with more than 4.2 million members that mirrors Southern California in its diversity by age, race, and ethnicity. Finally, our laboratory uses the MDRD equation for estimation of GFR instead of the newer CKD Epidemiology Collaboration equation, potentially underestimating the actual GFR.<sup>37</sup>

Our study shows that in patients with mild to moderate CKD, achieving the ACR target sUA of less than 6 mg/dL may have a beneficial effect on their kidneys. The OR of 30% improvement when the sUA is below 6 mg/dL for the entire cohort was 1.78 (95% CI = 1.42-2.23;  $p < 0.001$ ), with the primary benefit coming from the CKD Stage 3 subset with an OR of 2.23 (95% CI = 1.65-3.00;  $p < 0.001$ ). Goicoechea et al<sup>38</sup> prospectively followed up 113 patients for 2 years with assessments at 6, 12, and 24 months. Changes in sUA, inflammatory markers, and cardiovascular events and eGFR were apparent by 6 months.<sup>38</sup> This information and our previous study results suggest that improvement can occur within a few months (unpublished data); therefore, we elected to limit our follow-up period to 1 year.

## CONCLUSION

Our study shows the benefit to the kidney of treating hyperuricemia to the ACR sUA target of below 6 mg/dL, with the greatest beneficial effect in patients with CKD Stages 2 and 3. This study joins the growing body of research findings suggesting that ULT should be considered in patients with hyperuricemia and CKD.<sup>39</sup> ♦

## Disclosure Statement

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

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Keywords: chronic kidney disease, CKD, hyperuricemia, serum uric acid, treat to target, urate lowering therapy

## Gout

Causes of the gout are: ... hereditary disease, high living and exercises ...  
overabundance of wine and venery. Bacchus pater, Venus mater, ira obstetrix arthritidis.

— Sir William Rowley, KB, c 1690-1768, Admiral of the Fleet, British Royal Navy Officer



**Grand Canyon Winter**  
photograph  
**Abdalla Mallouk, MD**

This image of the Grand Canyon was captured in winter at sunset after a light snow.

Dr Mallouk is an Internist and Nephrologist for the Southern California Permanente Medical Group. He very much enjoys exploring and photographing the great outdoors. More of his photographs can be seen in previous issues of *The Permanente Journal*.

# Inadequate Clinical Indications in Computed Tomography Chest and Abdomen/Pelvis Scans

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## ABSTRACT

**Context:** As the use of computed tomography (CT) scans, which are expensive and result in considerable radiation exposure to the patient, continues to increase, communication between physicians and radiologists remains vital to explain the clinical context for the examination. However, the clinical information provided to the radiologist is often lacking.

**Objective:** To determine whether the clinical information provided in CT scan requests meets minimum criteria for requesting the examination.

**Methods:** We reviewed the clinical indications for 400 CT chest scans and 400 CT abdomen/pelvis scans performed from January 1, 2016, through March 8, 2016. We determined whether each CT study indication was complete on the basis of whether the clinical information included an adequate clinical history with 1) a primary symptom, 2) the location of the symptom, and 3) the duration of the symptom as well as a suspected etiology.

**Results:** Of the CT chest indications, 56 (14.0%) of the clinical histories were considered complete and 17 (4.3%) had none of the components. A principal etiology was included in 195 (48.8%) of the indications. Of the CT abdomen/pelvis indications, 94 (23.5%) of the clinical histories were complete and 13 (3.3%) had none of the components. A principal etiology was included in 173 (43.3%) of the indications. Only 23 (5.8%) of the CT chest studies and 35 (8.8%) of the CT abdomen/pelvis studies had information considered sufficient for the radiologist.

**Conclusion:** The percentage of complete clinical indications for both CT chest and abdomen/pelvis scans was much lower than 50%, suggesting that more emphasis should be placed on providing complete clinical indications.

## INTRODUCTION

Communication between physicians ordering imaging studies and the radiologists reporting the findings of those studies is important. In the advancing digital age, there are fewer face-to-face interactions between physicians, which increases the need for concise but complete written information. There have been considerable efforts made to standardize radiologic reports, especially for complex imaging studies such as computed tomography (CT) or magnetic resonance imaging. Most of this work has focused on how to best report the findings of such imaging studies using reporting templates. There has been less emphasis on the clinical information provided to the

radiologist explaining the indications for the examination and the clinician's principal diagnostic concerns.

In a study analyzing the radiologists' perspectives on communication with other clinicians, the authors found that insufficient information in the request forms from referring physicians was a major concern expressed by the radiologists.<sup>1</sup> Lack of relevant clinical information, unclear clinical questions, and use of uncommon abbreviations were also highlighted as problem areas.<sup>1</sup>

The purpose of our study was to determine whether the clinical indications and diagnostic concerns provided for CT studies of the chest and abdomen/pelvis meet minimum criteria for requesting the examination to better determine appropriate utilization of imaging as it is necessary for clinical interpretation by the radiologist. On the basis of the clinical experience of our staff radiologist and other colleagues in the Radiology Department, we predicted that less than 50% of the clinical indications would contain sufficient information.

## METHODS

This was a retrospective study approved by our institutional review board with a waiver of consent because this was a data-only study with no patient interactions. We reviewed the clinical indications associated with 400 sequential CT chest scans and 400 sequential CT abdomen/pelvis scans that were performed from January 1, 2016, through March 8, 2016. We estimated that this number of studies would yield an adequate sample size to identify statistically significant differences. We included only those CT scans ordered by primary care or emergency medicine physicians. Although specialists should also provide adequate information in their clinical indications, they often request specific CT studies for unique indications such as CT colography for detection of colon polyps by gastroenterologists and high-resolution chest CT for interstitial lung disease by pulmonologists. Therefore, we chose to focus this study on the clinicians who contribute the majority of orders for routine CT studies of the chest and abdomen/pelvis in this health maintenance organization. We also kept track of the individual ordering physicians so that no ordering physician comprised more than 5% of the total for each of the 2 types of imaging studies, potentially skewing the data. However, our results showed that no physician ordered more than 3% of the studies, meaning our concern was not an issue. All CT studies were performed on members of a health maintenance organization for whom

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all radiology orders are placed through an electronic medical record (EMR; Epic, version 2015, Epic Systems, Verona, WI).

We determined whether each CT study indication included an adequate clinical history and a suspected etiology. We defined the minimum criteria for an adequate clinical history as including 1) at least one primary symptom, 2) the location of the symptom, and 3) the duration of the symptom, as was recommended in a previous study by Ihuhua and Pitcher.<sup>2</sup> Additional clinical history such as pertinent laboratory results or prior imaging findings were noted but not required for the clinical history to be considered adequate. The Royal College of Physicians' definition of adequacy of clinical details for an imaging study requires inclusion of a clear clinical question.<sup>3</sup> Therefore, a complete clinical indication should also include a primary suspected etiology, meaning a primary suspected cause of the symptoms the patient is experiencing (ie, "suspect pneumonia" or "possible aortic dissection").

To account for subjectivity, 3 authors individually graded each CT study and determined whether they included the minimum criteria to constitute a sufficient clinical history. Discrepancies were discussed as a group to reach a consensus. We first recorded the relevant keywords for each field of the clinical history: 1) the primary symptom, 2) the location of the symptom, and 3) the duration of the symptom. See Table 1 for our scoring system. A score of 0 was given if the field was not complete and a 1 was given if it was complete. For the duration criteria, we graded continuous and ordinal data as complete, meaning that specific dates or amounts of time and words that provide a rough estimate of time such as "persistent," "ongoing," "acute," and "chronic" were all counted as a 1. A clinical history with a score of 3 was considered adequate. An additional point was given if there was a principal suspected etiology. If the CT request included both a complete clinical history (ie, including a primary symptom, a location, and a duration) as well as a principal suspected etiology, then the request was considered to have an adequate clinical indication with a total score of 4. We also identified the most frequently used words within each clinical criterion. Associations between the 2 categories of data, namely CT chest scans and CT abdomen/pelvis scans, were analyzed using the  $\chi^2$  test with significance defined as  $p \leq 0.05$ .

## RESULTS

The CT chest scans evaluated spanned a period from January 1, 2016, to March 8, 2016. Of the clinical indications analyzed, only 56 (14.0%) of the clinical histories were considered complete, 327 (81.8%) had 1 or 2 components, and 17 (4.3%) had none of the components. A principal etiology was included in 195 (48.8%) of the indications; 23 (5.8%) of the studies had both a complete clinical history and etiology present (Table 2). The CT abdomen/pelvis scans evaluated spanned a period from January 1, 2016, to February 15, 2016. Of the clinical indications analyzed, 94 (23.5%) of the clinical histories were complete, 293 (73.3%) had 1 or 2 components, and 13 (3.3%) had none of the components of a clinical history whatsoever. A principal etiology was included in 173 (43.3%) of the indications; 35 (8.8%) of the studies had both a complete clinical history and etiology present (Table 2).

Factor	Score
Primary sign/symptom	Present = 1 Not present = 0
Location of symptom	Present = 1 Not present = 0
Duration of symptom	Present = 1 Not present = 0
Primary suspected etiology	Present = 1 Not present = 0
Total score	Sum all scores

Clinical indications	CT chest (n = 400)	CT abdomen/pelvis (n = 400)
Clinical history score: 0	17 (4.3)	13 (3.3)
Score: 1	156 (39.0)	82 (20.5)
Score: 2	171 (42.8)	211 (52.8)
Score: 3	56 (14.0)	94 (23.5)
Suspected etiology	195 (48.8)	173 (43.3)
Complete clinical indication (score 4)	23 (5.8)	35 (8.8)

CT = computed tomography.

Component	CT chest (n = 383)	CT abdomen/pelvis (n = 387)
Symptom	350 (91.4%)	369 (95.3%)
Location	209 (54.6%)	299 (77.3%)
Duration	107 (27.9%)	119 (30.7%)

CT = computed tomography.

As shown in Table 2, CT chest scans were less likely to have a complete clinical history and etiology than CT abdomen/pelvis scans ( $\chi^2$ ,  $p < 0.001$ ). As shown in Table 3, CT abdomen/pelvis scans were more likely to have any component of the clinical history than CT chest scans ( $\chi^2$ ,  $p = 0.01$ ). The primary difference in the clinical histories arose in the inclusion or absence of a location. In CT chest scans, a location was provided in only 209 (54.6%), whereas it was provided in 299 (77.3%) of the CT abdomen/pelvis scans. We found that there was no significant difference in the presence of a primary sign or symptom and duration between CT abdomen/pelvis and CT chest scans ( $\chi^2$ ,  $p = 0.73$ ). There was no significant difference in the presence of a primary suspected etiology between CT abdomen/pelvis and CT chest scans ( $\chi^2$ ,  $p = 0.12$ ).

As shown in Table 3, the most consistently included component for CT scans of the chest was the primary symptom, which was found in 350 (91.4%) of the 383 studies where at least 1 component was present. Duration was the least commonly included component of the clinical history, as it was found in only 107 (27.9%) of the studies where at least 1 component was present. For CT scans of the abdomen/pelvis, a sign or symptom

was again the most included component; it was found in 369 (95.3%) of the 387 studies where at least 1 component was present. Symptom duration was found in 119 (30.7%) of the clinical histories, again making it the least included component.

As shown in Table 4, the most commonly used words to describe a sign or symptom among the CT chest scans were “nodule” or “mass,” as they were included in 90 (22.5%) of the 400 scans evaluated. The most common word used to describe location was “x lobe,” for example, right upper lobe. The most common word used to describe duration was “x months,” for example, 6 months. The most commonly used word to describe the primary sign or symptom for CT abdomen/pelvis scans was “pain,” as it was present in 267 (66.8%) of the clinical histories. The most common location was “x quadrant,” and the most common duration was “x days.”

A total of 181 referring physicians ordered at least 1 of the 400 CT chest studies that were analyzed. The largest number of studies ordered by a single physician was 12. There were 4 physicians whose CT requests had at least 1 clinical indication with a total score of 1 as well as at least 1 clinical indication with a total score of 4. Each of these physicians ordered between 6 and 12 studies, of which each physician had only 1 study with a complete clinical indication while 3 of these physicians had more than 1 study with a score of 1. A total of 173 physicians ordered at least 1 of the 400 CT abdomen/pelvis studies that were analyzed. The largest number of studies ordered by a single physician was 8. There were 4 physicians whose CT requests had at least 1 clinical indication with a total score of 1 as well

as at least 1 clinical indication with a total score of 4. Each of these physicians ordered between 6 and 8 studies. Two of these 4 physicians had 2 studies with complete clinical indications (ie, a score of 4), whereas the other 2 physicians each had 1 study with complete clinical indications. Three of the 4 physicians had more than 1 study with a clinical indication score of 1. There was no physician who accounted for more than 3% of CT chest studies or CT abdomen/pelvis studies, demonstrating that no single physician impacted the results of this study.

## DISCUSSION

In this study, we chose to focus on CT examinations of the chest and abdomen/pelvis because these studies result in considerable radiation exposure to the patient and are expensive.<sup>4</sup>

There is little controversy over the utility of providing adequate clinical information when ordering CT scans.<sup>5-7</sup> Despite the importance of having a comprehensive clinical history, several studies have suggested that the information given to the radiologist providing these cross-sectional studies is lacking.<sup>8-12</sup> For the purposes of this study, we defined clinical indication as comprising 2 fields: Clinical history and primary suspected etiology. In a study by Pack et al,<sup>9</sup> 6 neuroradiologists evaluated 100 clinical histories associated with requests for magnetic resonance imaging of the brain. They graded each test to be either low or high indication, which indicated the probability of a positive or negative result. They found that on the basis of the provided clinical history, 54 studies were considered low-indication and 46 were considered high-indication. When the

**Table 4. Five most common words used for each component, no. (%)**

Word ranking	CT chest symptom	CT chest location	CT chest duration	CT ab/pel symptom	CT ab/pel location	CT ab/pel duration
1	Nodule/mass, 90 (22.5)	X lobe, 61 (15.3)	X months, 17 (4.3)	Pain, 267 (66.8)	X quadrant, 110 (27.5)	X days, 28 (7.0)
2	Pain, 63 (15.8)	Lung, 17 (4.3)	Chronic, 14 (3.5)	Hematuria, 36 (9.0)	Flank, 49 (12.3)	Persistent, 17 (4.3)
3	Density/opacity, 25 (6.3)	Pleural, 17 (4.3)	Persistent, 9 (2.3)	Nausea/vomiting, 20 (5.0)	Lower abdomen, 25 (6.3)	X months, 17 (4.3)
4	Cough, 21 (5.3)	Bilateral, 12 (3.0)	X days, 8 (2.0)	Weight loss, 15 (3.8)	Epigastric, 16 (4.0)	Chronic, 7 (1.8)
5	Abnormal CXR/ abnormality, 20 (5.0)	Back, 12 (3.0)	X weeks, 7 (1.8)	Diarrhea, 16 (4.0)	Upper abdomen, 16 (4.0)	Yesterday, 7 (1.8)

Ab = abdomen; CT = computed tomography; CXR = chest radiograph; Pel = pelvis.

**Table 5. Examples of CT chest and CT abdomen/pelvis clinical indications with no clinical history compared with those with a complete clinical history**

Examples of CT chest clinical indications with no clinical history	Examples of CT chest clinical indications with complete clinical history	Example of CT abdomen/pelvis clinical indications with no clinical history	Examples of CT abdomen/pelvis clinical indications with complete clinical history
“metastatic lung cancer”	“12-month follow-up for right upper lobe pulmonary nodule. Suspect granuloma”	“CT renal stone protocol, no IV/ oral contrast, please evaluate for kidney stone”	“3 days of anorexia now with pain localizing to RLQ. Suspect appendicitis”
“f/u stg 3 lung ca, c/w prior imaging please”	“Suspect pneumonia in patient with 7 days of cough and right-sided rhonchi”	“abdominal pain, IV, and oral contrast”	“LLQ pain and tenderness for 1 week, now with fever and white count. Evaluate for diverticular abscess”
“sarcoma follow-up”	“1-day history of severe midline chest pain radiating to back. Possible aortic dissection”	“suprapubic pain”	“Diffuse abdominal pain and tenderness after no bowel movement for 5 days. Constipation versus SBO”

ca = cancer; CT = computed tomography; c/w = consistent with; f/u = follow-up; IV = intravenous; LLQ = left lower quadrant; RLQ = right lower quadrant; SBO = small-bowel obstruction; stg = stage.

neuroradiologists reviewed the patients' medical charts, they determined that 62 were low-indication requests, whereas 38 were high-indication. On the basis of the provided clinical information alone, 37% of the high-indication studies had positive findings. After full medical chart review, 61% of the high-indication studies yielded at least 1 positive finding.

When inaccurate information is provided, the report is also more likely to be inaccurate. In a prospective study of 50 consecutive patients undergoing CT scans, 2 radiologists interpreted each study before and after knowledge of the clinical information<sup>13</sup>; 19 of these reports were changed after clinical information was provided. On the basis of clinical follow-up, 10 reports were found to be more accurate after clinical information was provided, but in 5 cases the report was found to be more inaccurate. In 3 of those 5 cases where accuracy was reduced, the clinical information was incorrect.

Before the advent of an EMR, physicians filled out request forms on paper and wrote down the patient's information, which included patient's sex, age, and date of birth. This led to many opportunities for incomplete or inaccurate information to be supplied to the radiologist.<sup>8</sup> Now, all imaging studies ordered within this health maintenance organization are done so electronically. Therefore, when the request for a CT study is generated, some of the patient's demographic information, such as age and sex, as well as an International Classification of Diseases, 10th Revision code are automatically included as part of the clinical indication.

In our version of the EMR, there is currently no method to directly extract the primary symptom, duration, and location from the referring physician's electronic progress note or history and physical examination into the clinical indication. This problem is further complicated by the fact that the CT order can be placed before the physician's note has been completed in the EMR, which is especially common in orders from our Emergency Department. Finally, there is no requirement that the International Classification of Diseases, 10th Revision code, which the referring physician selects, must be the primary suspected etiology. Frequently, it can be a sign or symptom that initiated the patient's visit to the referring physician but not the reason for which the CT study was ordered.

Our results showed that only 5.8% of the CT chest studies and 8.8% of the CT abdomen/pelvis studies had information that we considered sufficient for the radiologist. One possible explanation for the difference between chest and abdominal CT studies could be that patients with suspected chest pathology often have nonlocalizing symptoms such as cough, hemoptysis, or shortness of breath. Ordering physicians usually provided a primary sign or symptom, but its location and duration were frequently missing. The primary suspected etiology was provided in less than half of the CT requests.

In a busy clinical practice, referring physicians cannot be expected to fill out long requisition forms, nor should radiologists

be expected to peruse the EMR of every patient with a CT study. Therefore, we believe a reasonable compromise is to require a 1 or 2 sentence clinical indication, which includes the chief sign or symptom, its location, and its duration, as well as the principal suspected etiology.

To write a concise 1- or 2-sentence indication that provides sufficient information, the physician's word choice is crucial. There were 17 CT chest scans and 13 CT abdomen/pelvis scans with no clinical history. Fortunately, all of the pertinent information for the clinical indication can be provided in 1 or 2 concise sentences.

Examples of clinical indications with no clinical history compared with clinical indications with a complete clinical history

expressed in 1-2 sentences are shown in Table 5. These incomplete clinical histories could have been readily supplemented with more information while still keeping the indication brief. "Metastatic lung cancer" could be changed to "Metastatic lung cancer, right upper lobe, 6-month follow-up, eval for progressive disease"; and "follow-

up stage 3 lung cancer, consistent with prior imaging please" could be changed to "stage 3 lung cancer, originated from right lower lobe, 6-month follow-up, eval for progressive disease." "Sarcoma follow-up" could be changed to "primary retroperitoneal sarcoma originally diagnosed 1 year ago, evaluate for metastases." "CT renal stone protocol, no IV/ oral contrast, please evaluate for kidney stone" could be changed to "right kidney pain, 3 days, please evaluate for kidney stone."

We sampled clinical indications from a large number of different requesting physicians for both the CT chest scans and CT abdomen/pelvis scans. The physicians who wrote a complete or incomplete clinical indication varied for both types of scans. In several cases, a physician had both a clinical indication that was complete for one CT scan request as well as another CT request in which the clinical indication contained only a single component.

To prevent this sort of variation, we propose including a short reminder at the beginning of every computerized order entry request that states, "To prevent a possible delay in scheduling, please include 1) sign/symptom, 2) location, 3) duration, 4) etiology." Another possibility would be to implement an EMR "hard stop" (with check boxes and area for comments or additional information) built in that does not allow clinicians to complete the order until the requested information is provided.

A limitation of this study is its retrospective nature as there was no requirement for physicians to input a complete clinical history to order a CT scan at the time they wrote the request. This was performed at one location at one point in time, which might not be reflective of clinical practice in other locations. Additionally, there is also currently no consensus on what constitutes a complete clinical history. We used the Royal College of Physicians' recommendation as a reference.<sup>3</sup> Finally, to our knowledge improved outcomes have not been proven in the medical literature even with provision of additional clinical history.

**To prevent a possible delay in scheduling, please include 1) sign/symptom, 2) location, 3) duration, 4) etiology.**



## CONCLUSION

The percentage of complete clinical indications for both CT chest and abdomen/pelvis scans was much lower than 50%, indicating a need for a method to assist clinicians in documenting the clinical indications for the studies they order. ❖

## Disclosure Statement

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

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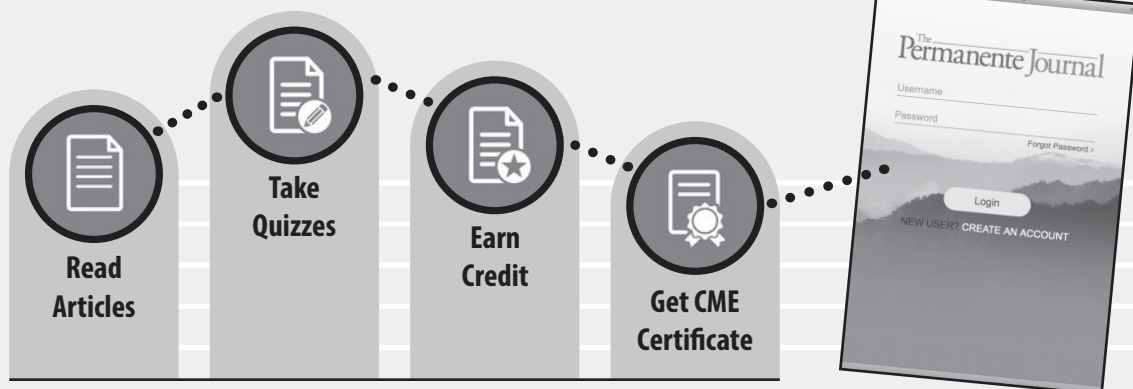
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# Clostridium Difficile-Associated Infection in Trauma Patients: Development of the Clostridium Difficile Influencing Factors (CDIF) Score

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## ABSTRACT

**Context:** *Clostridium difficile*-associated infection (CDAI) can result in longer hospitalization, increased morbidity, and higher mortality rates for surgical patients. The impact on trauma patients is unknown, however.

**Objective:** To assess the effect of CDAI on trauma patients and develop a scoring system to predict CDAI in that population.

**Methods:** Records of all trauma patients admitted to a Level I Trauma Center from 2001 to 2014 were retrospectively reviewed. Presence of CDAI was defined as evidence of positive toxin or polymerase chain reaction. Patients with CDAI were matched to patients without CDAI using propensity score matching on a ratio of 1:3.

**Main Outcome Measures:** Primary outcome was in-hospital mortality. Secondary outcomes included length of stay and need for mechanical ventilation. A decision-tree analysis was performed to develop a predicting model for CDAI in the study population.

**Results:** During the study period, 11,016 patients were identified. Of these, 50 patients with CDAI were matched to 150 patients without CDAI. There were no differences in admission characteristics and demographics. Patients in whom CDAI developed had significantly higher mortality (12% vs 4%,  $p < 0.01$ ), need for mechanical ventilation (57% vs 23%,  $p < 0.01$ ), and mean hospital length of stay (15.3 [standard deviation 1.4] days vs 2.1 [0.6] days,  $p < 0.01$ ).

**Conclusion:** In trauma patients, CDAI results in significant morbidity and mortality. The *C difficile* influencing factor score is a useful tool in identifying patients at increased risk of CDAI.

## INTRODUCTION

Since Trunkey et al<sup>1</sup> in 1983 first described the trimodal distribution of deaths for trauma patients, there has been major improvement in the management of critically injured patients. After the widespread implementation of trauma centers, several studies have demonstrated that the third peak of late deaths has diminished. However, despite those changes, there is still a high incidence of morbidity and mortality for patients who remain critically ill in the surgical intensive care unit (ICU) for more than 7 days. *Clostridium difficile*-associated infection (CDAI) is a modifiable factor that can result in significant morbidity

and has a higher prevalence in critically ill patients. Several recent studies have implemented severity assessment scores for hospitalized patients.<sup>2-4</sup> Although there is a plethora of studies about the impact of CDAI in the medical patient, there is a paucity of data for the trauma patient population. There currently exists no known predictive model or scoring system that can accurately predict the risk of *C difficile* infection in trauma patients using patients' admission characteristics.

The present study hypothesized that the development of CDAI in the setting of a traumatic injury results in significantly higher morbidity and mortality, and we set out to develop a scoring system that

would predict the probability of CDAI development after a traumatic injury.

## METHODS

### Patients and Setting

After institutional review board approval, the medical records from all patients admitted to an urban Level I Trauma Center from 2001 to 2014 were retrospectively reviewed from the prospectively maintained hospital trauma database. Patients in whom CDAI developed during the index hospitalization were identified. Verification of CDAI was based on either a positive assay for *C difficile* toxin or polymerase chain reaction result. The decision to assess for CDAI was physician driven. Patients were excluded if they were younger than age 18 years or pregnant. The following variables were extracted: Age, race, sex, mechanism of injury, admission physiologic parameters, injury severity indexes, and admission service.

The study population was divided into 2 groups on the basis of CDAI development. Patients in whom CDAI developed during the index hospitalization were matched to patients who did not contract the infection, using propensity score matching on a ratio of 1:3 to ensure homogeneity between the 2 groups. After propensity score matching, a chart review was performed to identify the specific patterns of injury, type of antibiotic given during the hospitalization, and white blood cell count (WBC) at admission.

The primary outcome was in-hospital mortality. Secondary outcomes included the need for ventilator support, ICU

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length of stay, total number of ventilator days, and hospital length of stay.

**Statistical Analysis**

The cohorts with and without CDAI were compared for differences in demographics and clinical characteristics using univariate analysis. Chi squared or Fisher exact tests were used to compare the proportions. Continuous variables were examined for normality of distribution using the Shapiro-Wilks test. Student *t*-test was used for normally distributed continuous variables, whereas the Mann-Whitney U test was used for nonnormally distributed variables.

Propensity score matching was used to minimize the variability of the study outcomes. Propensity score was generated using a binary logistic regression. Included in the regression model were all demographic and clinical baseline characteristics that differed between the 2 groups at *p* < 0.05. Each patient was matched with controls in a 1:3 ratio within a narrow caliper (0.003) of propensity, without replacement. The caliper was equal to one-fourth of the standard deviation of the generated propensity scores. After propensity score matching, the McNemar  $\chi^2$  test was used to compare proportions, and the Wilcoxon signed rank test was used to compare means, to ensure the suitability and applicability of the process.

Further univariate analyses were performed to identify differences between the groups. A stepwise logistic regression was then performed using variables that were different at *p* < 0.2. The dependent variable was development of CDAI. A simplified clinical risk assessment tool was derived by assigning point values to the ratios of the  $\beta$  coefficients. A composite risk score, the *C difficile* influencing factor (CDIF) score, was subsequently defined as the summation of these point values. The C statistic of the model was subsequently calculated to assess whether discriminative capacity was preserved.

To assess the validity of the model, we used a distinct cohort of patients from a different period. The CDIF score was calculated for each patient, and a multivariate logistic regression was performed using the development of *C difficile* infection as the outcome. Adjusted odds ratios with 95% confidence intervals were derived from the regression.

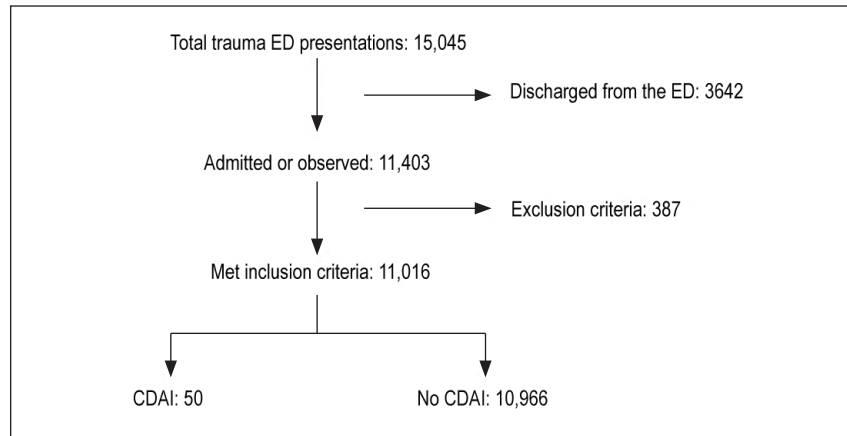


Figure 1. CONSORT diagram of study population.

CDAI = *Clostridium difficile*-associated infection; ED = Emergency Department.

The C statistic of the model was calculated to assess the validity of the model and whether discriminative capacity was preserved.

**RESULTS**

During the study period, a total of 11,016 patients were identified (Figure 1). Of those, only 0.45% (50) had a diagnosis

of CDAI. After propensity score matching, 50 patients with CDAI were matched to 150 patients without CDAI in a ratio of 1:3 (Table 1). The mean age of the study population was 32 years. The majority (68%) were men and African American (58%). Penetrating mechanism of injury accounted for 30% of the cases.

**Table 1. Demographics and admission characteristics of study population**

Variables	Overall (N = 200)	<i>Clostridium difficile</i> positive (n = 50)	<i>Clostridium difficile</i> negative (n = 150)	p value	Validation cohort (n = 875)
Age, years, mean (SD)	32 (11)	35 (13)	32 (9)	0.31	34 (5)
Men, no. (%)	136 (68.0)	33 (66.0)	103 (68.7)	0.73	551 (63.0)
Race, no. (%)					
African American	115 (57.5)	27 (54.0)	88 (58.7)	0.17	417 (47.7)
White	79 (39.5)	18 (36.0)	61 (40.7)		366 (41.8)
Admission physiologic values					
SBP, mmHg, mean (SD)	151 (36)	151 (39)	152 (32)	0.79	147 (30)
HR/min, mean (SD)	92 (23)	95 (28)	91 (22)	0.24	89 (19)
RR/min, mean (SD)	18 (5)	19 (6)	18 (5)	0.44	19 (4)
GCS, median (range)	13 (3-15)	13 (3-15)	13 (3-15)	0.6	
Injury severity indexes, no. (%)					
Head AIS < 3	79 (39.5)	20 (40.0)	59 (39.3)	0.15	144 (16.5)
Chest AIS < 3	83 (41.5)	19 (38.0)	64 (42.7)	0.11	109 (12.5)
Abdominal AIS < 3	52 (26.0)	16 (32.0)	36 (24.0)	0.09	45 (5.1)
Penetrating mechanism of injury	59 (29.5)	13 (26.0)	46 (30.7)	0.53	97 (11.1)
Admission service, no. (%)					
Trauma	163 (81.5)	37 (74.0)	126 (84.0)	0.1	524 (59.9)
Orthopedics	13 (6.5)	2 (4.0)	11 (7.3)		160 (18.3)
Neurosurgery	24 (12.0)	11 (22.0)	13 (8.6)		40 (4.6)

AIS = Abbreviated Injury Scale; GCS = Glasgow Coma Scale; HR = heart rate; RR = respiratory rate; SBP = systolic blood pressure; SD = standard deviation.

A total of 80 patients had a severe head injury defined by the Abbreviated Injury Scale (head AIS < 3), whereas 83 and 52 patients had a severe injury of the chest and abdomen, respectively (Table 1). Most patients were admitted to the Acute Care Surgery/Trauma Service (82%). After propensity score matching, there were no statistically significant differences between their baseline characteristics and admission physiologic values (Table 1).

Table 2 shows the injury patterns of the study population. Patients in whom CDAI developed were statistically significantly more likely than those without CDAI to sustain a renal injury (10% vs 1%,  $p = 0.01$ ), colonic injury (24% vs 3%,  $p < 0.01$ ), or spinal injury (22% vs 10%,  $p = 0.03$ ). Administration of clindamycin or of second-, third-, and fourth-generation cephalosporins were positively associated with significantly higher incidence of CDAI in the study population (Table 3). Clindamycin is generally administered in our hospital when a facial fracture is diagnosed during the workup. None of the patients who received clindamycin had a known penicillin allergy. All the patients who received clindamycin presented with a facial fracture. Similarly, the use of intravenous protein pump inhibitors resulted in a higher incidence of CDAI (24% vs 2%,  $p \leq 0.01$ ; Table 3).

The development of CDAI in trauma patients was associated with significantly higher morbidity and mortality. There was a 3-fold increase in the incidence of mortality for the CDAI group compared with their propensity-matched counterparts (12% vs 4%,  $p = 0.04$ ). Similarly, the need for ventilator support, ICU length of stay, total ventilator days, and hospital length of stay were significantly higher for the CDAI group (Table 4).

To develop the CDIF score, we performed a forward stepwise logistic regression, and the  $\beta$  coefficients were derived from that model. Table 5 depicts the independent predictors of CDAI development derived from the regression model. Admission WBC, use of intravenous proton pump inhibitors, use of a third-generation cephalosporin, colonic injury, use of clindamycin, spinal

injury, the need for surgical intervention after the injury, and the use of a fourth-generation cephalosporin were independently associated with CDAI

development. The area under the curve (95% confidence interval) of the model was 0.96 (0.94–0.99),  $p < 0.01$ . The CDIF score was derived from the summation

**Table 2. Patterns of injury**

Injury	Overall (N = 200), no. (%)	<i>Clostridium difficile</i> positive (n = 50), no. (%)	<i>Clostridium difficile</i> negative (n = 150), no. (%)	p value
Intracranial injury	50 (25.0)	15 (30.0)	35 (23.3)	0.35
Pelvic fracture	10 (5.0)	0 (0)	10 (6.7)	0.07
Rib fractures	31 (15.5)	10 (20.0)	21 (14.0)	0.31
Pancreatic injury	2 (1.0)	2 (4.0)	0 (0)	0.06
Renal injury	7 (3.5)	5 (10.0)	2 (1.3)	0.01
Pneumothorax/hemothorax	28 (14.0)	9 (18.0)	19 (12.7)	0.35
Small-bowel injury <sup>a</sup>	17 (8.5)	7 (14.0)	10 (6.7)	0.14
Colonic injury <sup>a</sup>	16 (8.0)	12 (24.0)	4 (2.7)	< 0.01
Hepatic injury	7 (3.5)	4 (8.0)	3 (2.0)	0.07
Splenic injury	7 (3.5)	3 (6.0)	4 (2.7)	0.38
Long-bone injury	65 (32.5)	16 (32.0)	49 (32.7)	0.93
Spinal injury	26 (13.0)	11 (22.0)	15 (10.0)	0.03

<sup>a</sup> Excluding mesenteric hematomas that were observed.

**Table 3. Antibiotic treatment before infection and peak white blood cell count<sup>a</sup>**

Antibiotic	Overall (N = 200)	<i>Clostridium difficile</i> positive (n = 50)	<i>Clostridium difficile</i> negative (n = 150)	p value
Quinolones	7 (3.5)	1 (2.0)	6 (4.0)	0.68
Trimethoprim-sulfamethoxazole	7 (3.5)	1 (2.0)	6 (4.0)	0.68
Macrolides	6 (3.0)	4 (8.0)	2 (1.3)	0.04
Clindamycin	8 (4.0)	3 (6.0)	5 (3.3)	0.42
Penicillin	13 (6.5)	4 (8.0)	9 (6.0)	0.74
Aminoglycoside	8 (4.0)	2 (4.0)	6 (4.0)	> 0.99
Ertapenem	4 (2.0)	4 (8.0)	0 (0)	0.04
Linezolid	8 (4.0)	4 (8.0)	4 (2.7)	0.11
First-generation cephalosporin	79 (39.5)	25 (50.0)	54 (36.0)	0.08
Second-generation cephalosporin	29 (14.5)	12 (24.0)	17 (11.3)	0.04
Third-generation cephalosporin	15 (7.5)	12 (24.0)	3 (2.0)	< 0.01
Fourth-generation cephalosporin	20 (10.0)	12 (24.0)	8 (5.3)	< 0.01
IV PPIs	29 (14.5)	16 (32.0)	13 (8.7)	< 0.01
Admission WBC, mean (SD), × 10 <sup>9</sup> /L	10.3 (6.1)	11.5 (5.1)	8.7 (6.2)	0.04

<sup>a</sup> Data are expressed as no. (%) unless otherwise indicated.

IV PPIs = intravenous proton pump inhibitors; SD = standard deviation; WBC = white blood cell count.

**Table 4. Outcomes**

Outcome	Overall (N = 200)	<i>Clostridium difficile</i> positive (n = 50)	<i>Clostridium difficile</i> negative (n = 150)	p value
Inhospital mortality, no. (%)	12 (6.0)	6 (12.0)	6 (4.0)	0.04
Need for ventilator support, no. (%)	66 (33.2)	28 (57.1)	38 (25.3)	< 0.01
ICU LOS, mean (SD), days	3.1 (0.5)	8.1 (4.1)	0.9 (0.3)	< 0.01
Ventilator days, mean (SD)	1.0 (0.2)	2.4 (0.2)	0.7 (0.1)	< 0.01
Hospital LOS, mean (SD), days	4.3 (2.1)	15.3 (1.4)	2.1 (0.6)	< 0.01

ICU = Intensive Care Unit; LOS = length of stay; SD = standard deviation

of the  $\beta$  coefficients of these variables, as depicted in Table 6. For assessment of the applicability of the model, the study population was subsequently divided into 5 groups on the basis of their CDIF score, and the probability of CDAI development was calculated for each group using the adjusted odds ratio (95% confidence interval) that was derived from the multivariate regression. The process was performed for both the derivation and the validation cohorts (Table 7). As the CDIF score increased, the probability of CDAI developing similarly increased (Figure 2).

**DISCUSSION**

The present study findings suggest that CDAI is a rare occurrence in patients sustaining a traumatic injury. To our knowledge, this is the first study to report the creation of a scoring system to risk-stratify patients on the basis of their probability of CDAI developing after trauma.

In 1983, Trunkey<sup>1</sup> postulated a trimodal distribution of death in trauma patients. The first peak of death was caused by massive vascular or solid organ injury and central nervous system injury, and it primarily occurred at the scene. The second peak of death was caused by hemorrhage. These patients could potentially be saved by prompt resuscitation and identification of injuries in the trauma bay with appropriate intervention. The third peak of death was reported to occur days to weeks later and occurred because of multiorgan system failure and sepsis. The percentage of deaths in the first peak was 45%, second peak was 34%, and third peak was 20% in the original description of trimodal deaths.<sup>1</sup>

Since Trunkey’s landmark study, multiple studies evaluated the trimodal distribution in the 21st Century at Level 1 Trauma Centers and found no trimodal distribution.<sup>5-7</sup> In comparison to Trunkey’s<sup>1</sup> original 20% of trauma mortality cases being late deaths, Demetriades<sup>8</sup> found a reduction to 7.6%. With the advances in critical care and postoperative care, this number could potentially decrease if modifiable risk factors were identified. Prevention and early recognition/treatment of infection is critical in all patients. *C. difficile* is the pathogen most commonly identified in cases of nosocomial antibiotic-associated diarrhea, and infection with this organism

**Table 5. Independent predictors for *Clostridium difficile* infection**

Step	Variable	Adjusted OR (95% CI) <sup>a</sup>	Adjusted p value	Cumulative R <sup>2</sup>
1	Injury Severity Score	1.99 (1.62-2.24)	< 0.01	0.196
2	IV PPIs	1.24 (1.10-1.54)	< 0.01	0.231
3	Third-generation cephalosporin	1.28 (1.07-2.01)	< 0.01	0.285
4	Colonic injury	3.52 (1.08-15.32)	< 0.01	0.304
5	Clindamycin	19.80 (4.96-31.34)	< 0.01	0.329
6	Spinal injury	41.46 (5.39-47.06)	< 0.01	0.384
7	Operating room for trauma	9.41 (2.29-38.78)	0.02	0.406
8	Admission WBC	8.17 (1.65-23.10)	0.012	0.456
9	Fourth-generation cephalosporin	4.65 (1.07-20.32)	0.041	0.487

<sup>a</sup> Area under the curve (95% CI): 0.97 (0.94-0.99), p < 0.001. CI = confidence interval; IV PPIs = intravenous proton pump inhibitors; OR = odds ratio; WBC = white blood cell count.

may have serious or even fatal consequences.<sup>9</sup> Outbreaks of *C. difficile* are occurring more frequently and are associated with increasing rates of toxic megacolon, septic shock, and death.<sup>10</sup>

Although ample studies exist on the management and impact of CDAI in the general population, there is a paucity of data in the trauma patient population. In this study, we assess the effect of CDAI on trauma patients and present a scoring system to predict the development of CDAI.

In our study, we matched the patients with CDAI to the patients without CDAI using propensity score matching to ensure similar baseline characteristics and

**Table 6. *Clostridium difficile* influencing factor score**

Influencing factor	Points
ISS 16-24	5
ISS $\geq$ 25	10
IV PPIs	3
Third-generation cephalosporin	2
Colonic injury	2
Clindamycin	2
Spinal injury	1
Operating room for trauma	1
WBC < 15,000/ $\mu$ L	1

ISS = Injury Severity Score; IV PPIs = intravenous proton pump inhibitors; WBC = white blood cell count.

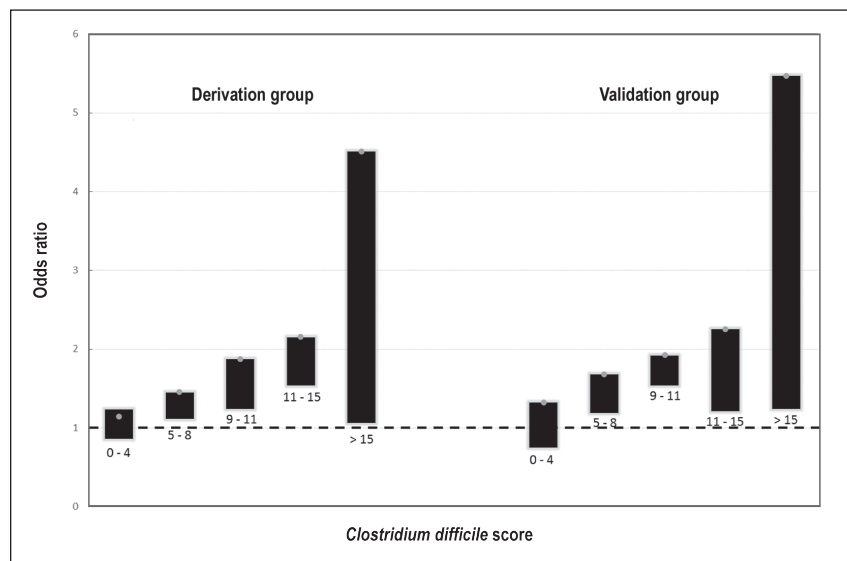


Figure 2. Probability of *Clostridium difficile* infection stratified by *C. difficile* influencing factor score (derivation and validation cohorts).

**Table 7. Probability of development of Clostridium difficile infection stratified by Clostridium difficile influencing factor score**

Score	Derivation cohort, adjusted OR (95% CI) <sup>a</sup>	Validation cohort, adjusted OR (95% CI) <sup>b</sup>
0-4	1.23 (0.86-1.41)	1.14 (0.75-0.32)
5-8	1.25 (1.11-1.45)	1.32 (1.19-0.68)
9-11	1.56 (1.24-1.87)	1.72 (1.54-0.92)
12-15	1.87 (1.54-2.15)	1.75 (1.21-0.25)
> 15	2.25 (1.06-4.51)	1.98 (1.24-5.47)

<sup>a</sup> C statistic for derivation cohort: 0.75 (95% OR 0.71-0.82),  $p < 0.01$ .

<sup>b</sup> C statistic for validation cohort: 0.69 (95% OR 0.67-0.71),  $p < 0.01$ .

CI = confidence interval; OR = odds ratio.

demographics. Our results show that trauma patients in whom CDAI developed had significantly higher mortality, need for mechanical ventilation, and hospital length of stay, which leads to increased direct and indirect costs.

The overall US costs of *C difficile* were close to \$1.1 billion annually in one study<sup>11</sup> and \$3.2 billion annually in another study.<sup>12</sup> Even when compared with other infections, CDAI is very expensive. The costs of CDAI range from \$2000 to \$72,000 per case,<sup>13,14</sup> compared with methicillin-resistant *Staphylococcus aureus*, which costs between \$5000 and \$40,000.<sup>15</sup>

Our CDIF score was created using 9 factors and assigning specific points for each. These points are then added to give a score, and the probability of CDAI development is predicted (Tables 6 and 7). For example, if a patient had a colonic injury, went to the operating room for trauma, and had a WBC greater than 15,000/ $\mu\text{L}$  ( $> 15 \times 10^9/\text{L}$ ), his/her composite score would be 4. The corresponding probability of CDAI development is above 80% (Table 7). With this information, clinicians can be hypervigilant about early detection and prompt treatment. There are many causes of diarrhea in trauma patients, so having a scoring system with the probability of CDAI development can be very useful. In addition, as with any infectious disease, early recognition of the risk and prevention of the development of *C difficile* infection may be of more importance than early recognition and treatment. For example, a patient with high CDIF score could raise the index of suspicion of the rounding physician, who then could institute a series of interventions (ie, early termination of antibiotics and/

or initiation of CDAI-appropriate hand hygiene) to not only prevent that specific patient from having an infection but also spreading the infection to surrounding patients. The utility of the CDIF score to prevent an infection might indeed be its most important clinical function.

## CONCLUSION

Our study demonstrated significantly higher morbidity and mortality in the setting of a traumatic injury with the development of CDAI. Our scoring system can be used to predict the probability of CDAI development after a traumatic injury, and it hopefully can guide clinicians when patients experience diarrhea. ❖

## Disclosure Statement

The author(s) have no conflicts of interest to disclose. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional review board and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. For this type of study, formal consent is not required.

## Acknowledgment

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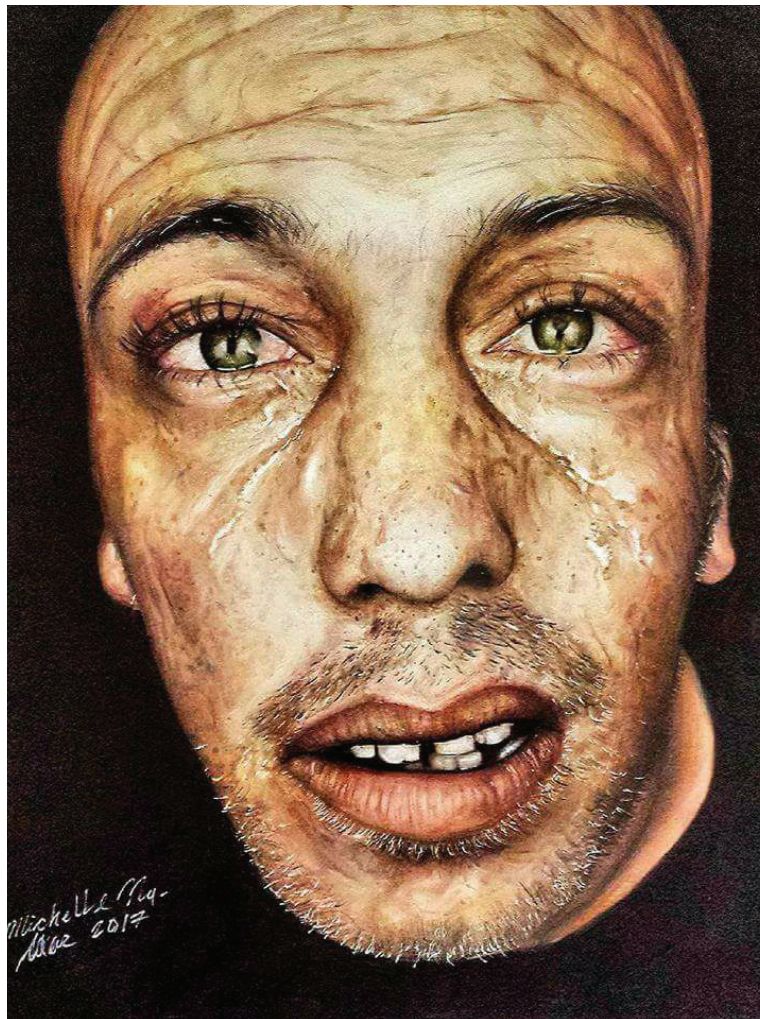
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Keywords: Clostridium difficile, critical care, morbidity, mortality, trauma, scoring system



**Face of Humanity**  
colored-pencil drawing  
**Michelle Nguyen**

This drawing was done completely with colored pencils. The artist began drawing in 2015 as a way to release and reveal difficult emotions. Art remains a valuable tool for her, and now she hopes to inspire and comfort others through her work.

Ms Nguyen is an X-ray Technician at Health Scan Imaging in Temecula, CA. More of her artwork can be seen in this issue of *The Permanente Journal*.

# Developing Community-Based Primary Health Care for Complex and Vulnerable Populations in the Vancouver Coastal Health Region: HealthConnection Clinic

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## ABSTRACT

**Introduction:** Designing, delivering, and evaluating high-performing primary health care services for complex and vulnerable subpopulations are challenging endeavors. However, there is a relative paucity of research evidence available to support such work.

**Objective:** To provide a case study using HealthConnection Clinic, a public primary care center located in Metropolitan Vancouver's North Shore.

**Methods:** Developmental evaluation approach operationalizing the 10 Building Blocks of High-Performing Primary Care framework using qualitative and quantitative methods.

**Results:** The clinic provided valuable insights to policymakers and researchers related to development of the Building Blocks' foundational elements, particularly engaged leadership, empanelment, and data-driven improvement. The study highlighted the key enablers, achievements, challenges, and barriers related to operationalizing each Building Block. The Building Blocks were a useful heuristic that enabled the development and evaluation of primary care for complex subpopulations. Particularly salient from a Canadian policy perspective was the demonstration that system integration was possible when highly engaged leaders from a Regional Health Authority and a Division of Family Practice shared a common vision and purpose. HealthConnection Clinic's entrepreneurial spirit has enabled the development of innovative, evidence-based tools such as the AMPS complexity assessment tool (attachment, medical conditions, psychological/mental health/addictions challenges, and socioeconomic status), designed to identify and assess biopsychosocial complexity and needs. The study also highlighted the importance of incorporating community orientation and equity into developmental work.

**Conclusion:** The study demonstrates how the Building Blocks approach can be adapted to operationalize high-performing primary care standards in settings serving complex and vulnerable populations.

## INTRODUCTION

HealthConnection Clinic, a primary care center located in Metropolitan Vancouver's North Shore area, is part of Vancouver Coastal Health (VCH), the largest by population of 6 publicly funded Regional Health Authorities in British Columbia (BC),



Figure 1. Logo of HealthConnection Clinic.

Canada. VCH serves more than 1 million ethnically and socioeconomically diverse subpopulations living across Canada's wealthiest and poorest postal codes. For example, VCH covers both Vancouver's Downtown Eastside (median household income of \$17,051 in 2015) and West Vancouver (median household income of \$145,481 in 2015).<sup>1</sup>

Although Vancouver's North Shore is composed of some of Canada's wealthiest municipalities, there exists a sizable minority of people who are poor, homeless, or at risk of homelessness.<sup>2</sup> It has been estimated that the North Shore has more than 3000 high-needs people lacking regular access to primary care (Table 1).<sup>2</sup> These vulnerable and diverse subpopulations often forgo medical care or resort to using hospital Emergency Departments (EDs) and primary care walk-in clinics, both of which are not designed to address complex biopsychosocial needs.

## Founding and Development of HealthConnection Clinic

In 2011 to 2012, a group of general practitioners (GPs) who had launched the Division of Family Practice (DFP) on the North Shore, VCH Health Authority staff, and local community agencies identified the need to work together to address the issue of unmet primary care needs for North Shore's most vulnerable and disenfranchised subpopulations.<sup>3</sup> The working group prepared a business plan for the development of a high-needs clinic and engaged with community agencies and partners, homeless shelters, and community mental health associations to design and help staff the clinic.<sup>3</sup>

Despite asking for relatively few resources, the business plan initially had no traction with the Health Authority. The work group therefore leveraged unused funds from other initiatives and formed the clinic with borrowed underused space from the Health Authority, with no means of sustainable funding.<sup>3</sup> The team worked carefully to brand the clinic and collaboratively developed a unique logo (Figure 1).

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**Table 1. Vancouver North Shore key statistics on homelessness, 2016<sup>2</sup>**

Statistic	Number <sup>a</sup>
Homeless individuals receiving health and social services in Vancouver's North Shore	736
Homeless individuals accessing multiple services	124
Homeless adults aged 25-54 years	453
Homeless youth under 24 years	103
Homeless seniors 55 years and older	178
Homeless or at-risk service recipients who reported domestic violence	136
Children accompanying homeless or at-risk parent or parents	143
Unique individuals who accessed homelessness services in 2016 and were considered at risk because of imminent risk of housing loss	295
Number (%) of the absolutely homeless population that accessed HealthConnection Clinic in 2016	366 (50)

<sup>a</sup> Unless otherwise indicated.

In July 2013, the clinic opened as a drop-in service (week-day mornings), using space that was not designed for primary care. Although the layout of the clinic's rooms was not ideal (eg, examination rooms did not have sinks), the space was in a storefront location that was accessible.<sup>3</sup> Funding was available to equip each room with necessary infrastructure and equipment, and to install hand hygiene stations. The HealthConnection Clinic management visited an existing Health Authority clinic in Vancouver to better understand essential equipment, staffing, safety, and infection control requirements. (HealthConnection Clinic was accredited in 2016 and scored high on all areas.)

In inception, HealthConnection Clinic was able to access one-time-only funding for GP fees and a Medical Office Assistant and was able to redeploy the one community nurse practitioner (NP) doing community outreach to the clinic. Community agencies were also approached to staff the clinic with social work and outreach supports. Physicians are funded through sessional payments, whereas NPs and other allied health staff are on salary from the Health Authority.

In 2015, a provincial initiative supported by the DFP provided grants to enable the clinic to open in the afternoons, to employ more GP time, and to hire a Social Services Support Coordinator. Sustainable operational funding to support clinical and administrative staffing was secured in 2016 to 2017 (\$435,000), although access to the clinic space remains uncertain. This funding was supplemented by NP funding that came from the provincial government's Nurse Practitioners for BC (NP4BC) initiative. This NP divides her time between HealthConnection Clinic (0.8 full-time equivalent [FTE]) and 2 newly developed primary care clinics, modeled in part on HealthConnection Clinic, in 2 First Nations communities on the North Shore (0.2 FTE).

### Population and Service Delivery Model

HealthConnection Clinic is officially mandated to serve its jurisdiction's unattached clients (ie, clients not rostered to

or without regular access to a primary care clinic or clinician) who have complex biopsychosocial needs. In the early days of operation, nearly half of all clients came from homeless shelters and nongovernmental organizations, resulting from the broad and inclusive engagement strategy with community partners.<sup>3</sup> HealthConnection Clinic worked with the shelter's outreach and community mental health workers, who would accompany clients to the clinic, giving a warm handoff. This enabled clinic staff to garner a more holistic understanding of clients' needs and backgrounds, and to engage with them in a way that enabled longitudinal relationships. Physicians in the ED also started referring clients, as they found the clinic to be an accessible and appropriate service delivery model.

To ensure the clinic was serving the right population, HealthConnection Clinic created the "AMPS tool" to assess clients' biopsychosocial complexity profile; AMPS stands for Attachment, Medical conditions, Psychological/mental health/addictions challenges, and Socioeconomic status.<sup>4-6</sup> The AMPS tool was based on the Minnesota Complexity Assessment Method and was integrated into the Health Authority's electronic medical record (EMR), providing a standard that enables clinicians to assess patient complexity and develop individualized care plans.<sup>4</sup>

To suit the clinic's context, there is a heavy focus on psychiatric, mental health, addiction, and social domains. The "attachment" component aligns to national and provincial policies related to rostering patients with primary care clinicians, which is particularly important for complex subpopulations.<sup>7</sup> It should be noted that AMPS items are meant to function interdependently of each other, to enable a contextualized approach to care delivery. The AMPS tool and user guide is freely available for download online.<sup>4-6</sup>

### HealthConnection Clinic Key Statistics

- *Health care providers:* Three GPs (0.6 FTE total), 3 NPs (2.5 FTEs total), a Social Services Support Coordinator (1.0 FTE), a chronic disease Nurse Coordinator (0.2 FTE), a half-time Team Lead, and 2 Medical Office Assistants (2.0 FTE total)
- *Number of unique clients marked as "active" in the EMR, with at least one care encounter:* 948 (55.6% male; 43.8% female; 0.5% transgender; 0.1% unknown)
- *Mean age of "active" clients:* 53 years (range = 0 to < 90 years)
- *Total visits:* 10,337 (28% walk-in, 11% home visit, 25% consult, 1.1% outreach)<sup>a</sup>
- *Average visits per client:* 8.75 (range = 1-159 visits)<sup>a</sup>
- *Opioid addiction:* 2.1%<sup>a</sup>
- *Clients with 1 or more diagnoses of diabetes, COPD, or CHF:* 13.6%<sup>a</sup>
- *Referrals to specialists:* 1272 referrals for 377 unique clients (mean = 3.4 referrals per client, range = 1-26 referrals)<sup>a</sup>

<sup>a</sup> Data from past 2 years, as of October 2017. Data sourced from Intrahealth Profile Electronic Medical Record (EMR; Intrahealth Systems Ltd, Vancouver, British Columbia, Canada). Note that there is a high possibility of underreporting figures because of coding issues.

CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; FTE = full-time equivalent; GP = general practitioner; NP = nurse practitioner.

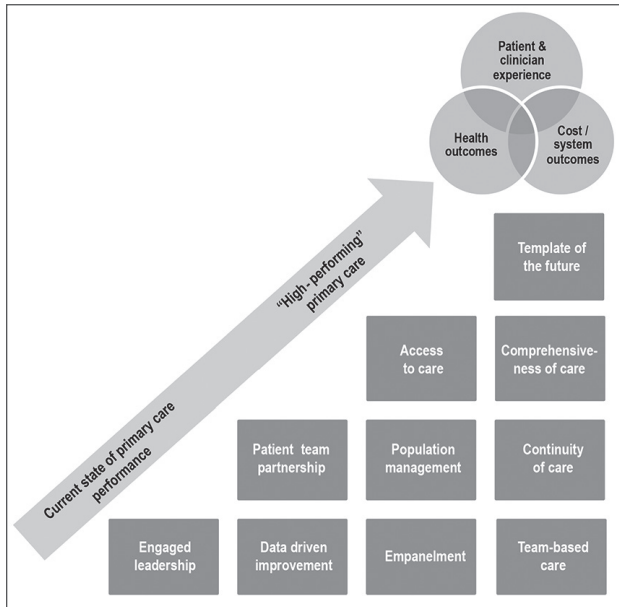


Figure 2. Developmental transition of HealthConnection Clinic.<sup>a</sup>

<sup>a</sup> Equity is a cross-cutting domain (ie, across the 10 Building Blocks and the Triple Aim).

To integrate the social determinants of health and to enable intersectoral coordination, HealthConnection Clinic recruited a former outreach worker at a nongovernmental organization to fill the Social Services Support Coordinator position.<sup>3</sup> Additionally, the clinic provides home visits to unattached housebound clients as well as outreach services to homeless clients.<sup>2</sup>

HealthConnection Clinic benchmarks 30-minute visits per client per primary care clinician and up to 60 minutes per social services support worker. Very-complex-needs clients can be booked for appointments that exceed an hour with a primary care clinician. The BC Practice Support Program was leveraged to establish standardized clinic processes and workflows. Some descriptive statistics of the population and service delivery model are highlighted in the Sidebar: HealthConnection Clinic Key Statistics.

### Aligning with the Broader Policy Context

From its inception, HealthConnection Clinic designed and conducted evaluations to assess its performance and to enable quality improvement, using the Triple Aim framework.<sup>8</sup> As of April 2016, the clinic received sustainable funding from the Health Authority, with the continued proviso of evaluating results.<sup>3</sup> Furthermore, HealthConnection Clinic is part of a primary care network (PCN), a BC provincial initiative that aims to integrate primary care and home and community care services for complex subpopulations.<sup>9</sup> Being part of a PCN enables the clinic to engage with other patient medical homes in the community, to optimize and align planning and strategy functions, share resources, and to participate in quality improvement initiatives.

HealthConnection Clinic is guiding its ongoing development using the University of California, San Francisco's 10 Building Blocks of High-Performing Primary Care approach, which provides a useful heuristic enabling a systematic approach to the ongoing development and evaluation of the clinic as a primary care home.<sup>9,10</sup> Figure 2 illustrates the use of the Building Blocks as a heuristic guiding the clinic's developmental transition, toward manifesting high-performing primary care and achievement of the Triple Aim.<sup>10</sup>

Despite growing policy and research interest, there has been relatively little attention or resources devoted to operationalizing and evaluating the Building Blocks and the patient-centered medical home (PCMH) models in public community health center settings.<sup>11-16</sup> Such research is particularly salient in light of recent proposals for major expansions of community health centers (CHCs) in the US.<sup>17</sup>

This article contributes to such desired knowledge, by providing a contextual narrative of the development of HealthConnection Clinic and a systematic descriptive evaluation of its content (ie, structures and processes) using the Building Blocks as a framework.<sup>10</sup> Together, the content and context will provide useful and meaningful insights for policymakers, administrators, providers, and academics interested in operationalizing and evaluating primary care serving complex subpopulations. The level of detail provided offers useful information for stakeholders involved in the design and evaluation of CHCs—a blueprint of mechanics (ie, structures and processes) as well as a synthesis of key innovations and challenges.<sup>18</sup> We hope that this article will fill a major gap in the health services research literature.

### METHODS

The study was based on a developmental evaluation approach, with the VCH Regional Primary Care Evaluator embedded as part of the HealthConnection Clinic team, from March to December 2017. The developmental evaluation was underpinned and guided by the University of California, San Francisco's Center for Excellence framework in Primary Care's 10 Building Blocks of High-Performing Primary Care.<sup>10</sup>

The framework was operationalized using both qualitative and quantitative data. Qualitative data were gathered using participative observation, document analysis, emails, and a series of meetings and iterative analytical processes with clinic team members. Quantitative data regarding the clinic's client population and health care utilization were derived from the primary care EMR (Intrahealth Profile EMR, Intrahealth Systems Ltd, Vancouver, British Columbia, Canada), the Patient Automated Records Information Systems (PARIS Home and Community Care EMR), and hospital administrative databases. These databases were queried by VCH's Decision Support Team and Practice Support Program, to generate simple descriptive statistics (Tables 2, 3, and 4). Quantitative patient experience data were derived using VCH's client experience survey tool, which was developed using the BC PREMS (Patient Reported Experience Measures) Steering Committee's indicator bank.

Themes and data were organized and synthesized according to the key primary care system domains of the 10 Building Blocks

framework, using thematic content analysis where appropriate. Data were input and updated into a central document, and were triangulated by each team member using the track changes feature of a word processing program (MS Word, Microsoft, Redmond, WA). The final draft was reviewed by the clinic’s team for accuracy and completeness.

**RESULTS**

**Leadership and Governance**

Although officially designated as a Health Authority clinic, the HealthConnection Clinic originated as, and remains, a formal collaboration between the North Shore DFP and VCH. The joint governance is operationalized through the Collaborative Services Committee, in which the senior leadership of both groups meet to collaboratively address key issues.

At an organizational level, a Health Authority Manager and DFP physician were the key players in the original design, implementation, and ongoing management of the clinic. Whereas HealthConnection Clinic is accountable for staffing, financials, safety, and client relations to the Health Authority, the GP component is accountable to the DFP. A Health Authority Manager and half-time (0.5 FTE) Team Lead oversee the clinic operations in consultation with a Medical Director from the DFP. Staff at HealthConnection Clinic address standardization of practices, use of the EMR’s components, billing procedures, and administrative office processes on a quality improvement basis. Clinical leadership and governance is provided by a DFP physician and the clinic’s NPs.

Community governance is central to the clinic, with community partners formally engaged from the outset in relation to the design, organization, staffing, and delivery of services. A Patient Advisory Committee provides feedback, used to improve clinic operations.

**Team-Based Care**

Services at the clinic are delivered by a multidisciplinary team, as mentioned in the Sidebar: “HealthConnection Clinic Key Statistics.” The Social Services Support Coordinator is frequently the first person seen by clients, which opens a window of opportunity to encourage clients to receive care from the GP or NP, who subsequently engage the required allied professionals.

The multidisciplinary team is designed to be person-oriented, and is therefore oriented around problems and needs rather than functions or roles. The team structure is flexible and inclusive, encouraging collaboration, sharing of ideas, and utilization of all staff. Team members work to full scope (eg, NPs are able to prescribe controlled drugs such as analgesics or buprenorphine-naloxone [Suboxone]), and they collaborate to consolidate extremely complex medical histories and to design appropriate care plans.<sup>19</sup> A strength deployment inventory (half-day session consisting of a professional facilitator and brief standardized assessment tools) was used to help the team understand the value and contribution of each member and to explore optimal mechanisms of teamwork and collaboration. Also, HealthConnection Clinic plans to use its EMR data (eg,

**Table 2. AMPS complexity score breakdown by age range<sup>a</sup>**

Active patients with complexity score in last 12 months (December 2017)				AMPS complexity score (maximum possible points)									
Age, years	Male	Female	Total	Total (33)		A: Attachment (3)		M: Medical (6)		P: Psychiatric-mental health-addictions (12)		S: Social support (12)	
				Mean	Median	Mean	Median	Mean	Median	Mean	Median	Mean	Median
Total	73	55	128	14.38	14	1.84	2	2.78	3	5.36	5	4.40	4
0-20	0	1	1	3		3	3	0	0	0	0	0	0
20-29	10	5	15	13.67	15	2	1	1.20	0	6.40	7	4.13	4
30-39	7	10	17	12.71	13	1.88	2	1.53	1	5.12	5	4.18	4
40-49	19	8	27	16.00	14	1.59	1	2.89	3	6.52	6	5.00	5
50-59	15	12	27	14.89	15	1.93	2	3.30	4	5.63	5	4.04	4
60-69	15	11	26	15.62	14.50	1.88	2.50	3.35	3.50	5.12	5	5.27	5
≥ 70	7	8	15	11.73	11	1.80	2	3.87	4	2.80	3	3.27	3

<sup>a</sup> Source: Intrahealth Profile electronic medical record (EMR; Intrahealth Systems Ltd, Vancouver, British Columbia, Canada).

**Table 3. AMPS complexity score breakdown by sex<sup>a</sup>**

Sex	AMPS complexity score (maximum points possible)									
	Total (33)		A: Attachment (3)		M: Medical (6)		P: Psychiatric-mental health-addictions (12)		S: Social support (12)	
	Mean	Median	Mean	Median	Mean	Median	Mean	Median	Mean	Median
Total (N = 128)	14.38	14	1.84	2	2.78	3	5.36	5	4.40	4
Male (n = 73)	15.67	9	1.86	2	2.89	3	5.82	3	5.1	5
Female (n = 55)	12.65	14	1.8	2	2.64	3	4.75	5	3.47	3

<sup>a</sup> Source: Intrahealth Profile electronic medical record (EMR; Intrahealth Systems Ltd, Vancouver, British Columbia, Canada).

length and type of visit; AMPS scores) to rigorously optimize staffing ratios and teamwork relative to patient complexity.

As a prototype PCN, HealthConnection Clinic has home-visiting NPs collaborate with a multidisciplinary team of home and community care providers who include nursing support, occupational therapists, physiotherapists, a social worker, a dietitian, a pharmacist, and a program assistant.

### The Panel

Attaching people to primary care is a pan-Canadian priority and is particularly important for complex and vulnerable subpopulations.<sup>17-21</sup> HealthConnection Clinic supports this priority by providing supportive, low-barrier primary care for unattached residents with complex needs. Identifying and attaching such patients to primary care is particularly challenging because of the chaotic nature of these patients' lives, along with the transitory nature of their housing situations.

HealthConnection Clinic designed the AMPS tool to accurately assess and address the complex biopsychosocial needs of the subpopulations it serves.<sup>4</sup> The AMPS scores help inform clinical judgment regarding which individuals to consider as having appropriately complex needs for the clinic (a total score of at least 13 of 33 is generally perceived to be a threshold for attachment) and to enable care planning functions and evaluation.<sup>6</sup> Tables 2 and 3 show disaggregated descriptive statistics of AMPS scores for active clinic patients.

Attachment is ultimately enabled through empanelment, which is one of the 10 Building Blocks of Primary Care and a prerequisite for basic functions related to population health needs planning, performance assessment, and quality improvement.<sup>10,22</sup> The Health Authority is currently in the process of developing standards for empanelment, for example, assigning most responsible clinician (referred to as Most Responsible Provider [MRP] in Intrahealth EMR) and point of service in the EMR. Assigning point of service is challenging because the EMR is shared across all the Health Authority's owned and operated primary care clinics (eg, transient clients may use multiple services by different clinicians at different Health Authority clinics). Assigning MRP is also challenging because nonclinical staff (eg, the Social Services Support Coordinator) are often the de facto MRP for patients with highly complex needs who are averse to or refuse medical care.

### Data-Driven Improvement and Population Management

Data sources to inform data-driven improvement include Intrahealth Profile EMR, PARIS, and hospital databases. Substantial attention and resources are being devoted toward standardizing EMR data entry rules and evidence-based clinical workflow processes. The EMR and administrative data sources, along with standardized organizational, health care team, and patient experience surveys are being used to operationalize a Triple Aim-oriented evaluation framework. Results from an inaugural VCH patient experience survey are undergoing evaluation for quality improvement purposes. The commitment to rigorous, comprehensive, and standardized evaluation is supported by the sustainable funding that was obtained as

**Table 4. Health care utilization indicators for HealthConnection Clinic clients**

Utilization indicator	% change in 2017 vs 2016
Home health/home support visits (case management, nursing, occupational therapy, and physiotherapy)	+48.7
Emergency Department (ED) visits	-2.9
ED visits with admission (Canadian Triage and Acuity Scale 4 and 5)	-13.5
Hospital admissions	-12.7
Average length of stay per admission	-11.8

of 2016. The Health Authority is currently in discussions with the Doctors of BC to explore the possibility of adapting the provincial patient medical home Self-Assessment Tool (BC's version of the University of California, San Francisco's Building Blocks of Primary Care Self-Assessment Tool), to better suit the unique context of public CHCs.

The Health Authority is also developing standardized workflows for high-priority clinical conditions such as HIV, hepatitis C, type 2 diabetes, chronic obstructive pulmonary disease, depression, and psychosis. Currently, HealthConnection Clinic is in the early stages of developing standards around opioids and addiction, and is anticipating introduction of opioid agonist therapy as a maintenance service to patients over the coming months.

### Access

HealthConnection Clinic has designed its service delivery model with specific attention to cross-cutting dimensions of access.<sup>20</sup> The storefront location clinic is accessible to those with disabilities and is open weekdays. The mornings are for walk-ins, whereas appointments are available during afternoons. The clinic is close to the local hospital and is in the downtown area, close to public transit and police. Waiting rooms have magazines, adult coloring books, food, coffee, and water. During special seasons such as Christmas, cards and other games and activities are made available.

If the clinic is busy in the mornings, clients are triaged and offered appointments that afternoon or the next day. Two afternoons a month are reserved for staff meetings and administrative purposes. Because of a lack of funding, no after-hours, weekends, or holiday services are available; however, the clinic has opened during statutory holidays for half-days on occasion to reduce ED utilization surges.

Homebound patients are seen by an NP, the Social Services Support Coordinator, and the PCN team as needed; furthermore, NPs, the Social Services Support Coordinator, and community agency outreach workers visit areas where homeless people are located.

### Comprehensiveness

HealthConnection Clinic provides comprehensive primary care services addressing the complex biopsychosocial needs and challenges of their clients (ie, housing, food security, nutrition,

addictions, social isolation), supported by the multidisciplinary composition of the team. The clinic offers standard health promotion and illness prevention services, primary care for minor or episodic illnesses, primary reproductive care, chronic disease management, mental health and substance use services, and coordination and access to rehabilitation, as well as support for hospital, home, and long-term facility care and support for terminally ill individuals. HealthConnection Clinic is commencing a formal partnership with the Health Authority's Mental Health and Substance Use Program to integrate mental health services on-site for clients (eg, opioid agonist therapy).

Also, HealthConnection Clinic accesses local community-based chronic disease management and public health services. Some chronic disease management services have also coordinated with the clinic so they can arrange to see clients on-site. This removes access barriers and enables clients to receive these services in a familiar, trusted, and safe setting.

### Coordination

Coordination of care is a challenging yet critical function of the clinic. Clients with extremely complex and continuously changing biopsychosocial problems receive care from a large number of multidisciplinary clinicians cutting across oft-siloed sectors. The BC Provincial eHealth Viewer, CareConnect, which is embedded in the EMR system, is potentially especially useful, because it enables clinicians to understand health care utilization of patients. CareConnect could enable better coordination of care across sectors, because it is an online portal that provides authorized caregivers a secure, view-only access to integrated clinical information from various sources, including provincial laboratory results), diagnostic imaging, hospital encounters, community summaries (PARIS), and PharmaNet (the provincial drug information and claims processing system that links all community pharmacies in BC).

HealthConnection Clinic continues to strengthen processes related to coordination with hospitals (eg, discharge planning, medication reconciliation); community-based programs (eg, use of PARIS, PCN initiative, and the "Care Conferencing" function); mental health and substance use programs (ie, integration with outreach teams for clients with addictions); public health services (eg, harm reduction, naloxone programs); community agencies and nongovernmental organizations; and other CHCs and private-community GPs.

### Continuity

Maintaining continuity of care for clients with highly complex needs is extremely important and challenging.<sup>23</sup> Many of the clinic's clients are transient and receive different services from different clinicians across the Health Authority (and even other Regional Health Authorities). HealthConnection Clinic has processes in place to ensure routine follow-up with the vulnerable subpopulations it serves, such as homebound and homeless individuals. Systematic and routine follow-ups are performed for critical planned care functions for patients with hepatitis C and HIV. The Health Authority is currently developing standards for empanelment, which will enhance continuity of care.

### Patient-Team Partnership

Patient engagement, let alone activation and empowerment, is difficult for many of the clinic's patients. For many patients, traditional goal-setting approaches are not realistic, appropriate, or desirable. HealthConnection Clinic promotes the use of approaches that are sensitive to the contexts of patients' lives, which are often chaotic and precarious. For example, the clinic does have a chronic conditions nurse who has the ability to provide self-management guidance and supports; however, these functions are often not appropriate for clients with highly complex needs. Enabling patient adherence and compliance is a challenge, often achieved by having clients come in almost daily for medications (eg, pain) or to do certain tests (eg, urinalysis). After-visit summaries are provided to patients verbally and are printed out if requested. Longitudinal relationships with the NP have enabled successful chronic disease management for some patients.

In addition, the clinic holds inclusive group and self-help activities (eg, for pain) that aim to indirectly support the patient-team partnership. There have also been a number of fun events around holidays, which pull people together in an intentional community. The team also prepares meals for clients, helps create activities for clients to engage in when waiting in the waiting room, and most recently has invited a small group of regular clients to have a meal with the team. The clinic has a Patient Advisory Committee, conducts patient experience surveys and interviews, and has a suggestion box.

### Health Care Utilization (System Outcomes)

The VCH Decision Support Team provides access to updated statistics of the utilization of HealthConnection Clinic's clients of home and community care and hospital (ED and inpatient) services, by querying the respective hospital administrative databases. These metrics are useful proxy indicators of the profile of patients and the potential impact of primary care services over time. Indicators that are routinely reported are volumes and intensity of home health services by discipline (eg, case management, nursing, social work, occupational therapy, physiotherapy); ED visits (eg, disaggregated by admission status, Canadian Triage and Acuity Scale, Chief Complaint, Family Practice Sensitive Conditions), and hospital admissions indicators (eg, alternate level of care, length of stay), as shown in Table 4.

## DISCUSSION

This study demonstrates how the 10 Building Blocks of High-Performing Primary Care can be adapted to inform the development and evaluation of primary care for complex subpopulations. Vancouver's HealthConnection Clinic is reaching a mature state of primary care development and provides valuable insights related to the development of foundational elements of the Building Blocks framework, particularly *engaged leadership, empanelment, and data-driven improvement*.<sup>10</sup>

### Engaged Leadership

HealthConnection Clinic represents what is possible when highly engaged leadership from a Health Authority and DFP

share a common vision and purpose.<sup>3</sup> The clinic highlights an alternative to the generic problems that Canadian policymakers, administrators, and clinicians face when attempting to integrate multisectoral services cutting across differing governance, funding, and accountability streams.<sup>24</sup> It demonstrates that a satisfactory degree of integrated person-oriented primary care can be achieved within the confines and limitations of the current system.

Unlike the common practice of most shared governance endeavors, the leadership of both the Health Authority and DFP purposefully chose to delay a formal memorandum of understanding. Rather than basing their partnership understanding in a bureaucratic or legal document, they relied on mutual trust, honest communication, and a profound respect for one another. Although the leadership team recognized that a memorandum of understanding is useful to limit liability, the leaders recognized that successful integration would only be truly possible if they were willing to take a certain degree of risk. The risk was tempered by a high level of trust and a mutual understanding of institutional and regulatory requirements and boundaries.

Rather than being risk-averse, the archetypal attribute of bureaucratic governance, the leadership team exhibited classic attributes of entrepreneurialism: A willingness to take risk, goal orientation, creativity, resourcefulness, confidence, flexibility, adaptability, self-reflexivity, learning, inclusivity, and an interest in promoting and marketing the HealthConnection Clinic brand (Figure 2).

The leadership team shared a clear purpose and vision relating to effectively addressing the unmet biopsychosocial needs of highly complex, vulnerable, and marginalized subpopulations. They recognized the need to think outside the box; they were therefore keen on leveraging and adapting available resources, and engaging and coordinating with diverse multisectoral and local community partners. This study provides an example of how the PCMH can be operationalized as a community-based strategy.<sup>25</sup> Evaluation, continuous reflection, and learning were, and remain, cornerstones of the evidence-based development of the clinic.

### The Panel: Identifying and Assessing Biopsychosocial Complexity and Needs

The entrepreneurial attributes of the leadership team were underpinned by a genuine drive to meet the needs of their clientele—their panel. It was therefore critical to develop effective and efficient mechanisms to identify appropriate clients, encourage their enrollment, and to comprehensively and accurately understand their complex biopsychosocial needs.

Vulnerable populations are often the hardest to find and identify; therefore, the clinic was designed to operationalize low barriers to accessibility. It is within walking distance of the local hospital, which has enabled ED physicians to make effective referrals. The leadership engaged with homeless shelters and nongovernmental organizations, whose workers would accompany clients to the clinic. This personalized approach enabled clinicians to garner a holistic understanding of clients' needs, to develop longitudinal relationships, and to coordinate with other service providers.

Understanding the nature of the clinic panel's needs remains a priority of the clinic. Assessing patients' biopsychosocial complexity using a standardized and consistent approach is critical in HealthConnection Clinic, because it serves a population labeled as highly complex, often with a history of challenging patient-clinician relationships (eg, the difficult patient who has been recently "fired" by his/her GP). Such patients are often described as overserved but underserved. However, it is important to note that it is perceived that many clients presenting at the clinic are both underserved and underserved.

**Assessing patients' biopsychosocial complexity using a standardized and consistent approach is critical ... because it serves a population labeled as highly complex, often with a history of challenging patient-clinician relationships ...**

After reviewing the scientific literature on the measurement and assessment of patient complexity, the leadership team found that published research to be scant. The leadership team decided to adapt the Minnesota Complexity Assessment Method to suit HealthConnection Clinic's needs, resulting in the development of the AMPS tool.<sup>4,6,26</sup> The AMPS tool is now embedded as a standardized form in the Health Authority's EMR system and is being tested across its clinics. Composite and disaggregated AMPS complexity scores are used to assess service utilization and to inform evaluation, planning, and design functions.

### Rostering and Empanelment

The AMPS complexity scores can also inform the formal processes of EMR rostering and empanelment. The Health Authority's empanelment work is building on the guidance of BC's Practice Support Program, the University of California's Center for Health Quality and Innovation and Center for Excellence in Primary Care ("Tools for Transformation"), and the Safety Net Medical Home Initiative empanelment resources.<sup>24-28</sup> The Health Authority has also leveraged empanelment research by the Ontario Association of Health Centers.<sup>29,30</sup> The recent attention to empanelment by the Federally Qualified Community Health Centers has yielded valuable insights and is encouraging.<sup>22</sup>

Like the Ontario Association of Health Centers, the Health Authority has learned that empanelment processes for its system of public primary care clinics are more complicated than for community GP settings.<sup>22</sup> First, the Health Authority must consider the transient nature of patients with highly complex needs. These patients are often difficult to follow-up with and may access several of the Health Authority's clinics. Although this is a positive sign of low-barrier care, it renders aspects of continuity and "longitudinality" of care (continuity over time) challenging. The lack of integration with the community GPs' EMRs also makes it difficult, if not impossible, to accurately assess utilization to inform empanelment decisions.

The experience of HealthConnection Clinic also challenges the notion of having to designate an MRP, which is found in

much of the contemporary primary care literature. Designations of MRP in the clinic can be rather arbitrary, because the whole of the team supports clients. Furthermore, nonclinical staff may be the de facto MRPs; for example, the Social Services Support Coordinator often has the most comprehensive relationship with clients who are either reluctant to receive medical care or refuse it outright.

The concept of MRP within the context of CHCs serving complex subpopulations warrants further research and policy attention. Studies have demonstrated that CHC patients receive higher quality care when they have a regular provider and that continuity with the CHC and with a specific clinician is associated with increased levels of appropriate preventive ambulatory care.<sup>31-33</sup>

### Data-Driven Improvement

The clinic and Health Authority in general are focusing on the development and testing of data and measurement standards to systematically assess primary care performance. The priorities are to 1) develop EMR standards for panel management and data input and output; 2) standardize the measurement of patient experiences, caregiver/family experiences, and clinician experiences; 3) standardize organizational surveys; and 4) standardize the measurement of patient-reported outcomes. The focus will be on testing possible tools and ensuring alignment across Health Authority, provincial, and national standards.

Currently, HealthConnection Clinic is piloting the development and testing of evaluation tools, to inform decisions related to broader rollout across the Health Authority. This evaluation work also has broader national and international implications because it will inform the development of tools specifically tailored to meet the needs of CHCs serving marginalized, vulnerable, and highly complex subpopulations.

### Reflections on the Building Blocks Developmental Approach

The 10 Building Blocks approach is proving to be a valuable and practical heuristic that enables systematic assessment of the current state of primary care development.<sup>10</sup> Using the approach with diverse stakeholders involved in the development of primary care has enabled recursiveness and self-reflection, thereby promoting a culture of evaluation and a synthesis of diverse worldviews. The approach provides a common framework that enables different stakeholders to reflect on and evaluate their activities with a wider contextual lens.

The framework also enables systematic, efficient, and effective cross-learning. A simple descriptive evaluation outlining the core content (ie, standard structures and processes) of each PCMH should be considered basic good practice because this would enable effective communication and comprehensive understanding between clinical sites and regions. The Building Blocks could enable alignment in relation to the development of primary care standards for CHCs in Health Authorities as well as provincially and internationally.<sup>11,13-15,23</sup> This study also highlights the importance of incorporating community orientation and equity within the Building Blocks and PCMH approaches.<sup>14,25</sup>

## CONCLUSION

There is growing research and policy interest in relation to operationalizing the attributes of high-performing primary care in community health settings.<sup>11,13</sup> This study demonstrates how the framework and tools of the 10 Building Blocks of High-Performing Primary Care are enabling the development and evaluation of primary care services for vulnerable and complex subpopulations. This study provides valuable insights related to the development of foundational elements, particularly engaged leadership, empanelment, and data-driven improvement. HealthConnection Clinic demonstrates what is possible when highly engaged leadership share a common vision and purpose, and it highlights the importance and effectiveness of entrepreneurialism and innovation. The clinic's innovative evaluation work will inform the development of evidence-based tools specifically tailored to meet the needs of public primary care clinics serving highly complex and marginalized subpopulations. ❖

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

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### Author Contributions

*Ali Rafik Shukor, MSc, is the developmental evaluator who conceptualized the article and collected and synthesized data. Ali Rafik Shukor, MSc; Sandra Edelman, MA; Dean Brown, MD; and Cheryl Rivard, MA, jointly analyzed and interpreted data, and drafted the content of the article.*

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Keywords: community health centers, complexity assessment, patient-centered medical home, primary care home, ten building blocks of primary care

## Know Life As It Is

It is a happy sign of the times when medical men understand that they must study sociology, that they must appreciate economic conditions, that they must face the facts and know life as it is, and not as their wishes would have it to be.

— Denslow Lewis, MD, 1856-1913, American physician and author



# Cognitive Behavioral Therapy with Heart Rate Variability Biofeedback for Adults with Persistent Noncombat-Related Posttraumatic Stress Disorder

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## ABSTRACT

**Objective:** To test the effectiveness of a mental health therapy designed to reduce noncombat-related persistent posttraumatic stress disorder (PTSD) symptoms in 30 adult outpatients with a diagnosis of PTSD. The individual treatment offered modules to address PTSD nightmare distress, dissociation, general core skills, alterations in arousal and reactivity, avoidance, intrusion, and negative alternations in cognitions and mood. The therapeutic approach centered on cognitive behavioral therapy and heart rate variability biofeedback.

**Methods:** The study had 2 components: The quality improvement project that performed the treatment within a standard care environment, and a retrospective medical chart review process that analyzed the results. The Clinician-Administered PTSD Scale for the *Diagnostic and Statistical Manual, Fifth Edition*, was used to confirm the initial PTSD diagnosis and was the primary measure used to monitor change in the diagnosis following treatment.

**Results:** None of the patients who completed the PTSD treatment met criteria for a PTSD diagnosis in the posttreatment assessment. A 1-sample test of proportions, with a 95% confidence interval and a significance level of  $p < 0.05$ , showed  $p = 0.0008$ , and that the proportion of patients who would not have PTSD if the study was repeated would be 86.77% to 100.00%. The treatment dropout rate was 13% (4 patients).

**Conclusion:** The study findings suggest that this intervention is an effective treatment for helping adult patients, including those with a history of childhood abuse, remit their PTSD diagnosis.

## INTRODUCTION

Epidemiology studies have estimated lifetime rates of post-traumatic stress disorder (PTSD) in the US to range from 6.8% to 16.6%, with the current (past 12 months) PTSD prevalence ranging from 3.5% to 9.1%.<sup>1-3</sup> By its very definition, PTSD entails having many disabling and/or significantly distressing symptoms related to exposure to at least one traumatic experience.<sup>4,5</sup> Those who have PTSD can have significant increases in overall medical issues and expenses independent of their PTSD diagnosis.<sup>6-8</sup> Persistent PTSD, which indicates having PTSD symptoms for more than 1 year,<sup>1</sup> and exposure to many traumatizing events and/or exposure at a younger age seem to

be related to a more complex picture.<sup>9-12</sup> Having treatments to efficiently and effectively address the suffering and costs of PTSD is of great importance.

The objective of this study was to examine the effectiveness of a PTSD treatment that was designed to help clinicians incorporate the important lessons gained from research with the unique needs of individual patients, all within the context of a fast-paced, real-world practice. Because this study took place in a setting where it was not possible to have a control group, it was important to select patients who were not likely to have their condition change simply owing to the passing of time. In their epidemiology study, Kessler et al<sup>1</sup> report that most people who have been through a traumatizing event have their symptoms disappear within months, but if those symptoms persist for a year, people are less likely to remit from their PTSD diagnosis. In our study, all of the patients had PTSD symptoms for more than a year, with 29 of 30 dealing with those symptoms for more than 5 years. The intention of this study was to create a flexible protocol that could be used by a range of licensed mental health clinicians without prolonged additional training and supervision and still be effective with patients with co-occurring issues and other complexities, such as early age of exposure to traumatic events and a persistence of PTSD symptoms over time. This article describes the procedure of the study in extended detail to enable clinicians to replicate and more fully understand the treatment.

There is no one specific standard to determine whether mental health treatment for PTSD is effective. One credible way to determine effectiveness of treatment is to determine whether patients no longer qualify for a PTSD diagnosis by the end of their treatment.<sup>13</sup> We used this method to measure treatment effectiveness. Because our study did not have a control group, we used the rates of effectiveness in controlled studies that had similar populations and similar measurements to set a cut point (a target) for what proportion of patients needed to remit their PTSD diagnosis for it to be considered an effective treatment. In 2 meta-analytic studies that examined the results of 32 studies and more than 50 treatment conditions, the rate of patients no longer having a PTSD diagnosis after PTSD-specific treatment was approximately 70% and approximately 50% to

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60% for those who entered (but did not necessarily complete) PTSD-specific treatment.<sup>14,15</sup> The results in our study surpassed those results: 100% of patients who completed treatment and 87% of patients who entered treatment no longer had a PTSD diagnosis immediately following treatment. Statistical analysis suggests that if the study were replicated with other patients with PTSD, it could continue to surpass the rates of PTSD diagnosis remission in the meta-analytic studies.

## METHODS

### Participants

This study involved 30 adult outpatients in the Mental Health Department within an outpatient medical facility at Kaiser Permanente Northwest. The patients were referred to the PTSD treatment by mental health clinicians at that facility who had initial contact with the patients. The referral criteria were very broad: English-speaking adults with noncombat-related PTSD. Many patients who participated in the treatment had a range of co-occurring conditions and several had substantial suicidal ideation and/or substance abuse issues. There were 22 female patients (73%) and 8 male patients (27%). The mean age was 44 years (range, 20–65 years); 21 (70%) of the patients were white, 5 (17%) were Other (Native American, African American, or mixed race), and 4 (13%) were Asian American. The majority (20 [67%]) were married or cohabitating with 5 (17%) divorced or separated and 5 (17%) single. Table 1 provides traumatic experience details for all patients in the study; Table 2 lists co-occurring disorders.

### Procedure

In this study, all treatment was provided by one master's-level clinician who was licensed to provide mental health therapy in Oregon, the state where the study occurred. The overall treatment protocol can be conceptualized as individual cognitive behavioral therapy with heart rate variability biofeedback. It was intended both to reduce PTSD symptoms and to provide skills for future resilience in the face of stressors. The treatment was organized into several modules that correspond to common PTSD symptoms or frequently needed skills: Nightmares, dissociation, general core skills, hyperarousal and reactivity, avoidance, and negative cognitions and moods. Patients completed only the modules that were relevant to their specific profile of PTSD symptoms. The demonstrated acquisition and mastery of the skills to address each area of symptoms determined how many sessions were allocated to each topic. Treatment length varied from 6 to 14 sessions with an average of 11 weekly sessions.

The biofeedback component of the treatment was central in the hyperarousal and reactivity module. A variety of handouts and worksheets were provided to help guide patients with their home practice between sessions and to use in the future to remember skills, successes, and motivations and thus prevent and/or assist them with any relapses of symptoms.

When patients practiced skills between sessions, they often faced challenges, which they discussed with the therapist. Refinements in how to apply skills were made. This sometimes resulted in scripts and/or reminders that could be accessed

when needed. To be considered acquired, each skill was both demonstrated in session and declared consistently and successfully used outside of the session by the patient.

The initial session was designed to assist with building therapeutic rapport and momentum. This orientation-to-treatment session included goal setting, psychoeducation, and teaching a few basic skills.

The process of evaluating the patient's PTSD is, in itself, an exposure experience (ie, patients are deliberately thinking and talking about memories of the trauma and its effects). It can be clinically inappropriate to put people into that experience

**Table 1. Traumatic experience details for all patients in the study of a therapy to reduce noncombat-related PTSD symptoms (N = 30)**

Variable	No. (%)
Type of DSM-5 traumatic experience <sup>a</sup>	
Childhood physical and emotional abuse	18 (60)
Childhood sexual abuse	10 (33)
Adult physical and emotional abuse	3 (10)
Adult sexual assault	2 (7)
Death of other(s)	3 (10)
Time since traumatic experience	
> 10 years	27 (90)
5 - 9 years	2 (7)
1 - 4 years	1 (3)
History of child abuse	
At least 1 type of child abuse	29 (97)
2 or more types of child abuse	25 (83)

<sup>a</sup> 6 individuals had physical and emotional abuse and sexual abuse. DSM-5 = *Diagnostic and Statistical Manual, Fifth Edition*; PTSD = posttraumatic stress disorder.

**Table 2. Co-occurring disorders for all patients in the study of a therapy to reduce noncombat-related PTSD symptoms<sup>a</sup>**

Variable	No. (%)
Medical diagnoses	
Chronic pain	12 (40)
Insomnia	10 (33)
Obesity	10 (33)
Asthma	9 (30)
Obstructive sleep apnea	8 (27)
Diabetes	7 (23)
Migraine	7 (23)
GERD	6 (20)
Mental health diagnoses	
Depression	21 (70)
Generalized anxiety disorder	14 (47)
Panic disorder	5 (17)

<sup>a</sup> This table includes information for all 30 patients in the study regarding diagnosed conditions with 5 or more participants. Although only 10 participants came into the PTSD treatment with an insomnia diagnosis, 21 (70%) of the patients in this study met the Clinician-Administered PTSD Scale for *Diagnostic and Statistical Manual, Fifth Edition* clinical threshold for sleep disturbance. GERD = gastroesophageal reflux disease; PTSD = posttraumatic stress disorder.

without making sure they have the skills to deal with it and without showing them how the process of evaluation itself can contribute to healing. In contrast, it is clinically valuable to use the assessment process overtly as part of the treatment. This is more likely to occur if patients know how to use the assessment process proactively.

Distress tolerance (effectively and actively dealing with the experience of distress), physiological calming (calming the body in the face of stress and/or distress), and self-soothing (self-talk and/or behaviors that are supportive to oneself) were discussed and practiced in the initial session. Patients were encouraged to use nonjudgmental self-talk and curiosity. The therapist had patients practice self-talk out loud to assess the use of the skill. Emphasis was placed on the curative value of facing the basic details of their story of trauma and survival without avoiding their emotions or judgments. They practiced how to focus their attention in a way that acknowledges, rather than avoids, discomfort while proceeding with what they choose to do in the moment. Patients were provided with psychoeducation about how avoidance can increase PTSD symptoms and how, with exposure, it is important to allow the experience of distress.

Session 2 and, at times, session 3, comprised administration of the Clinician-Administered PTSD Scale for the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (CAPS-5)*, past month version, including the Life Events Scale-5. Emphasis was placed on the process of the assessment as well as the content of the scales. Patients were taught how to use their physical, mental, and emotional awareness to monitor and to pace themselves during the session.

After the assessment, patients progressed through treatment modules in sessions 3-14. Those with distressing nightmares started with the nightmare treatment protocol. It is possible to have nightmares that do not cause distress. If the nightmares were not distressing, this module would not have been provided. In this study, before treatment every patient who reported nightmares reported that they were distressing. Those with moderate-to-high levels of dissociation started the dissociation protocol after the nightmare protocol if they also had distressing nightmares, or immediately if they did not have distressing nightmares. The rationale behind this sequencing is that sleep issues related to distress caused by nightmares and the process of dissociation can interfere with the benefits that can otherwise be achieved in treatment.

#### Nightmares Module

This module took 1 to 3 sessions and was reviewed as needed throughout the treatment. The basic technique used was modified Image Rehearsal Therapy, which involved writing down, drawing, or talking about a recent nightmare; changing a detail of the dream in a way that seems helpful to the patient and was positive; and then rehearsing the changed dream frequently throughout the day. Patients practiced this skill in-session until they felt confident about being able to do it on their own. The therapist helped them refine their practice. The patients gave

reports about their use of the skills between sessions. Although many patients had fewer nightmares, the target was reducing distress, not reducing the nightmares themselves. The key skill was effectively using image rehearsal to reduce distress accompanying PTSD nightmares.

#### Dissociation Module

Many patients with PTSD experience depersonalization where they feel distant from themselves and/or derealization where things in the world don't feel real. Those experiences are dissociative. At times patients with dissociation can even lose conscious memory for parts of their experience. If patients dissociated automatically and/or frequently when discussing or thinking about their trauma, it was important for them both to understand what they were doing and to learn alternatives. The therapist and the patients discussed how allowing oneself to be present for one's experience in the moment allows a person to gain more control of choices. It also teaches that person that most situations are safe. The patients were taught skills to help them be present in the moment.

Mindfulness was introduced as a way to notice internal and external experiences nonjudgmentally while expanding awareness of these experiences beyond habitual patterns. In this context, mindfulness indicates having conscious awareness of these internal and external experiences in a new and more helpful way that includes less negative self-talk and less distress. Recognizing, labeling, and regulating emotions were an important part of this module. Patients were given rationales for being present in the moment, even if they felt uncomfortable. Examples of potentially compelling reasons to be present included helping individuals to feel closer to people they care about, improving parenting, or achieving a sense of mastery by using the cognitive and other resources to deal with distress without dissociation. A list of pros and cons of dissociating was developed. From this list, patients created individualized affirmations, which they used to focus on being present (even when uncomfortable). There was discussion about viewing life experiences on a continuum instead of in absolute terms (eg, 0%-100% dissociated or associated). Patients were asked to develop a written statement about how and when dissociation was helpful and a list of alternatives to dissociation, noting times they have successfully used them, even when distressed.

Most patients with this issue had 1 to 3 sessions specifically focused on learning the skill of being present even when distressed. The skill was refined and strengthened during the core module. Patients were encouraged to practice mindfulness skills every day.

#### General Core Skills Module

In this module, all patients received treatment related to healthy incorporation of the trauma into their definition of themselves and the world. Many of the core skills they learned focused on how to change threat-related thinking patterns and how to decrease their anxiety response. The target was to

... allowing oneself to be present for one's experience in the moment allows a person to gain more control of choices. It also teaches that person that most situations are safe.

experience discomfort without responding as if it is necessarily dangerous.

General core skills materials were offered toward the beginning of the module, although specific handouts related to additional categories of skills were provided when those skills were taught (ie, not all patients focused on and completed all worksheets, although everyone used the core skills handout and worksheet). Throughout the modules, patients were directed back to worksheets and handouts that they had used before in order to add depth of understanding and to see how many of the skills and ideas applied across situations. The order of the skills and sections was sometimes changed to accommodate individual needs. In the general core skills module, the key for the patients was developing healthy perceptions of themselves and the world and learning any combination of other individualized skills that was needed to attain this.

#### **Hyperarousal and Reactivity Module**

Patients learned skills for relaxation, rest, and stress recovery in 1 to 3 sessions. The target was to reduce hyperarousal and reactivity. Hyperarousal and reactivity mean that the patient's level of tension, alert awareness, as well as speed and intensity of responsiveness to internal and external cues were more than the situation warranted. The most important element was for them to develop personalized understanding about how their body responds to a variety of situations, along with the impact/importance of those responses and having a personalized relaxation response that could be used in any setting. Heart rate variability biofeedback assessment and training with the emWave system (HeartMath, Boulder, CA; [www.heartmath.com](http://www.heartmath.com)) was provided. Although additional research is needed, positive changes in heart rate variability have been associated with improvement in many mental health and wellness areas, including reduction of PTSD symptoms.<sup>16</sup>

Patients wore a photoplethysmographic-enabled device on one of their fingers or earlobes. The heart rate variability information gathered from these devices was amplified, filtered, and then displayed on a laptop computer screen to enable patients to see (via pictures on the computer screen) and hear (via tones from the computer speakers) their current heart rate variability information. As they used skills such as paced diaphragmatic breathing, they could see and hear the positive changes that occurred on the computer display. Between sessions, patients would practice the skills they learned in the sessions. In this study, the skill was acquired when the patient reported successful use of the skill outside of sessions and when, without looking at the computer display, patients were in the green "coherence" zone at least 80% of the time on a 3-minute trial. The focus of this treatment module was on resilience and autonomic balance. All patients were given resources and skills that were individualized to their interests, although they were encouraged to practice breathing skills daily and were asked about their use of these skills at each session. The key skill was regular use of strategies that would effectively reduce hyperarousal and reactivity.

#### **Avoidance Module**

An individualized program for becoming comfortable with anxiety and with "triggers" was created. In this context, "triggers"

referred to specific cues that were associated with a patient's traumatic experiences. Patients were instructed both in how to increase their ability to cope with stress and uncertainty and in how to break down stressors into more manageable parts. They set and followed through with goals for exposing themselves to experiences they previously had avoided. Care was given to working with the patient to avoid dissociation and use of inappropriate self-soothing during this important part of treatment. The key skill was facing (versus avoiding) fears and challenges. This was practiced during the session initially with role-play and/or imaginal exposure. The skill was considered acquired when patients had successfully faced situations, people, emotions, and/or thoughts that they had previously avoided. They also discussed with the therapist how they would deal with anxiety and "triggers" without avoiding in the future.

#### **Negative Cognitions and Moods Module**

In addition to psychoeducation about how thoughts and moods differ from reality, patients were taught general skills for identifying and dealing with thoughts and emotions. Efforts were made to provide both conscious articulation of the emotional learning (that supports the symptoms) and juxtaposition experiences (that allow an alternative understanding in which the symptoms are no longer necessary). The key skills included becoming self-collaborative (ie, having the ability to use appropriate self-talk, self-care, and pacing), seeking support and assistance regularly, participating in activities they value, and understanding how to deal effectively with their thinking traps and ineffective behaviors.

#### **Intrusion/Re-experiencing Module**

Patients learned more about boundaries (ie, limits) with others and within themselves. Through discussion and activities, patients practiced how to establish thicker and thinner boundaries, as appropriate to the context.

All patients developed skills to compartmentalize their traumatic experience(s). They learned how to pay enough attention to the traumatic experience(s) to resist avoiding, while also gaining a stronger sense of control over managing their response to "intrusions." For many patients, noticing patterns about intrusions of thoughts, emotions, images, or other sensory input related to the traumatizing event(s) led to a greater understanding of triggers that may have been contributing to the symptoms. The key skills were to clearly express themselves related to the traumatic experience(s), compartmentalization, and awareness of triggers.

The final session and 3-month follow-up sessions each included assessment with the CAPS-5 and a review of progress.

#### **Measures**

The measure that was used to establish the PTSD diagnosis and to measure change within the PTSD symptoms following treatment was the CAPS-5, 1-month version. This scale addresses many aspects of PTSD including the 20 *Diagnostic and Statistical Manual, Fifth Edition*, PTSD symptoms, the dissociative subtype, subjective distress, and the impact of the symptoms on functioning. The CAPS-5 was administered in the initial sessions of treatment, following treatment completion, and 3 months after treatment completion. In addition to

providing a detailed picture of PTSD symptoms, the Life Events Checklist portion of the measure provided an opportunity for exposure where participants told the story of the traumatizing event that initiated their PTSD.

The CAPS-5 is endorsed as a “gold standard” in PTSD assessment and as having excellent psychometric properties.<sup>17</sup> The scale has been used and studied in a range of populations, including adult outpatients with noncombat-related PTSD.<sup>13</sup> Although the primary analysis in this study was based on whether patients met criteria for PTSD after treatment, additional details from CAPS-5 were provided to allow readers to compare results from this study with the results of other studies that use CAPS-5 data in different ways than this study did. In this study, the same clinician who provided treatment administered the CAPS-5.

### Data Analysis

The primary data analysis started by determining the proportion of patients in the study who still had a PTSD diagnosis after treatment. This proportion was then compared with a preset cut point from comparison studies where 70% of patients who completed treatment and 50% to 60% of patients who entered treatment remitted their PTSD diagnosis.

To evaluate the significance of the changes in the proportion of patients with PTSD at the beginning of treatment vs after completion of treatment, statistical software was used to calculate the one proportion test. MedCalc (Ostend, Belgium; www.medcalc.org/calc) was used to calculate the significance level and the confidence intervals. To augment the primary inquiry regarding remission of PTSD diagnosis after treatment for those patients who completed treatment, additional calculations were run to assess the significance of the proportion of all

patients, including those who dropped out of treatment, who no longer had a PTSD diagnosis after treatment.

The CAPS-5 scores for all patients in the study are presented in Table 3. From this grouped but not statistically analyzed data, basic figures are presented to assist readers in comparing more detailed information in this study with other studies that may have used other ways of analyzing similar data to report their results. There were no missing data.

### RESULTS

Of the 26 patients who completed the PTSD treatment, all (100%) no longer met criteria for a PTSD diagnosis in the posttreatment assessment. A 1-sample test of proportions, with a 95% confidence interval and a 5% significance level, showed  $p = 0.0008$  with a confidence interval of 86.77% to 100.00%. The treatment dropout rate was 13% (4 patients). Using intent-to-treat analysis, which evaluates the effectiveness of the treatment for all of the patients, not just for the patients who completed the treatment,  $p = 0.0422$  and the confidence interval is 69.69% to 96.42%.

When this information is considered in light of the likelihood that the patients did not improve from the passage of time alone<sup>1</sup> and that prior controlled studies treating PTSD with mental health therapy achieved a rate of 70% remission from a PTSD diagnosis for those completing treatment<sup>14,15</sup> and a 50% to 60% rate of remission of a PTSD diagnosis for all patients who enter treatment, it lends credibility to the claim that this treatment is effective in helping patients improve their PTSD.

Although remission of the PTSD diagnosis was used as the primary measure of treatment effectiveness, other studies have used different measures. “Several symptom rating scales have been used to define response in PTSD; the most commonly used

**Table 3. CAPS-5 scores for all patients in the study of a therapy to reduce noncombat-related PTSD symptoms<sup>a</sup>**

CAPS-5 Scores	Initial, no. (%)		Posttreatment, no. (%)		Follow-up, no. (%)	
	Yes	No	Yes	No	Yes	No
PTSD diagnosis present	30 (100)	0 (0)	0 (0)	26 (100)	1 (4)	24 (96)
Dissociative subtype	13 (43)	17 (57)	2 (8)	24 (92)	2 (8)	22 (92)
Distressing dreams (B2)	15 (50)	15 (50)	1 (4)	25 (96)	3 (13)	21 (87)
Sleep disturbance (E6)	21 (70)	9 (30)	6 (23)	20 (77)	4 (17)	20 (83)
Score averages <sup>b</sup>						
Average total score for criteria B-E	44.93 (80)		10.46 (80)		8.66 (80)	
Criterion B average	12.5 (20)		3.42 (20)		1.96 (20)	
Criterion C average	5.97 (8)		23 (8)		0.17 (8)	
Criterion D average	15.7 (28)		3.42 (28)		3.29 (28)	
Criterion E average	10.5 (24)		3.27 (24)		2.46 (24)	
Subjective distress average	3.23 (4)		1 (4)		1 (4)	
Social impairment average	2.43 (4)		0.69 (4)		0.67 (4)	
Occupational impairment average	2 (4)		0.69 (4)		0.54 (4)	
Global severity average	2.9 (4)		0.9 (4)		0.75 (4)	
Global improvement average			1.69 (4)		1.63 (4)	

<sup>a</sup> There were 30 patients in the pretreatment group, 26 patients in the posttreatment group, and 24 patients in the follow-up (at 3 months) group.

<sup>b</sup> Average score followed by total possible score for that category.

CAPS-5 = Clinician-Administered PTSD Scale for *Diagnostic and Statistical Manual, Fifth Edition*; PTSD = posttraumatic stress disorder.

definitions are a  $\geq 30\%$  reduction in the Clinician-Administered PTSD Scale or a score of at least 'much improved' (score less than or equal to 2) on the Clinical Global Impressions-Improvement scale," according to Dunlop et al.<sup>18</sup> Both of the criteria proposed for a positive treatment response were met in this study. The posttreatment average global improvement on the Clinical Global Impressions-Improvement scale was 1.69 ( $< 2$ ), and the overall percentage of change in the CAPS-5 total (B+C+D+E) scores was  $-43\%$ , which indicates a  $43\%$  reduction in the CAPS-5 scores ( $\geq 30\%$ ).

All patients who completed the treatment reported that they experienced a reduction in their PTSD symptoms as a result of the treatment. They also said that they appreciated learning the skills and perspectives that they could use in the future. Each patient demonstrated skill acquisition in a session with the therapist and reported successful use of each skill outside of the sessions. The patients noted many positive changes in their lives that were not captured by the changes in their PTSD status and their CAPS-5 scores. Many said that a key element of treatment was having a supportive and knowledgeable person with whom they could discuss their traumatizing experiences.

## DISCUSSION

The most significant limitation of this study was that it was not controlled. The organization where the treatment took place did not permit randomization to various treatments or a wait-list control group. The data analysis could not compare this study's patients with other patients treated in the same site because basic data such as diagnosis and change in PTSD symptoms were not tracked in a consistent manner. Although comparing the results of this study with similar results in other settings as was done in this study is reasonable, it is not ideal.

The Hawthorne effect likely played a role in this study because the same clinician who provided treatment measured the results of the treatment. In other words, patients may have been trying to please the clinician who provided treatment by reporting better results of the treatment than they actually experienced. Further, the treating clinician was not blind to the fact that these patients had received the treatment and thus may have unintentionally slanted the results to be more positive.

The study would have been strengthened if the follow-up time had been longer to examine whether treatment gains were maintained over time. If various clinicians at multiple sites had used the treatment protocol, it would have been clearer that it was the treatment protocol rather than something related more specifically to the treating clinician or the site that created the change in patients.

To test this PTSD treatment with more rigor, more patients would be needed; more measures would need to be statistically analyzed; the measures would need to be administered by someone who did not know whether the patient they were measuring had received the treatment; the groups of patients would need to be randomized and controlled; and the measures would need to be repeated over several years at several sites by several different clinicians.

Despite these limitations, we hope that this protocol will be used more widely to further test the positive results in our study. Because the intervention is relatively easy for clinicians to administer and is easily adapted to the wide variety of PTSD symptoms found in outpatient clinics, it could be useful for other clinicians to apply the protocol and assess the results. Using the PTSD Checklist for the *Diagnostic and Statistical Manual, Fifth Edition*, as an instrument to measure initial PTSD intensity and changes from treatment may streamline the procedure further. Though a structured interview like the CAPS-5 is the gold standard for diagnosing PTSD and measuring change in PTSD symptoms, the PTSD Checklist for the *Diagnostic and Statistical Manual, Fifth Edition*, takes only a few minutes and captures similar information as the CAPS-5.<sup>19</sup> It could be of value for health care organizations to consider using efficient, affordable, valid, and standardized ways both to confirm mental health diagnoses and to measure changes in the diagnoses and other important parameters over time so that it would be easier to compare results from different methods of treatment and from different clinicians. This information could be analyzed to help improve the quality of care.

## CONCLUSION

This study found that the PTSD treatment provided using the protocol to treat 30 adult outpatients was effective in remitting the PTSD diagnosis for those patients who completed the program. The 3-month follow-up data showed that only 1 patient returned to a PTSD diagnosis, but that patient just barely met the criteria. Each patient left our study with many personalized written materials from the skills acquisition portions of the study. We hope that these materials, along with the skills, resources, and experiences they gained during the study will help patients who completed the study to maintain long term remission of their PTSD diagnosis.

Patient handouts are available on request to any licensed mental health clinician by contacting: Shawn R Criswell, PhD, LPC, at [shawn.r.criswell@kp.org](mailto:shawn.r.criswell@kp.org). ❖

## Disclosure Statement

*The author(s) have no conflicts of interest to disclose. This material is based on a doctoral dissertation for Saybrook University that was completed by Shawn R Criswell with substantial assistance from Richard Sherman and Stanley Krippner. The dissertation was published by ProQuest. An academic poster with the study information was also presented at Saybrook University. This study was an unfunded study.*

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Keywords: abuse, ACE survey, ACEs, adverse childhood experiences, adult therapy, alternative therapies, biofeedback, cognitive behavioral therapy, mind-body therapies, noncombat-related posttraumatic stress disorder, posttraumatic stress disorder, psychotherapy, PTSD

## Outrageous Optimism

There is within medicine, somewhere beneath the pessimism and discouragement resulting from the disarray of the health-care system and its stupendous cost, an undercurrent of almost outrageous optimism about what may lie ahead for the treatment of human disease if we can only keep learning.

— *The Medusa and the Snail*, Lewis Thomas, 1913-1993, American physician, poet, etymologist, essayist, educator, and researcher



**Serendipity Meets Extemporaneity**  
photograph  
Richard Bruce Hovey, MA, PhD

From the artist: "While I sat in a park in Montreal, listening to a man playing the piano, a young woman appeared and began to dance. It was perfectly serendipitous and extemporaneous, and it moved me and lifted my spirit. I oversaturated the photograph to highlight and capture the surreality of this experience."

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# Spotlight on Antidiabetic Agents with Cardiovascular or Renoprotective Benefits

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## ABSTRACT

Type 2 diabetes mellitus often goes hand in hand with cardiovascular and renal comorbidities. Stroke, myocardial infarction, heart failure, and chronic kidney disease are high-risk complications of type 2 diabetes that contribute to morbidity and mortality. Recent clinical trials have uncovered evidence that certain antidiabetic agents may confer cardiovascular and/or renal benefits such as reduced cardiovascular and all-cause mortality and reduced need for renal replacement therapy. Two landmark trials in particular, EMPA-REG OUTCOME (Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes) and LEADER (Liraglutide Effect and Action in Diabetes: Evaluation of Cardiovascular Outcome Results), demonstrated the cardioprotective and/or renoprotective effects of empagliflozin and liraglutide, respectively. These trials led to new US Food and Drug Administration indications for empagliflozin and liraglutide as risk reduction for major cardiovascular events in adults with type 2 diabetes and established cardiovascular disease. Other trials are under way to determine whether these benefits are class effects and what other agents may have a role in risk reduction for cardiovascular and renal disease. This review will summarize the evidence for noninsulin antidiabetic drugs with benefits beyond glycemic control, discuss proposed mechanisms for these effects, and consider their place in therapy.

## INTRODUCTION

Type 2 diabetes mellitus is a known risk factor for cardiovascular disease (CVD) and chronic kidney disease (CKD), as well as a major contributor to morbidity and mortality. The alluring possibility of antidiabetic agents with protective cardiac and renal effects is the subject of several recent trials. Two landmark trials, EMPA-REG OUTCOME (Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes) and LEADER (Liraglutide Effect and Action in Diabetes: Evaluation of Cardiovascular Outcome Results), demonstrated the cardiovascular (CV) and renal benefits of empagliflozin, a sodium-glucose cotransporter-2 (SGLT-2) inhibitor, and the CV benefits of liraglutide, a glucagon-like peptide-1 receptor (GLP-1) agonist. Table 1 (available online at: [www.thepermanentejournal.org/files/2018/18-034-Table.pdf](http://www.thepermanentejournal.org/files/2018/18-034-Table.pdf)) summarizes the dosing, mechanisms, expected hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) lowering, advantages and disadvantages, and evidence for cardiac and/or renal benefits of these 2 agents, as well as the other mainline noninsulin treatments of diabetes.

## EMPA-REG OUTCOME TRIAL

The EMPA-REG OUTCOME trial assessed whether patients with type 2 diabetes at high risk of CV events may see a reduction in CV mortality, nonfatal myocardial infarction (MI), or nonfatal stroke when treated with empagliflozin added to standard care (statins, renin-angiotensin-aldosterone system inhibitors, and aspirin).<sup>1</sup> This multicenter, double-blind, placebo-controlled trial randomly assigned 7020 patients to receive empagliflozin, 10 mg; empagliflozin, 25 mg; or placebo daily for a 3.1-year follow-up period. Empagliflozin was associated with significant reductions in the composite of CV mortality, nonfatal MI, or nonfatal stroke (10.5% vs 12.1%; hazard ratio [HR] = 0.86, 95% confidence interval [CI] = 0.74-0.99;  $p = 0.04$ ), CV mortality (3.7% vs 5.9%; HR = 0.62, 95% CI = 0.49-0.77;  $p < 0.001$ ), heart failure hospitalization (2.7% vs 4.1%; HR = 0.65, 95% CI = 0.50-0.85;  $p = 0.002$ ), and all-cause mortality (5.7% vs 8.3%; HR = 0.68, 95% CI = 0.57-0.82;  $p < 0.001$ ). Empagliflozin did not reduce the risk of nonfatal MI or stroke individually. Compared with placebo, both empagliflozin groups had significantly higher rates of genital infections, a class effect stemming from SGLT-2 inhibitors' augmentation of the urinary excretion of glucose, which increases the risk of genital microorganism growth. A secondary outcomes analysis of the trial also found empagliflozin to be associated with a reduction in incident or worsening nephropathy (12.7% vs 18.8%; HR = 0.61, 95% CI = 0.53-0.70;  $p < 0.001$ ), doubling of serum creatinine (1.5% vs 2.6%; HR = 0.56, 95% CI = 0.39-0.79;  $p < 0.001$ ), and renal replacement therapy (0.3% vs 0.6%; HR = 0.45, 95% CI = 0.21-0.97;  $p = 0.03$ ).<sup>2</sup>

## LEADER TRIAL

The LEADER trial assessed similar CV endpoints for liraglutide added to the standard of care in patients with type 2 diabetes.<sup>3</sup> This multicenter, double-blind, placebo-controlled trial randomly assigned 9340 patients with type 2 diabetes and high CV risk to liraglutide, 1.8 mg (or maximum tolerated dose), or placebo administered subcutaneously daily for a 3.8-year follow-up period. Liraglutide demonstrated reductions in the composite of first occurrence of CV mortality, nonfatal MI, or nonfatal stroke (13% vs 14.9%; HR = 0.87, 95% CI = 0.78-0.97;  $p < 0.001$  for noninferiority;  $p = 0.01$  for superiority), CV mortality (4.7% vs 6.0%; HR = 0.78, 95% CI = 0.55-0.93;  $p = 0.007$ ), and all-cause mortality (8.2% vs 9.6%; HR = 0.85, 95% CI = 0.74-0.97;  $p = 0.02$ ). Liraglutide was also associated

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with reduced nephropathy compared with placebo (5.7% vs 7.2%; HR = 0.78, 95% CI = 0.67-0.92;  $p = 0.003$ ). Nonfatal MI, nonfatal stroke, and heart failure hospitalization rates were all nonsignificantly lower with liraglutide. In terms of adverse events, liraglutide had significantly higher rates of gastrointestinal side effects, acute cholecystitis, and injection site reactions compared with placebo.

### MECHANISMS OF CARDIOVASCULAR AND RENOPROTECTIVE EFFECTS

The mechanisms behind these CV and renoprotective effects remain speculative. Empagliflozin's beneficial cardiac effects may in part be caused by a reduction in cardiac workload and myocardial oxygen consumption.<sup>4,5</sup> The drug's capacity for modest blood pressure lowering, reduced arterial stiffness and vascular resistance, and its mild diuresis and natriuretic activity leading to weight loss are proposed hemodynamic explanations.<sup>4,8</sup> Empagliflozin's renal benefits may be related to a reduction in glomerular hyperfiltration (which, in turn, reduces albuminuria), as well as improvements in intraglomerular hypertension through reduced vascular stiffness.<sup>4,5,7-9</sup> Liraglutide's cardioprotective mechanism is even more elusive. It may be related to a reduced progression of atherosclerotic disease through the modulation of weight, blood pressure, lipids, and other metabolic factors.<sup>6</sup> It is unclear from the LEADER findings alone whether liraglutide truly improves renal outcomes and, if so, by what mechanism.

### OTHER DRUGS WITH CARDIOPROTECTIVE OR RENOPROTECTIVE EFFECTS

To date, empagliflozin and liraglutide are the only antidiabetic agents to earn US Food and Drug Administration indications for risk reduction of major CV events in adults with type 2 diabetes and established CVD. Trials are currently under way to determine whether these may be class effects and if antidiabetic agents from other classes confer similar benefits.

CANVAS (Canagliflozin Cardiovascular Assessment Study), a multicenter, placebo-controlled, randomized trial with 10,142 participants and a mean follow-up of 3.6 years, found that canagliflozin may reduce both CV and renal events in subjects with type 2 diabetes and high CV risk.<sup>10</sup> In CANVAS, participants receiving canagliflozin had a risk reduction in the composite of death owing to CV causes, nonfatal MI, or nonfatal stroke (26.9% vs 31.5%; HR = 0.86, 95% CI = 0.75-0.97;  $p < 0.001$  for noninferiority,  $p = 0.02$  for superiority) compared with placebo. The prespecified criteria for renal outcomes did not meet statistical significance; however, there was the suggestion of a potential reduction in the progression of albuminuria (HR = 0.73, 95% CI = 0.67-0.79) and the composite outcome of sustained 40% reduction in estimated glomerular filtration rate, need for renal replacement therapy, or death owing to renal causes (HR = 0.60, 95% CI = 0.47-0.77). In addition to the previously described adverse effects associated with SGLT-2 inhibitors, canagliflozin recipients also experienced a higher rate of amputations, primarily of the toe or metatarsal, compared with placebo (6.3 vs 3.4 subjects per 1000 patient-years; HR = 1.97, 95% CI = 1.41-2.75). This finding led to a boxed warning of

lower limb amputation for canagliflozin. Empagliflozin and dapagliflozin have not been found to increase amputation risk and do not display this boxed warning.

A 2018 systematic review and meta-analysis included 35 randomized, placebo-controlled trials of SGLT-2 inhibitors (which included EMPA-REG OUTCOME and CANVAS) in nearly 35,000 subjects with type 2 diabetes. The review authors concluded that, as a class, SGLT-2 inhibitors reduce all-cause mortality (odds ratio [OR] = 0.79, 95% CI = 0.70-0.89;  $p < 0.001$ ), major cardiac adverse events (OR = 0.8, 95% CI = 0.76-0.92;  $p < 0.001$ ), nonfatal MI (OR = 0.85, 95% CI = 0.73-0.98;  $p = 0.03$ ), and heart failure/hospitalization for heart failure (OR = 0.67, 95% CI = 0.59-0.76;  $p < 0.001$ ) compared with placebo.<sup>11</sup> The review found no difference in risk reduction among all 3 SGLT-2 inhibitors tested (empagliflozin, canagliflozin, and dapagliflozin).<sup>11</sup>

Evidence for CV and renal risk reduction as a possible class effect for GLP-1 agonists is less robust than for SGLT-2 inhibitors. To date, semaglutide, a recently approved GLP-1 agonist for the treatment of type 2 diabetes, is the only GLP-1 agonist with demonstrated CV and renal benefits.<sup>12</sup> In its preapproval noninferiority study, semaglutide demonstrated a lower risk of first occurrence of CV death, nonfatal MI, or nonfatal stroke compared with placebo (6.6% vs 8.9%; HR = 0.74, 95% CI = 0.58-0.95;  $p < 0.001$ ). Semaglutide also lowered the risk of new or worsening nephropathy (3.8% vs 6.1%; HR = 0.64, 95% CI = 0.46-0.88;  $p = 0.005$ ) compared with placebo. In randomized, placebo-controlled trials, 2 other GLP-1 agonists, exenatide and lixisenatide, did not demonstrate renal or CV benefits.<sup>13,14</sup>

Pioglitazone, a thiazolidinedione, has also demonstrated a trend toward CV risk reduction in 2 trials, IRIS (Insulin Resistance Intervention After Stroke) and PROactive (PROspective pioglitazone Clinical Trial in macroVascular Events).<sup>15-17</sup> In the IRIS trial, 3876 nondiabetic individuals with demonstrated insulin resistance and a recent stroke or transient ischemic attack were randomly assigned to receive either pioglitazone or placebo.<sup>15</sup> Participants were allowed to use other CV risk-modifying therapies such as antihypertensive agents, antiplatelet agents, and statins in addition to their study drug. After a 4.8-year follow-up period, pioglitazone reduced the composite risk of fatal or nonfatal stroke or MI (9.0% vs 11.8%; HR = 0.76, 95% CI = 0.62-0.93;  $p = 0.007$ ). There was no difference in all-cause mortality between pioglitazone and placebo. A secondary analysis of the IRIS trial also found that, compared with placebo, pioglitazone reduced the composite risk of acute coronary syndrome, defined as MI or unstable angina (4.3% vs 6.0% HR = 0.71; 95% CI = 0.54-0.94;  $p = 0.02$ ).<sup>16</sup> The study was not powered to detect whether pioglitazone reduced the risk of unstable angina or MI individually. Whether these findings are applicable to patients with type 2 diabetes—a population that was excluded from the IRIS trial—remains to be seen.

PROactive, a prospective, placebo-controlled, randomized trial of 5238 patients with type 2 diabetes and evidence of macrovascular disease, found that pioglitazone added to standard diabetes treatment (antidiabetic agents with or without insulin,

statins, antihypertensive agents, and antiplatelet agents) for a mean follow-up of 2.9 years did not reach statistical significance for its primary endpoint.<sup>17</sup> The primary endpoint was a composite of all-cause mortality, MI, acute coronary syndrome, coronary intervention, major leg amputation, bypass surgery, or leg revascularization. However, pioglitazone did reduce the risk of the secondary endpoint, the composite of all-cause mortality, nonfatal MI, or nonfatal stroke (11.6% vs 13.6%; HR = 0.84, 95% CI = 0.72-0.98;  $p = 0.02$ ). Antiatherogenic effects and improvements in insulin resistance are proposed mechanisms for pioglitazone's potential cardioprotective effects.<sup>16,17</sup> More trials are needed to assess whether pioglitazone truly reduces CV risk and whether these results still apply in diabetic patients in whom macrovascular disease has not yet developed.

There are trends toward CV and/or renal protection seen with other antidiabetic agents, including metformin, sulfonylureas, and dipeptidyl peptidase-4 inhibitors. However, the data for these agents are mixed and would need further evaluation in clinical trials. Table 1 includes a summary of the possible cardiac and/or renal protective effects of these agents.

#### EMPAGLIFLOZIN AND LIRAGLUTIDE: PLACE IN THERAPY

The American Diabetes Association's 2018 Standards of Medical Care in Diabetes guidelines recommend metformin as the first-line treatment of type 2 diabetes.<sup>18</sup> Clinicians are encouraged to consider insulin in patients with a new diagnosis of type 2 diabetes who are symptomatic and/or have a HbA<sub>1c</sub> at or above 10%. Clinicians should also consider initiating dual therapy in patients with a new diagnosis and a HbA<sub>1c</sub> of 9% or higher. The American Diabetes Association guidelines make a Level A (highest level) recommendation that patients with type 2 diabetes and established atherosclerotic CVD are treated first with metformin and lifestyle management, and subsequently with an antidiabetic agent that has demonstrated CV benefits (empagliflozin or liraglutide). Canagliflozin is named as an alternative to empagliflozin or liraglutide that can be considered for CV risk reduction, although this is a Level C recommendation, meaning that its evidence comes from poorly controlled or uncontrolled studies.

There are notable advantages and disadvantages to empagliflozin and liraglutide. In terms of HbA<sub>1c</sub> lowering, empagliflozin and liraglutide are not the most potent antidiabetic agents. The SGLT-2 inhibitors lower HbA<sub>1c</sub> by a mean 0.5% to 1%, and GLP-1 agonists lower HbA<sub>1c</sub> between 0.5% and 1.5%. Metformin, sulfonylureas, and thiazolidinediones each produce, on average, a stronger HbA<sub>1c</sub> lowering of 1% to 1.5%. Although SGLT-2 inhibitors carry a low risk of hypoglycemia and can confer modest weight loss and blood pressure-lowering effects, they also increase the risk of genitourinary infections, bone fractures (canagliflozin), amputations (canagliflozin), and diabetic ketoacidosis. They should be avoided in patients with existing moderate-to-severe renal impairment and are contraindicated when the estimated glomerular filtration rate is below 30. They carry a US Food and Drug Administration warning for acute kidney injury, which in EMPA-REG OUTCOME stabilized in about 4 weeks.<sup>1</sup> Such GLP-1 agonists as liraglutide also carry

a low risk of hypoglycemia and are sometimes used for their effects on weight loss. Most, such as liraglutide and semaglutide, can be used in patients with renal impairment, although data for their use in CKD Stages 4 and 5 are limited. The GLP-1 agonists carry a boxed warning for thyroid C-cell tumor risk (a finding seen in rats and mice) and are contraindicated in patients with a personal or family history of medullary thyroid carcinoma. Additionally, GLP-1 agonists may increase the risk of cholecystitis and pancreatitis.

Empagliflozin and liraglutide are high-cost agents. At the time of this writing, the average wholesale price of empagliflozin, whose formulary status varies by Kaiser Permanente Region, is roughly \$558 for a 30-day supply. Liraglutide, which is currently nonformulary for most Kaiser Permanente Regions, costs between \$645 and \$968 for a 30-day supply. Some pharmacoeconomic studies have suggested that both empagliflozin and liraglutide may be cost-effective adjuncts when added to standard care for type 2 diabetes.<sup>19,20</sup> Using a Markov model, empagliflozin was estimated to result in higher total lifetime treatment costs (\$371,450 vs \$272,966) but greater quality-adjusted life-years (10.712 vs 9.419) compared with standard treatment without empagliflozin.<sup>19</sup> This finding was based on a willingness-to-pay threshold of \$100,000 for each additional quality-adjusted life-year, which would make empagliflozin use for such patients cost-effective in 96% of 10,000 iterations. A systematic review of pharmacoeconomic studies of liraglutide as an adjunct for type 2 diabetes estimated liraglutide's probability of cost-effectiveness to be 58% compared with sitagliptin (a dipeptidyl peptidase-4 inhibitor) and 93% compared with glimepiride (a sulfonylurea).<sup>20</sup> It is difficult to conclude that liraglutide is a cost-effective adjunct across the board because not all studies included patients with high CV risk, the incremental cost-effectiveness ratios were based on projections of liraglutide's long-term benefits, and these studies hailed from health systems across the globe and had to be converted into US dollars for comparison.

Ultimately, we lack long-term data directly comparing the efficacy, safety, and cost-effectiveness of our many second-line antidiabetic agents (GLP-1 agonists, SGLT-2 inhibitors, sulfonylureas, thiazolidinediones, and dipeptidyl peptidase-4 inhibitors). GRADE (Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study), a randomized controlled trial of an estimated 5000 individuals with type 2 diabetes, is currently under way to compare long-term outcomes for people who are already receiving metformin and are randomly assigned to 1 of 4 add-on treatments: Glimepiride, sitagliptin, liraglutide, or insulin glargine.<sup>21</sup> Participants will be followed-up for as long as 7 years to assess which of these agents, when added to metformin, confers the best glycemic control, is the most tolerable, and offers the best overall health benefits for people with type 2 diabetes. Unfortunately, the study does not include any SGLT-2 inhibitors in its analysis because they were not yet available in the US at study initiation. The estimated primary completion date is July 2021. In the meantime, formulary status and cost considerations of antidiabetic agents should be taken into consideration along with the projected risks vs benefits for individual patients.

## CONCLUSION

At this time, empagliflozin and liraglutide are the antidiabetic agents with the most robust evidence for lowering CV and/or renal risk in patients with type 2 diabetes and established CVD. As this population ages, additional comorbidities will develop in many that will further elevate their risk of major CV events and CKD. In our stride toward individualized medicine, the opportunity to offer our patients diabetes treatments with potential morbidity benefits that transcend glycemic control is exciting. Depending on what ongoing and future trials uncover, it may be the way of the future. ❖

## Disclosure Statement

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

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Keywords: cardiovascular diseases, clinical trials, diabetes, nephrology, primary care, renal

## Tomorrow

The church and the law deal with the yesterdays of life; medicine deals with the tomorrows.

— William J Mayo, MD, 1861-1939, American physician and surgeon, cofounder of the Mayo Clinic

## “Do You Really Need This Appointment?”

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Dawn called me for an appointment. Her story is a sad one. At age 35 years, this once-vibrant executive secretary and devoted single mom was diagnosed with multiple sclerosis. During the 2 years preceding her request for an appointment with me, the disease had ravaged her nervous system. She was now wheelchair bound. She needed help dressing, bathing, and even feeding herself. Her mother, who had moved in to be her caregiver, was now changing her diapers.

I will be honest. I did not want to see Dawn. I knew there was nothing I could do. At past visits, I had asked my usual neurologic questions. I had performed my cursory neurologic examination. I felt powerless. The thought of seeing Dawn in person again, frankly, saddened me.

So, hoping to avoid the face-to-face visit I was not looking forward to, I had my nurse call Dawn with these questions:

Was there any change in her condition? Dawn replied, “No.”

Did she have any specific concerns? Dawn replied, “No.”

Could we handle this appointment by phone? Dawn replied, “No.”

Did she think this appointment was necessary? Dawn replied, “Yes.”

Dawn and her mother came to my office for the appointment.

There was nothing new.

There was no change in her condition.

I asked my usual medical questions.

I did my cursory neurologic examination.

Yet, strangely enough, Dawn and her mother seemed pleased with the appointment, an appointment, frankly, I had considered a waste of my precious “doctortime.”

Upon leaving, Dawn turned to me and smiled. She said, “We knew there was nothing you could do for me, Dr Abramson. We just wanted to hear your voice.”

The healing power of our presence.

It matters.

Too bad we physicians and healers too often forget.

Mea culpa.



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# Evidence-Based Medicine and Bioethics: Implications for Health Care Organizations, Clinicians, and Patients

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## ABSTRACT

Since its beginning in the 1990s, enthusiasm for evidence-based medicine (EBM) has flourished. As its methodology becomes more sophisticated and its breadth expands, EBM increasingly is referred to in patient care, insurance coverage decisions, technology assessments, medical education, and health care policymaking. Despite this growth, the intersection of EBM and bioethics often is not explored.

This article discusses the deontologic and utilitarian aspects of EBM and assesses EBM according to 4 bioethical principles: Respect for autonomy, beneficence, nonmaleficence, and justice. Strong ethical arguments support EBM as the best approach to patient care. However, practitioners and health care organizations must be aware that each principle involves complex issues that challenge EBM's ethical values.

## INTRODUCTION

In an August 2017 monthly physician update from the Southern California Permanente Medical Group, Nicole Lorey, MA, Chief Communications Officer, described 6 pillars of Permanente Medicine: Patient centered, physician led, evidence based, team delivered, culturally responsive, and technology enabled. She went on to state that Permanente Medicine is ethical care.<sup>1</sup> Without describing the ethics associated with all these pillars, I will discuss the ethics of evidence-based patient care from a treatment perspective (although many of the concepts presented likely apply to prevention, diagnosis, and prognosis as well). Assessing the ethics of evidence-based medicine (EBM) is important because professional societies, health care organizations, and insurance companies are encouraging clinicians to practice EBM with the underlying assumption being that it is an ethical approach to patient care. I will describe the ethical underpinnings and challenges surrounding an evidence-based approach to patient care by way of its 4 principles (respect for autonomy, beneficence, nonmaleficence, and justice).

### Utilitarian and Deontological Evidence-Based Medicine Approaches

According to leading early proponents, EBM “is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual

clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected ... in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients’ predicaments, rights, and preferences in making clinical decisions about their care.”<sup>2</sup> Thus, as originally formulated, EBM involved both quantitative and qualitative aspects.

A number of EBM approaches to treatments may be adopted.<sup>3</sup> When using the standard approach, a clinical question leads to a systematic review. A literature search is performed using terms that cast a broad net across the medical literature. The retrieved articles are then reviewed against a set of inclusion and exclusion criteria for the clinical question and relevant articles are selected. These articles are assessed and the results are combined either qualitatively or quantitatively (eg, in a meta-analysis). The conclusions of this analysis can then be translated into clinical practice guidelines on the basis of factors such as the weight and quality of evidence, patient values and preferences, and cost. This translation from evidence to guideline publication typically is accomplished with a multidisciplinary team. This process often necessitates substantial time and expense; consequently, organizations may use other methods when developing guidelines, such as reviewing previously published systematic reviews or adapting guidelines produced by other organizations.

Ethics approaches described in the West include utilitarian, deontologic, virtue, ethics of care, feminist, casuist, and liberation.<sup>4-6</sup> The ethics underlying EBM involve both utilitarian and deontologic aspects. Let’s start with utilitarianism, which is a branch of consequentialism. In consequentialism, the right action is the action that maximizes good consequences and minimizes bad consequences.<sup>7</sup> It is outcome-oriented, and the result of an action is the item of interest. In utilitarianism, the right ethical choice is the one that produces the greatest good for the greatest number. Another formulation is that utilitarianism seeks to produce the greatest balance of good over harm. Ethicists continually discuss what constitutes “good.” Classically, good was pleasure and the absence of pain.<sup>8,9</sup> More recent discussions expand “good” to include health and well-being.<sup>6</sup>

In treatment-related articles, EBM looks for clinical outcomes. Common examples of clinical outcomes, both beneficial and harmful, are morbidity, mortality, functional status, quality of life, and treatment side effects. These outcomes can be measured in a variety of ways depending on the clinical

question being asked. Treatment articles compare the results of a specific treatment (usually a new treatment) with either another treatment's results (usually an established treatment) or placebo. Researchers are looking to determine which treatment maximizes good clinical outcomes in the research population without producing undue harm. Provided that similar articles have reported similar results as determined by our systematic review and provided there are no significant barriers to implementation, EBM would recommend we use the treatment that maximizes clinical outcomes for the most patients who have a specific condition. On the basis of these descriptions of utilitarianism and EBM goals, both appear to have similar approaches.

Utilitarianism has many critics because a strict utilitarian approach to patient care dictates that the end justifies the means, and some utilitarians are not particularly concerned about how we get to our end.<sup>4,6</sup> For example, a utilitarian might not hesitate to take 1 kidney from a patient with 2 normal kidneys and give that kidney to a patient who is on dialysis because the greatest good is being done for the greatest number of people. The assumption is that the donor can live a healthy life with 1 kidney, and the recipient should now experience a better quality of life. A utilitarian might make this choice over a donor's protests and without informed consent.<sup>6</sup> Although this is an extreme example, it illustrates a common criticism of utilitarianism.

To counter this overreaching definition of utilitarianism, an ethical approach that takes into account patient rights and clinician or researcher duties and obligations is needed. This is the territory of the deontologist (from the Greek *deon*, meaning duty). In this example, the deontologist would not take the donor's kidney without consent if clinicians had to respect patient autonomy or if a patient right stated that no surgical procedure would be allowed without consent and after disclosure of a procedure's risks, benefits, and alternatives. In deontology, a person should not be used only as a means to reach another person's goals but should be treated as an end in themselves.<sup>10</sup>

From a medical research perspective, deontology has been applied to human experimentation.<sup>4</sup> Researchers are obligated to account for research subjects' rights to carry out their studies, and subjects should provide voluntary informed consent before study enrollment. This approach respects autonomy and validates dignity. Subjects are not just a means to satisfy a researcher's goals. These rights and obligations also protect subjects from unnecessary harm while maximizing potential benefit. Although this deontologic check on utilitarianism is important, it was put in place only relatively recently for human experimentation purposes.<sup>11-14</sup>

A deontologist might feel obligated to take a certain action even if s/he knows that by doing so, a worse outcome may result. For example, in classical deontology, certain duties apply regardless of consequences such as keeping promises, telling the truth, and not killing innocent people.<sup>4</sup> These absolute duties, however, may be problematic if they conflict with other duties such as beneficence or nonmaleficence. In 1 example, the psychiatrist treating James Holmes, the gunman in the 2012 Colorado movie theater mass shooting, was sued by the relatives of 1 of the victims.<sup>15</sup> The plaintiffs claimed that the psychiatrist should have

broken patient confidentiality and prioritized nonmaleficence by acting more assertively when she became concerned that her patient might be a danger to others.

### Evidence-Based Medicine Ethics

EBM ethics incorporate aspects of both deontology and utilitarianism. For example, our population studies approach shares many aspects with utilitarian ethics, and our approach to medical research incorporates many deontology aspects. For several decades, a popular approach to understanding Western bioethics has involved the 4 principles. These principles—respect for autonomy, beneficence, nonmaleficence, and justice—initially were described by Beauchamp and Childress in 1979.<sup>16</sup> The principles are deontologic and follow the *prima facie* (conditional) obligations initially described by WD Ross in 1930.<sup>17</sup> Ross broke with classical deontologists to assert that there are no absolute duties, only conditional duties. When a conflict of duties arises, the duty that ultimately is chosen is based on the circumstances of that particular case.

The ethical concepts of beneficence and nonmaleficence warrant definition and discussion. Beneficence entails promoting the well-being of others; nonmaleficence is an intention to avoid harming or injuring others.<sup>6</sup> Although head-to-head comparisons of EBM and other approaches to patient care<sup>18-20</sup> are not readily available, we can argue that it is our moral duty to follow an EBM approach because it allows practitioners to determine the true benefits and harms of a particular intervention.<sup>21,22</sup> The EBM process described earlier led us to reach conclusions and to provide recommendations on the basis of the medical literature. We are less confident about true benefits and harms if we let tradition or expert opinion guide our practice. Using an EBM approach, we should be able to distinguish the range of benefits and harms among possible treatment options. And provided there is little difference between efficacy and effectiveness for a particular intervention, patient, or population, we should be able to quantify both benefits and harms (eg, number needed to treat, number needed to harm, etc). Among all patient care approaches, EBM should foster confidence that we are providing beneficent and nonmaleficent care.

However, issues in the medical research and publication process can affect certainty regarding beneficence and nonmaleficence. For example, we know from the pediatric literature that about one-half of pediatric trials are not completed or do not get published,<sup>23</sup> and industry-sponsored pediatric trials are twice as likely to go unpublished. We also know that industry may suppress publication of research results if the data have adverse marketing implications.<sup>24</sup> Besides publication bias, ethical issues arise regarding published yet underpowered studies. These studies may contain type II errors; there may be a difference in treatments studied, but researchers have not identified the difference and may conclude that treatments are equivalent (a larger trial might demonstrate a new treatment as inferior to an established treatment).<sup>25</sup> Selection, reporting, and attrition bias also may exist. Although EBM possesses tools that allow us to identify and to adjust for biases (eg, funnel plot, power analysis, Cochrane risk of bias tool), to some extent EBM investigators

are at the mercy of the research establishment and the way in which it conducts and publishes its research.

Other issues may affect certainty regarding beneficence and nonmaleficence. There may be large differences between efficacy and effectiveness. Data frequently originate from optimized, resource-intensive care processes that may not translate well into the real world. Also, patients can be harmed when practitioners follow EBM too rigidly and adhere to evidence-based clinical practice guidelines without accounting for unique patient situations.<sup>26</sup>

These biases and other issues have ethical implications because they make predictions of beneficence and nonmaleficence on the basis of EBM less certain.<sup>20</sup> Guideline developers who take these biases and other issues into account likely will produce more ethical guidelines than those who do not. Searching and adjusting for these biases may be time- and resource-consuming, but the effort and expense likely will provide value in the end.

### Patient Autonomy and Bias

Autonomy entails respecting the right of another individual to determine that person's own course.<sup>6</sup> This definition fits nicely with the EBM injunction to account for patient preferences. However, EBM has been criticized for overemphasizing the calculated science of medical research and deemphasizing patient values and preferences.<sup>27,28</sup> Although values and preferences typically are not accounted for in individual research articles or during systematic reviews, they may be considered when clinical practice guidelines are developed. A recent structured approach to guideline development (GRADE: Grading of Recommendations, Assessment, Development and Evaluation) lists 4 factors, each to be assigned a value when determining strength of a recommendation: Patient values and preferences, balance between desirable and undesirable effects, quality of evidence, and costs.<sup>29</sup> Patient values and preferences apply at the population level; ideally, patients or patient advocacy groups have input into scoring this factor. If population values and preferences are uncertain or vary substantially, this factor gets a low score, and the overall strength of a recommendation may be reduced. Although consideration of patient values and preferences is laudable, we see a number of challenges. If guideline developers do not use GRADE or a similar approach, values and preferences will not be considered. If the applicable population is variable, as it will be in many urban environments, or if the geographic area is large (such as the case for many health care organizations), the population likely will be diverse. Determining population values and preferences under these circumstances can be challenging. Several studies have demonstrated that values and preferences among patients in similar situations are variable.<sup>30,31</sup> Also, the processes and tools for accounting of values and preferences are not standardized.<sup>32</sup>

Another challenge regarding autonomy is that the ethical perspective of a patient may differ from the ethical perspective of a health care organization. We might say that a patient's goal during his/her clinical encounter is consequential but not from a utilitarian perspective. A patient is interested in getting well and usually is less concerned, or not concerned, about how diagnosis and treatment affects the larger population (although

s/he may have some concerns about effects on family, friends, or coworkers). This patient likely will value personal wellness and prefer that the consequences of treatment will quickly lead to a better state of health. This self-interest appears to have elements of egoism in which the best ethical actions are those that maximize a person's own welfare. Although egoism frequently is regarded in a negative light,<sup>4</sup> it is common during clinical encounters. A patient's self-interest goal may not align with the population-interest goal of a health care organization, and this can pose a challenge when costs are involved. Some patients may want treatment that provides only a small incremental benefit at a large cost, whereas a health care organization may take the utilitarian approach, contending that those resources are better used in treating other patients for greater benefit.

**Although shared decision making that involves a discussion of benefits, harms, alternatives, and costs likely is the best approach in these situations, discussion outcomes may conflict with guideline recommendations depending upon how much flexibility the guideline allows for the shared decision-making process.**

From a clinician perspective, patient values and preferences typically are addressed at the individual patient level. This can lead to major ethical dilemmas for practitioners who may find themselves caught between values and preferences of both the patient and health care organization as reflected in evidence-based guideline recommendations. Although shared decision making that involves a discussion of benefits, harms, alternatives, and costs likely is the best approach in these situations, discussion outcomes may conflict with guideline recommendations depending upon how much flexibility the guideline allows for the shared decision-making process. Some studies have demonstrated that clinician values and preferences frequently are at odds with patients' values and preferences.<sup>33,34</sup> It is unclear how much of this discordance reflects a clinician's values and how much it reflects a clinician's role as the organization's representative. This discordance can be compounded if a health care system is monitoring practitioner adherence to guidelines and patient satisfaction with individual practitioners. Some regulatory agencies do not penalize a practitioner or institution if a patient's preferences do not meet regulatory requirements.<sup>35</sup>

It may be difficult for EBM practitioners to fully acknowledge patient autonomy for all of these reasons. Patient values and preferences, if taken into account at all, are at the population level when guidelines are produced, and they may not represent the values and preferences of individual patients. Furthermore, the ethical approach of the health care organization, as reflected in its guidelines, more closely resembles utilitarianism, whereas the ethical approach during patient encounters more closely resembles egoism. The goals of these approaches may clash, the clinician may be caught in the middle, and EBM may not be particularly ethical when it comes to respecting autonomy.



Justice in the setting of EBM warrants discussion as well. According to Beauchamp and Childress, “Justice [is] fair, equitable, and appropriate treatment in light of what is due or owed to persons. ... Injustice involves a wrongful act or omission that denies people resources or protections to which they have a right.”<sup>6</sup> Provided that inclusion or exclusion study criteria are not biased, EBM should promote justice to individuals and groups because it provides scientific guidance on the best treatments for patients with specific conditions regardless of characteristics such as sex, race, or socioeconomic status. Health care disparities, which are well documented, are closely related to access to services, economic inequality, language barriers, and biased health care systems.<sup>36</sup>

Injustice can result from study design and publication bias and also from funding bias. An example is funding for cystic fibrosis (CF) and sickle cell disease (SCD) research. The severity of these 2 illnesses is similar. Despite the fact that CF prevalence is one-third that of SCD, research funding for CF is an order of magnitude higher than funding for SCD.<sup>37</sup> This increased funding probably has resulted in twice as many CF publications as SCD publications and more FDA-approved medications for CF than SCD. Because EBM reflects published research, more evidence will emerge and may lead to higher-level evidence-based recommendations for CF than for SCD. It is no secret that most people with CF are white and that SCD almost exclusively occurs in blacks. A bioethicist looking at these data probably would say that an injustice is affecting a marginalized society on the basis of race. This is in keeping with the perspective of liberation ethics that those at the margins of society are kept at the margins by systematic biases against them promulgated by the “majority society.”<sup>5,38,39</sup> In this case, the majority society is composed of funding institutions and a research community that drive medical research and publications. Although EBM is the recipient and not the cause of these biases, EBM still reflects bias through the reporting of evidence. As with beneficence, nonmaleficence, and respect for autonomy, justice issues may render EBM less ethical when these issues reflect unjust research and publication processes.

## DISCUSSION

EBM ethics have both utilitarian and deontologic aspects. The medical literature recommends treatments that produce the greatest good for the greatest number; researchers and clinicians should perform certain duties for patients and to respect patient rights. Among the various approaches to patient care, an evidence-based approach should be most ethical because those who employ it seek to quantify patient benefits and harms. Clinicians and patients with knowledge of these benefits and harms should be able to make more sound treatment decisions. EBM-related issues may make this approach less ethical, however.

No head-to-head studies have compared EBM with other approaches to patient care. In theory, EBM should be most ethical because it introduces scientific rigor. Practitioners should be able to more accurately predict the benefits and harms of specific treatments and provide beneficent and nonmaleficent

care to their patients. However, ethical problems arise when biases influence the EBM process. Such issues render predictions of benefits and harms less reliable and EBM potentially less ethical. Guideline developers who account for these biases and other issues more likely will produce a more accurate guideline and better serve patients and clinicians.

EBM originally was designed to account for patient preferences. However, it is difficult to regard individual patient values and preferences when the accounting of values and preferences during the guideline development process takes place at the population level. Also, health care organization and patient goals may differ. The health care organization usually takes a more utilitarian approach and values the health of the population. The patient takes a more egoist approach and values his/her own health more so than population health. Ethical dilemmas arise for practitioners when patient values and preferences conflict with organization-sponsored, evidence-based recommendations. A shared decision-making process likely is needed to reach the best solution.

Because of its rigorous methodology, EBM should support justice and help to decrease health care disparities. However, EBM reflects decisions about funding, study design, and publication and consequently reflects any injustices inherent in these decisions. As a result, health care organization leaders must realize that EBM may not be as accurate as originally constructed. Some EBM issues can be addressed during the guideline development process, but many issues cannot be addressed because EBM is at the receiving end of the medical research and publication process. To more effectively ensure beneficence and nonmaleficence, organizations that create guidelines should strive to address as many biases as possible. Organizations that develop guidelines must carefully review all content to reduce potential bias and fully deploy their guidelines so clinicians can discuss the evidence during meaningful patient encounters.

## CONCLUSION

Clinicians and patients may arrive at shared decisions that conflict with organizational guidelines. Organizations should accept the outcomes of these discussions to support patient autonomy. Clinicians and patients should be allowed to opt-out of a guideline recommendation (with reasons cited), and organizations should not force clinicians into ethical dilemmas in which they are caught between organizational expectations and patient values and preferences. This degree of latitude will go far toward supporting collaborative patient-centered care and respecting patient values, preferences, and shared decision making.

Health care organizations should produce guidelines for treatment of conditions unique to marginalized populations. Guideline topics often are chosen on the basis of disease prevalence or cost—a utilitarian approach. Utilitarianism can harm the minority to the benefit of the majority, but harm may be reduced by addressing minority health care needs and potentially decreasing disparities.

Clinicians should be familiar with the evidence behind treatments and feel empowered to deviate from evidence-based recommendations for a good cause. They should encourage

patients to discuss their values and preferences and make shared decisions. Patients should be open to the evidence presented during clinical encounters yet feel empowered to discuss their own values and preferences and make decisions that may contradict guideline recommendations. ❖

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Keywords: bioethics, EBM, evidence-based medicine, GRADE, guidelines, Western medicine, autonomy, beneficence, nonmaleficence, and justice

## My Siren

Alex Battaglia, MD

Perm J 2018;22:18-072

E-pub: 09/06/2018

<https://doi.org/10.7812/TPP/18-072>

This night,  
at 4 am in the OR,  
an HIV-tainted blade cuts my finger,  
and like Ulysses I visit the dead,  
life and death  
no longer separated.  
I close my eyes to ward off the virus,  
but apparitions appear  
and I see her,  
my lost love.  
Her eyes more important than blood,  
she replaces  
the black intestines and retractors.  
She calls  
and that distant animal inside me  
awakens,  
the wild beast with no beliefs,  
only sensations.  
I am entranced once again,  
and she asks  
what happened to the deep forest we brought to each other  
where we once kissed under  
the dark canopy and scarlet macaw  
with tucan colors.  
Amidst the Amazon fog, silent iguanas and gibbon cries,  
she surrounded me,  
she, my siren,  
she,  
my river of possibility.

How can I explain her snapshot death,  
how it arrived in a frozen moment  
in the depths of Brazil?  
I relive how  
her voice  
faded,  
her breath  
slowed,  
her last glance  
left  
an onyx imprint.  
I am reluctant  
to finish anything  
without her,  
but like Ulysses I am tied to the mast  
of this ship,  
I am the captain of this OR,  
and must open my eyes  
and leave her behind.  
I must grow  
accustomed to dark viruses,  
Surgeon,  
I.

### How to Cite this Article

Battaglia A. My siren. Perm J 2018;22:18-072.  
DOI: <https://doi.org/10.7812/TPP/18-072>

## Sensory Inattention

Nandini Bakshi, MD

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Snowflakes drifting  
from a soundless sky  
are startled  
by the wail of an ambulance  
piercing through the gap  
left open just enough  
to let in the winter chill.

I linger by the bathroom window  
allowing the icy breeze  
to arouse me  
from my stupor.

It's been a long night  
of breathing stale air  
shared with the sick  
and dying.

Oriented to place and time,  
it's December 1989  
the AIDS rotation is next.  
Stories are told  
it's a test  
of who will leave and who  
is staying.

I join my fellow  
sleep-hungry interns  
stalking the halls like ghosts  
reacting to beeps and codes  
oblivious to the sound  
of an ambulance  
and softly falling snow.

## ■ 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.

## FLK

Monique Canonico, DO

E-pub: 10/22/2018

Perm J 2018;22:15-208

<https://doi.org/10.7812/TPP/15-208>

I sat in the cramped, beige exam room of the military hospital's pediatric neurology clinic. I gazed at the rambunctious 5-year-old boy who was being referred for possible oppositional defiant disorder. He wore a red Pokemon t-shirt. There was no question that he was a funny-looking kid—his eyes were set close together, and his lips were a thin, pink horizontal sliver of quiver on the lower face. Someone, perhaps his father, had

insisted on a crew cut. His harried mother, who was holding a wide-eyed toddler, gave me the lowdown.

Cody had been expelled from preschool for biting and for consistently resisting all authority. He picked fights with kids in the neighborhood who were twice his size. He made no eye contact, but he was transfixed by the stuffed Kermit the Frog puppet I had on my office shelf. After listening to the mother's complete story, I asked, "What seems to be the one thing he's good at?"

"Well," his mother said, "he's strong, brave, and independent, and he's got street smarts you wouldn't expect from a 5-year-old boy."

Cody imperiously stared up at me and told me he liked Kermit. He liked him a lot. Cody's mother and I discussed plans, and therapy, and interventions that could help Cody comply and become obedient, but I sensed this wasn't a hidden sociopath lying in wait, ready to shoot a robin with his BB gun and then pluck its wings off while it lay dying on the cement. No, this was a misunderstood little boy. I calmly explained our plans to his mother and told her as much. "Jenelle," I said, "with our interventions, Cody will be fine. He just marches to the beat of a different drummer."

She looked initially forlorn, but then she stared thoughtfully at me. She realized it was true. There was not much wrong with him. "He needs understanding," I said. "Sometimes we need to listen to a different drumbeat to understand the music." ❖



### How to Cite this Article

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**FLK**  
by Seamus Heffernan

## Patient as Healer

June Pham, MD

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It was my first appointment after 4 days off to attend an unanticipated illness, death, and funeral for a beloved aunt. I was quiet, solemn, and ready to be back at work, but ... changed. My first patient was a Christian minister. Not my own denomination, but that was never relevant. He was a middle-aged, overly nourished Hispanic man who was serious about his work and overall contented, but he was never able enough to control his type 2 diabetes despite massive insulin injections and extensive coaching. Quickly into the visit, after the usual questions and answers and advice, he asked me what had changed in my life. I told him and tears came to my eyes. He sat with me in silence, then asked if I would like him to pray with me. I hesitated only momentarily, then said, yes. I was grateful. This was the first time a patient ministered to me. I felt healing. ❖

### How to Cite this Article

Pham J. Patient as healer. Perm J 2018;22:15-134.

DOI: <https://doi.org/10.7812/TPP/15-134>

*The story "Patient as Healer" was originally published in leaflet, 2017;5(2). Available from: [www.leaflet-ejournal.org/archives-index/item/patient-as-healer](http://www.leaflet-ejournal.org/archives-index/item/patient-as-healer).*

## ■ NARRATIVE MEDICINE

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# DNR

Felicitas Livaudais, MD

Perm J 2018;22:15-254

E-pub: 10/01/2018

<https://doi.org/10.7812/TPP/15-254>

As an intern at Charity Hospital, I was responsible for night call duties. There was a woman on our service with cancer. She was not expected to live long, so she and her daughter decided to have Do Not Resuscitate orders. One night the patient went into agonal breaths. They called me, the intern, so I sat with her daughter as she listened to her mother's raspy breaths until they became less, more quiet, then nothing.

They held hands the whole time. Even when I pronounced the mother dead and finished my work, her daughter was still there by her bedside. It was dark and silent. The bond between the two would stay even though one body had expired. I expressed my condolence and the daughter gave me a half smile. When I die, I hope someone who loves me will sit next to me and hold my hand too. ❖

### How to Cite this Article

Livaudais F. DNR. Perm J 2018;22:15-254.  
DOI: <https://doi.org/10.7812/TPP/15-254>

Accompanying artwork:  
**DNR**  
by Reid Psaltis



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Reid Psaltis lives in Portland, OR, where he makes illustrations, comics, and sculptures about science, nature, and natural history.

## To Pace or Not To Pace? A Narrative Review of VIP Syndrome

Ching Soong Khoo, MD, MRCP (UK)

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E-pub: 09/10/2018

<https://doi.org/10.7812/TPP/18-081>

### PHYSICIAN STORY

“Hi, would you mind seeing my dad?”

I received an urgent call on a lovely Sunday evening from a Consultant Dermatologist, who was my excolleague. It was a brief phone consultation about her father, who had just been admitted to the Cardiology Unit for recurrent syncope. He was strongly advised to have a pacemaker implanted. In the midst of helping her father make this major decision, my excolleague boiled it down to a very crucial question: Was it a cardiac or a neurogenic syncope?

“Certainly, I would love to see your father tomorrow at my neurology clinic,” I replied. My prompt and positive response seemed to have soothed her nerves, which resulted in immediately discharging her father at her own risk from the Cardiology Unit.

She came along with her father the next day. Her father was a moderately built man in his late 50s. He was a teetotaler and a nonsmoker. His first syncopal attack happened 1 year before this consultation. The first attack was triggered by profuse vomiting and epigastric pain. He regained consciousness quickly upon arrival at the Emergency Department. Extensive investigation including a brain computed tomography (CT) was performed. The only significant finding detected was his slow regular heart rate, ranging around 40 to 50 beats per minute (bpm). The electrocardiogram at that juncture revealed sinus bradycardia with no ischemic changes. His cardiac enzymes were repeatedly within normal limits, and he denied any angina symptoms. He had no other previous significant medical history or family members with coronary artery disease. Twenty-four-hour Holter monitoring did not reveal any sinister arrhythmias. His echocardiogram was grossly normal with an ejection fraction of 60%.

He had remained well until a couple of days before my consultation with him. He reported having dizziness with a spinning sensation and a presyncopal attack, which sounded to me like vertigo. Owing to his previous history of bradycardia, he was rushed to the Cardiology Unit again for opinions. Apart from the sinus bradycardia at around 40 to 50 bpm, there were no other examination results of concern. In view of the relationship between the recurrent syncope and bradycardia, he was advised to have a pacemaker implanted.

After obtaining the above history from the patient and confirming it with my excolleague, I proceeded with a physical examination. There were no cerebellar signs or other neurologic deficits. Otoscopy showed no abnormal findings. Other systems including the cardiovascular, respiratory, and abdominal systems were grossly normal. The electrocardiogram revealed sinus bradycardia at a rate of 50 bpm. Before I was able to sum up my findings and inform them of the most possible diagnosis, my excolleague started suggesting a plethora of plans, such as a

repeated brain CT, magnetic resonance imaging, CT of the coronary arteries, an Ear, Nose, and Throat referral, a second opinion from the cardiologist, etc.

“Look, your anxiety about missing something in your father might overemphasize the work-up and subsequent treatment, which might further lead to an inferior outcome,” I replied to her plans.

“Clearly, as you would concur with me, he had vertigo this time possibly because of vestibular neuritis. The first syncope was most likely caused by the vasovagal attack after the vomiting. He had a baseline heart rate of 40 to 50 bpm, and repeated monitoring did not pick up any malignant arrhythmias. I would suggest an Ear, Nose, and Throat consultation, and in the mean time, some antivertigo medications would ameliorate his partially resolving symptom ...”

Her anxiety seemed to start ebbing away. Her emotional response had blurred her vision to appreciate the risks and benefits of her previously suggested management plans. She conceded that she had overreacted and downplayed my role as the attending clinician.

I told her, “Don’t worry, I understand that you want to seek the best treatment for your father, which is why you are here today. And I am going to treat your father exactly like I would my other patients. The standard of care would most benefit your father.”

Both the patient and his daughter were satisfied with my advice. The patient went home happily with some cinnarizine and betahistine tablets, and he refused further referrals unless he remained vertiginous.

One month later, my excolleague texted me to express her gratitude for my unbiased clinical acumen. Her dad completely recuperated without a pacemaker implantation.

### DISCUSSION: VIP SYNDROME

The term VIP (very important person) syndrome was introduced by Dr Walter Weintraub in 1964.<sup>1</sup> Managing VIPs poses a great challenge to health care practitioners. A VIP, by definition, is a person given special privileges in view of his or her status or wealth. Examples of VIPs include royalty, politicians, celebrities, corporate leaders, and wealthy individuals. In my very humble opinion, medical personnel or their relatives have increasingly become VIPs for special treatment.

The care of VIPs is highly varied from one clinic to another because of ethical dilemmas, different perceived benefits for the VIPs, and a vastly heterogeneous group of clinicians and VIPs. VIP medicine is a seemingly insidious phenomenon. Whereas it has been believed implicitly that because of their unique status VIPs are given the best care, faster and greater access, enhanced and more convenient facilities, and special attention



from physicians, VIP care can be singularly harmful. The late world-renowned singer Michael Jackson was unquestionably a victim of VIP medicine. He had unlimited access to propofol with the VIP services rendered by his personal physician. His physician acceded to the singer's demands to receive propofol to help him sleep, which ultimately was a cause of his death. The shocking death of the pop-star Prince opened the door to questions of whether he was an unfortunate victim of VIP syndrome. He succumbed to an accidental overdose of fentanyl. These two tragedies highlight not only the "side effects" of VIP syndrome, but also underscore the complexity of the VIP issue when treating celebrities—for example, demands by the VIPs for potentially life-threatening drugs or procedures, ethical tensions and dilemmas, and breach of heightened privacy and confidentiality when providing evidence in court.

Hospitalizing VIPs (like celebrities, politicians, and elected leaders) could make hospital staff feel uneasy, especially in a hospital that is not prepared for their admission. VIP hospitalization causes a great deal of mass-media attention. VIPs need or demand secluded areas for treatment, which could be disruptive to the care for more medically indicated, non-VIP groups of patients. Reputable reporters trying hard to get unmediated information about VIPs' admission records or notes could cause disharmony in the hospital involved and subsequent ethical dysfunction.

To date, very scarce guidelines have been established and few empirical studies have elucidated this VIP issue. A recent survey performed in an inpatient setting revealed that a majority of the physicians in the study were under pressure by a VIP patient or his or her family members to order additional tests or treatment that were deemed medically unnecessary. Reportedly 36% of the physicians were pressured by hospital representatives to comply with the VIP demands.<sup>2</sup> Unnecessary investigation is often masqueraded as "more is better." Contrary to this conventional belief, this may do more harm. For example, by exposing an individual with no indications to radiation injury by doing a CT scan; by causing emotional stress and fear after detection of slightly elevated blood levels, false positives, or mildly raised cancer markers in an asymptomatic patient; or by inappropriate escalation of an antibiotic to a more broad-spectrum class drug may result in antibiotic resistance. In clinics with limited resources, health budgets, and medical facilities, such practice of care inequities may deprive non-VIP patients of standardized care.

Guzman et al<sup>3</sup> offer 9 principles in handling VIPs that are handy and worth reading. Principle 1: Don't bend the rules. Any deviation of clinical practice when caring for a VIP can compromise delivery of the right care. Principle 2: Work as a team, not in "silos." Teamwork is crucial in ensuring good clinical outcomes. Principle 3: Communicate, communicate, communicate. Heightened communication should include the patient, family, and other health staff members involved in providing care. Principle 4: Carefully manage communication with the media. Confidentiality in the physician-patient relationship must be guarded. Principle 5: Resist "chairperson's syndrome." Chairperson's syndrome is pressure from the patient, family member, hospital representative, or even the VIP patient to be cared for

by the department chairperson. Principle 6: Care should occur where it is most appropriate. Decisions on where to place the VIP patient should be made on the basis of the venue where the optimal care can be delivered. Principle 7: Protect the patient's security. Ensuring security is of paramount importance in managing VIP syndrome. Principle 8: Be careful about accepting or declining gifts. It is suggested that physicians decline gifts graciously to minimize unmet expectations and misunderstandings, and also affirm the care that is free of gifts. Principle 9: Work with the patient's personal physicians. Effective interactions with the VIP's personal caregivers can facilitate communication and decision making for the patient.

Of these 9 rules, I suggest that effective communication is quintessential. Engaging sustained and focused eye contact is one of the most unbelievably powerful means of communication. Listening to the patient's own account of his or her complaints and history, not fully from family members, is of paramount importance in getting to the bottom of the most possible diagnosis. As in the pacemaker case, my excolleague, who was a Consultant Physician, gave me a long list of differentials that could have unintentionally clouded my clinical acumen. Furthermore, as a specialist, she probably had formulated the most possible diagnosis for her father, which was cardiac syncope, before seeing me. Such immense pressure from a Consultant might be why our Cardiology colleagues pushed for inappropriate steps by recommending a pacemaker implantation.

Physicians providing care for a physician or a physician's family member may feel conflicted in their dual roles of colleague and practitioner. When managing a physician's family, collegial interactions with the physician during the family meeting, respecting his or her professional suggestions or ideas, offering unbiased professional management plans, reminding all involved about the potential risks of unnecessary testing, and offering reassurance that the right care will be delivered to the patient are all important steps to take. I must stress that reassurance, and emphasizing standard of care for VIP patients, is the next key to success after effective communication, as in this pacemaker case.

VIP syndrome is an exigent issue and needs to be managed appropriately. Clinicians should be well-conversant with handling this issue in order to not compromise care by simply bending the rules for VIPs. Remember, *primum non nocere*—first, do no harm—is always our fundamental guiding principle in our daily clinical practice. ❖

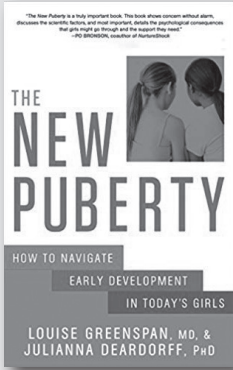
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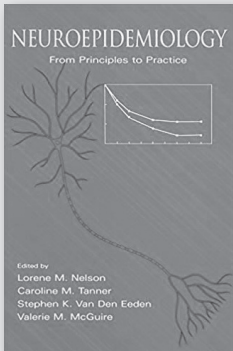
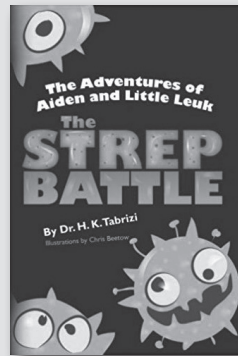
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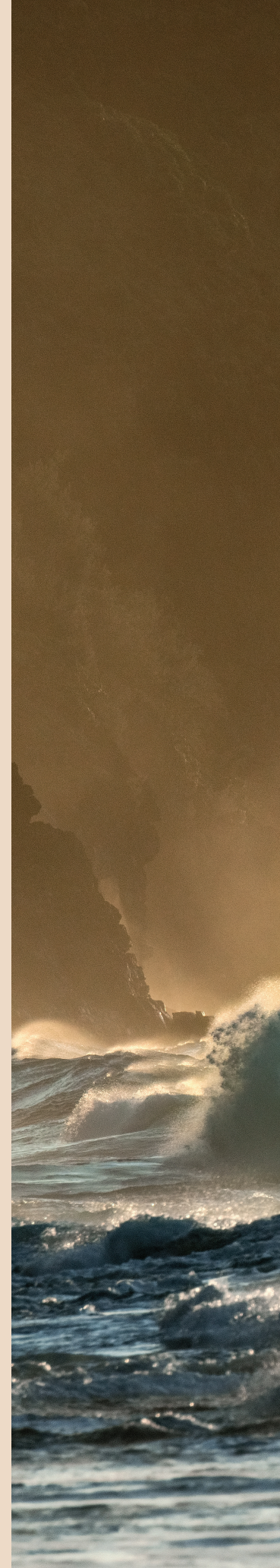
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## Addressing Basic Resource Needs in Health Care Settings: From Clinic to Community



### Commentary

- 4 Food Insecurity—Addressing Basic Resource Needs in Health Care Settings

### Original Research & Contributions

- 6 Evaluation of the Learning to Integrate Neighborhoods and Clinical Care Project: Findings from Implementing a New Lay Role into Primary Care Teams to Address Social Determinants of Health
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John F Steiner, MD, MPH

### ORIGINAL RESEARCH & CONTRIBUTIONS

- 6 Evaluation of the Learning to Integrate Neighborhoods and Clinical Care Project: Findings from Implementing a New Lay Role into Primary Care Teams to Address Social Determinants of Health.** Clarissa Hsu, PhD; Erin Hertel, MPA; Eric Johnson, MS; Carol Cahill, MLS; Paula Lozano, MD, MPH; Tyler R Ross, MA; Kelly Ehrlich, MS; Katie Coleman, MSPH; June BlueSpruce, MPH; Allen Cheadle, PhD; Juno Matthys; Michelle Chapdelaine, MPH; Marlaine Gray, PhD; Janice Tufte; Michele Robbins

The authors analyzed data from staff interviews, patient focus groups, clinic site visits, patient surveys, the electronic health record, and administrative sources. Primary care teams reported workload easing. Patients who used community resource specialists (CRSs) and participated in focus groups reported behavior changes and improved health, although no changes were detected from electronic health records or patient survey data. Key learnings include the need to clearly define the CRS role, ensure high visibility to clinical staff, and facilitate personal introductions of patients (warm handoffs).

- 17 Perceptions and Experience of Patients, Staff, and Clinicians with Social Needs Assessment.** Courtnee Hamity, PhD; Ana Jackson, PhD; Lunarosa Peralta, MPH; Jim Bellows, PhD
- Qualitative and descriptive analysis of data from member and clinician focus groups, interviews, and surveys among 68 members and family caregivers who had participated in social needs assessment programs and 90 clinicians and staff in the Kaiser Permanente Colorado, Georgia, Northern California, Northwest, and Southern California Regions. Careful attention to communications is required because members may be uncertain or concerned about the purpose of the assessment and the dissemination of sensitive information. Messaging should assure members about data use and dissemination and what they can expect after screening.

- 22 Professional Medical Association Policy Statements on Social Health Assessments and Interventions.** Geoff Gusoff, MD; Caroline Fichtenberg, PhD; Laura M Gottlieb, MD, MPH

Among the 42 professional medical associations included in this study, 9 (21%) published 39 relevant statements. Fourteen of these statements referred to clinic-based social or economic health-screening activities, 34 referred to clinical interventions to promote social or economic health, and 3 referred to strategies for financial support for these activities. Thirty-six of the 39 statements (92%) were published after 2008.

- 28 Using Neighborhood-Level Census Data to Predict Diabetes Progression in Patients with Laboratory-Defined Prediabetes.**

Julie A Schmittiel, PhD; Wendy T Dyer, MS; Cassandra J Marshall, DrPH, MPH; Roberta Bivins, PhD

Retrospective cohort study of all 157,752 patients aged 18 years or older from Kaiser Permanente Northern California with laboratory-defined prediabetes. Patients were more likely to progress to diabetes if they lived in an area where less than 16% of adults had obtained a bachelor's degree or higher, where median annual income was below \$79,999, or where Supplemental Nutrition Assistance Program benefits were received by 10% or more of households.

- 33 Universal Screening for Social Needs in a Primary Care Clinic: A Quality Improvement Approach Using the Your Current Life Situation Survey.**

Kumara Raja Sundar, MD

Kaiser Permanente's Care Management Institute created a screening tool, Your Current Life Situation, to identify social needs for populations at risk of high health care utilization. In a rapid stakeholder analysis, concerns were the tool's length and low screening acceptability and the possibility that too few or too many patients may have social needs. Of 125 office visits and 111 patients screened, 27% had positive findings and requested help. Of the 14 patients not screened, only 1 opted out of screening. Practitioners and medical assistants stated that the tool did not disrupt clinic work flow.

- 40 Measuring Patients' Basic Resource Needs: The Role of a Small Survey to Guide Operational Decisions.**

John F Steiner, MD, MPH; Tina K Kimpo; Christopher I Lawton; Andrew T Sterrett, PhD; Andrea R Paolino, MA; Chan Zeng, PhD

A well-validated, 2-item food-insecurity measure had fewer false-positive responses than a previously used single-item measure. Individuals with food insecurity commonly reported concurrent difficulties paying for housing, transportation, and utilities, and cost-related medication nonadherence. These basic resource needs persisted during a 3-month period. Of the 110 older adult members surveyed from Kaiser Permanente Colorado, 47.4% had delayed paying for food to pay for housing, and 22.0% had delayed paying for housing to pay for food.

### SPECIAL REPORTS

- 48 Health Care Steps Up to Social Determinants of Health: Current Context.**

Loel S Solomon, PhD, MPP; Michael H Kanter, MD

As the articles in this Supplement demonstrate, the social determinants of health are a major focus for Kaiser Permanente and the broader US health care system. The question is now what the role is for the US health care system in creating the right policy context for innovation and how health care can partner more effectively with providers of social services to meet patients' most pressing needs given the fragmented, typically underresourced nature of the social sector.

- 53 Interventions to Address Basic Resource Needs in Kaiser Permanente: A Care Continuum and an Outcomes Wheel.**

John F Steiner, MD, MPH; Jim Bellows, PhD; Matthew P Banegas, PhD, MPH; Laura M Gottlieb, MD, MPH

This framework combines a care continuum with an outcomes wheel with 5 steps: 1) plan new interventions to generate evidence of effectiveness, 2) assess basic resource needs in broad or targeted membership groups, 3) connect individuals to community organizations that can fulfill basic resource needs, 4) improve health outcomes through these interventions, and 5) spread effective programs to other settings. Each step has multiple subcomponents that support implementation and evaluation. The outcomes wheel identifies health outcomes at the individual, clinical, social, and system levels that can address these different priorities.

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**A Social Needs Network for Evaluation and Translation**  
SONNET is committed to helping Kaiser Permanente leaders, front-line clinicians and staff design and evaluate effective interventions to address the social needs of our members.



**The Social Interventions Research and Evaluation Network**

SIREN is an initiative housed at the University of California, San Francisco. SIREN's mission is to catalyze and disseminate high quality research that advances efforts to identify and address patients' social risks in health care delivery contexts. It is supported by Kaiser Permanente and the Robert Wood Johnson Foundation.

## SPECIAL REPORTS

### 58 Uses and Misuses of Patient- and Neighborhood-level Social Determinants of Health Data.

Laura M Gottlieb, MD, MPH; Damon E Francis, MD; Andrew F Beck, MD

Some screening tools rely on patient- or household-level screening data collected from patients during medical encounters. Others rely on data available at the neighborhood-level that can be used to characterize the environment in which patients live or to approximate patients' social or economic risks. Four case examples were selected from different health care organizations to illustrate strengths and limitations of using patient- or neighborhood-level social and economic needs data to inform a range of interventions. This work can help to inform health care investments in this rapidly evolving area.

### 63 Toward Addressing Social Determinants of Health: A Health Care System Strategy.

Nicole L Friedman, MS; Matthew P Banegas, PhD, MPH, MS

Kaiser Permanente Northwest (KPNW), an integrated health care delivery system, implemented a comprehensive approach for patients' Social Determinants of Health (SDH). Tools included use of electronic health record-based data elements, International Classification of Diseases, Tenth Revision social diagnostic codes (Z codes), and the development of novel work flows via nonclinical patient

navigators to address patients' SDH through community resource referrals. From March 2016 to March 2018, KPNW patient navigators screened 11,273 patients with SDH identifying and documenting 47,911 SDH in the electronic health record, and 18,284 community resource referrals were made for 7494 patients.

### 71 Lessons Learned from Implementation of the Food Insecurity Screening and Referral Program at Kaiser Permanente Colorado.

Sandra Hoyt Stenmark, MD; John F Steiner, MD, MPH; Sanjana Marpadga, MSc; Marydale DeBor, JD; Kathleen Underhill; Hilary Seligman, MD, MAS

Traditionally, health care systems have addressed gaps in patients' diet quality by providing dietary counseling and education. This article describes barriers and lessons from implementation and expansion of the Kaiser Permanente Colorado's clinical food insecurity screening and referral program, operating in collaboration with a statewide organization (Hunger Free Colorado) to manage clinic-to-community referrals. Immediate goals are to identify households experiencing food insecurity, connect them to sustainable (federal) and emergency (community-based) food resources, alleviate food insecurity, and improve dietary quality, and additionally to improve health outcomes, decrease health care utilization, improve patient satisfaction, and better engage patients in their care.

## NARRATIVE MEDICINE

### 78 The Best Year of Angela's Life. Kumara Raja Sundar, MD

Using a patient story, this narrative demonstrates why health care organizations, specifically primary care clinics, should strive to identify and address social needs. This story demonstrates how Kaiser Permanente Washington, by using community resource specialists, has empowered primary care clinics to address social needs in a health care setting to improve patient care and experience.

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Introduction

# Food Insecurity—Addressing Basic Resource Needs in Health Care Settings

John F Steiner, MD, MPH

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## EDITOR'S NOTE

In my practice in a safety-net clinic I care for uninsured patients, most of whom must regularly weigh the difficult decision as to how best to use their few dollars: Medications? Food? Gas/transportation? Even the very act of getting to a clinic can be a challenge. Understanding this critical—and often life-threatening—decision-making process is essential to total health care. To best care for this population of patients, health care organizations must develop a strategy to deal with this commonly forgotten problem.

Through the Kaiser Permanente (KP) research groups, various KP Regions have developed programs to respond to this need and continue to review the success of these programs and options for additional or improved programs.

*The Permanente Journal* is pleased to present this supplemental issue featuring work from KP researchers and their academic colleagues and collaborators on the role of basic resource needs in patient care. This special issue represents the support and importance *The Permanente Journal* gives to this important health care initiative. We value our partnership with the KP research groups, and this special supplement is a reflection of that relationship. We thank John Steiner, MD, MPH, for his partnership and for his leadership in bringing together these talented researchers to create this collection of peer-reviewed articles to improve the health and welfare of the patients we serve.

— Lee Jacobs, MD  
Associate Editor-In-Chief

Charles Albert Tindley (1851-1933) was a prominent pastor in Philadelphia and a prolific composer of gospel hymns, including the lyrics that later became the civil rights anthem, “We Shall Overcome.” Another of his hymns, “We’ll Understand It Better By and By,” includes a few simple verses that address a day-to-day reality for his African American congregation at the beginning of the 20th century.<sup>1</sup>

We are often destitute

Of the things that life demands,  
Want of food and want of shelter,  
Thirsty hills and barren lands ...

Food insecurity, inadequate or unaffordable housing, and other basic resource needs remain too common in the US to this day.<sup>2,3</sup>

As the articles in this Supplement to *The Permanente Journal* emphasize, public- and private-sector organizations that finance health care and clinical systems that deliver care are increasingly convinced that addressing the social determinants of health is a pathway to better health. The papers by Gusoff et al (page 22) and Solomon and Kanter (page 48) take the “macro” perspective, summarizing the current thinking of funders, regulators, and professional organizations about the need to recognize a wide array of social determinants in health care systems. These articles also provide guidance to frontline clinicians and delivery systems about how to address those needs.

Most papers in this supplement, by design, take a “micro” perspective. Out of the expansive array of social determinants,<sup>4</sup> these papers focus on 1 or more of 5 basic resource needs (housing, food,

transportation, and resources to pay for utilities and medical costs). Steiner and colleagues (page 53) propose a 5-step continuum of care that can help clinical delivery systems develop and improve their ability to address these basic resource needs, and can help evaluators and researchers assess the success of these efforts. The majority of the papers address the first 3 of these 5 steps: the need for thoughtful *planning* of new programs (page 17; page 71), the use of valid measures of basic resource needs to *assess* needs at the individual (page 33; page 40; page 63) and community level (page 28; page 58), and the development and testing of interventions to *connect* patients to community resources (page 6; page 63; page 71). Among these interventions, Hsu et al (page 6) showed *improvements* in satisfaction among patients and the primary care team, whereas both Friedman and Banegas (page 63) and Stenmark et al (page 71) found that many individuals had needs that were not mitigated by these programs. None of the articles describe efforts to *spread* their programs within their original health care system or to other settings. In this, they reflect the broader state of the literature and the nascent state of most programs.

Policy directives and statistical tests are not the only way to conceptualize these programs, however. As both Tindley’s hymn<sup>2</sup> and Sundar’s narrative (page 78) show, art and story are uniquely able to bring lofty pronouncements and population-based evaluations back to the level of an individual who struggles to meet her basic human needs.



Structuring the health care system to identify and mitigate basic resource needs is a hard problem. By their very nature, hard problems require multidisciplinary solutions that cross conventional domains of responsibility and bureaucratic reporting lines. As these papers suggest, collaboration within health care systems to identify patients with basic resource needs requires the engagement of operational leaders, clinicians, office staff, information technology professionals, population health specialists, social workers, and patient navigators. These systems must also collaborate with the skilled and committed leadership and staff of the community organizations that ultimately provide basic resources to address these needs.

Some of the studies in this Supplement are small and few are definitive, but all reflect the efforts of dedicated professionals to evaluate approaches to addressing the basic resource needs that Reverend Tindley so eloquently captured more than a century ago. We hope that these articles speak to our intended audience of leaders, clinicians, and staff who have recognized the need to address social determinants of health and will design and conduct the programs to do so. ❖

#### How to Cite this Article

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Keywords: food insecurity, resource needs, social determinants of health

## A Piece of Bread

The greatest disease in the West today is not TB or leprosy; it is being unwanted, unloved, and uncared for.

We can cure physical diseases with medicine, but the only cure for loneliness, despair, and hopelessness is love. There are many in the world who are dying for a piece of bread but there are many more dying for a little love.

— Mother Teresa, 1910-1997, also known as Saint Teresa of Calcutta, Roman Catholic nun and missionary

# Evaluation of the Learning to Integrate Neighborhoods and Clinical Care Project: Findings from Implementing a New Lay Role into Primary Care Teams to Address Social Determinants of Health

Clarissa Hsu, PhD; Erin Hertel, MPA; Eric Johnson, MS; Carol Cahill, MLS; Paula Lozano, MD, MPH; Tyler R Ross, MA; Kelly Ehrlich, MS; Katie Coleman, MSPH; June BlueSpruce, MPH; Allen Cheadle, PhD; Juno Matthys; Michelle Chapdelaine, MPH; Marlaine Gray, PhD; Janice Tufte; Michele Robbins

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## ABSTRACT

**Introduction:** Health systems increasingly recognize the impact of social determinants of health such as access to housing, transportation, and nutritious food. Lay health workers have been used to address patients' social determinants of health through resource referral and goal setting in targeted populations, such as individuals with diabetes. However, we know of no studies that evaluate this type of role for a general primary care population.

**Objective:** To assess the implementation and impact of the Community Resource Specialist (CRS) role in Kaiser Permanente Washington.

**Methods:** We analyzed data from staff interviews, patient focus groups, clinic site visits, patient surveys, the electronic health record, and administrative sources.

**Results:** Satisfaction with CRSs was high, with 92% of survey respondents choosing "very satisfied" or "somewhat satisfied." Of patients with a resource referral and follow-up encounter, 45% reported using the resource (n = 229) and 86% who set a goal and had a follow-up encounter (n = 218) progressed toward their goal. Primary care teams reported workload easing. Patients who used CRSs and participated in focus groups reported behavior changes and improved health, although no changes were detected from electronic health records or patient survey data. Key learnings include the need to clearly define the CRS role, ensure high visibility to clinical staff, and facilitate personal introductions of patients (warm handoffs).

**Conclusion:** Adding an individual to the primary care team with expertise in community resources can increase patient satisfaction, support clinicians, and improve patients' perceptions of their health and well-being.

with improved patient outcomes and care quality,<sup>4</sup> posits that health outcomes improve when primary care practices partner with community organizations to address patients' needs. The Expanded CCM<sup>5,6</sup> emphasizes the key roles of community agencies in self-management support and health skills development, decision support, and healthy living activities. Examples include local YMCAs with exercise programs for seniors and obesity prevention programs that clinicians can prescribe for patients to help prevent or treat chronic conditions.

As a result of this growing recognition of the interconnection between SDH and chronic disease management, health systems and researchers have been experimenting with roles to support patients in accessing community resources. One approach is adding lay or community health workers to primary care teams to help patients through resource referral, goal setting, and follow-up.<sup>7,8</sup> A recent literature review revealed growing evidence of the impact of lay or community health workers in primary care settings.<sup>9-15</sup> However, existing studies tend to target specific clinical populations, such as patients recently discharged from the

## INTRODUCTION

By 2020, an estimated 157 million Americans are expected to have at least 1 chronic illness, with 81 million having 2 or more.<sup>1</sup> Chronic illness accounts for more than 85% of health care spending in the US.<sup>2</sup> Recognition is increasing that

social determinants of health (SDH)—economic and social conditions that influence health such as inadequate housing, social isolation, and food insecurity—have a role in preventing and managing chronic illness.<sup>3</sup> The Chronic Care Model (CCM), which is associated

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hospital or those with specific chronic conditions such as diabetes, rather than a general primary care population.<sup>9,11,12,14,15</sup> Our study addressed this gap by using a patient-centered design process to create and implement a lay health worker role into primary care, with the intent of testing the feasibility and impact of this type of role on a more broadly defined population.

Supported by funding from the Patient-Centered Outcomes Research Institute, our team launched the Learning to Integrate Neighborhoods and Clinical Care (LINCC) project. LINCC created a new primary care team role focused on helping patients connect to community resources using motivational interviewing and goal setting, and resource referral and follow-up. We piloted the role in 3 primary care clinics (A, B, and C) in a health system that is now spreading the role throughout its 25 primary care facilities. Clinic A was in a suburban area, serving about 14,000 members whose average census median household income was \$56,000. Clinic B served approximately 7000 members in an urban area with a diverse population; average census median household income was \$60,800. Clinic C was in a suburban area, serving about 16,000 members whose average census median household income was \$69,700.

This article describes the process and outcome findings from our evaluation of the implementation and impact of the LINCC project. Our results will be useful to health systems that want to use lay health workers to increase clinical staff efficiency and patient satisfaction, integrate new roles into care teams, and address their patients' SDH by referral to community health resources. Additionally, our findings will help inform future research and implementation of similar interventions to address SDH.

## METHODS

### Role and Setting

This project was carried out at Kaiser Permanente Washington (KPWA, formerly Group Health), an integrated health system in Washington State with nearly 600,000 members in 2015. KPWA serves a primarily insured population. The pilot

clinics were selected with the aim of balancing geographic, racial/ethnic, and income diversity. We involved 12 patients, 11 primary care team members (including primary care providers, registered nurses [RNs], medical assistants [MAs], behavioral health/social workers, and front desk staff), and delivery system leaders who provided high-level oversight in a participatory design process for the new primary care role. The outcome of the design process was a role called the Community Resource Specialist (CRS) along with a job description, training schedule and outline, draft electronic health record (EHR) referral and visit documentation templates, and an information sheet for patients. The CRS role was piloted at 3 KPWA primary care clinics. The job description, hiring process, training program, tools, and workflow remained relatively constant over time, although efforts were made throughout the project to improve on CRS workflow processes and tools. The CRSs were hired by the health system (rather than the research team) and were supervised by Clinic Managers. Figure 1 shows a timeline of key implementation events. Because the position was created de novo (no similar roles existed in the organization), finalizing, approving, and posting the job description and hiring CRSs took approximately 3 months. Throughout the project, the research team provided extensive support for the CRS role, including from a hired consultant with experience coaching clinical staff to use motivational interviewing and health coaching techniques. Unlike many community health worker interventions, the CRS role was not designed to serve a specific subpopulation such as patients with the highest health care utilization or a specific condition such as diabetes. Rather, the role was designed to serve a broad array of patients who may need additional support and resources to improve or maintain health with a strong emphasis on those with moderate health care needs and utilization.

The CRS role focused on 3 key activities: 1) working directly with patients to help them access community resources and set health-related goals, 2) researching and becoming familiar with community

resources, and 3) increasing the primary care team's knowledge of those resources. Patients could be referred to the CRS by clinic staff through a warm handoff or the EHR referral process. *Warm handoffs* were defined as in-person introductions from a member of the primary care team who had an existing relationship with the patient. Patients could also self-refer. On referral or at their first visit with the CRS, patients were automatically entered into an EHR-based CRS registry. The CRSs had a series of EHR-based tools to help them work with patients, including templates for intake, action planning, and follow-up.

In December 2014, about 5 months after CRSs started seeing patients, both the CRS and the Clinic Manager (the CRS's supervisor) at Clinic A resigned. Because of staffing instability at the clinic, the CRS position was moved to Clinic C approximately 10 miles away. The second original pilot clinic (Clinic B) had a stable CRS for 14 months, after which the CRS resigned to relocate. Sufficient notice was provided to allow the CRS at Clinic B to train her successor (Figure 1). In late April 2015, a follow-up design event was held to troubleshoot challenges and improve workflow for the CRS role. Key issues addressed included better guidelines and communication efforts to clinic staff regarding appropriate patients to refer to the CRS and increasing warm handoffs.

### Mixed-Methods Approach

Our mixed-methods approach to documenting and evaluating the LINCC intervention included analyzing the following: 1) EHR-CRS documentation, 2) site visits/implementation observations, 3) a patient survey, 4) patient focus groups, 5) staff interviews, and 6) administrative data. For most analyses, we included data from all 3 clinics. For follow-up qualitative data (ie, interviews and focus groups), we used only Clinics B and C, because Clinic A had no active CRS service at the time. The time frame for most data collection activities was from onset of implementation in April 2014 through December 2015. The CRS documentation of patient encounters was collected through December 2016.

**Analysis of Community Resource Specialist Documentation**

The EHR tools developed to support CRSs included a patient registry for tracking and documenting care and services provided. We conducted a chart review of all CRS documentation in the EHR and carried out a detailed coding process to abstract more reliable data on types of resource referrals and goal setting, follow-up, progress made toward goals, and resources used by patients.<sup>a</sup> After coders achieved a high rate of agreement, they coded all encounters for patients of all ages who had worked with a CRS from July 2014 (the month that CRSs began seeing patients) through December 2016.

**Site Visits and Observations**

Clinic observations provided formative feedback for quality improvement and documented training and implementation of the CRS role, with a focus on observing successes and barriers. Each pilot clinic was visited every 2 to 4 months, with more frequent visits and observation early and fewer visits once the position stabilized. The research team developed a daylong site visit/clinic observation protocol<sup>a</sup> that was based on results of previous studies. The protocol included a

combination of observation, shadowing, and informal interviewing. Two observers (EH and CH) took detailed notes, which were transcribed and summarized. Summaries were shared with the research team, Clinic Managers, and CRSs.

**Patient Survey**

We surveyed patients aged 18 years and older who were referred or self-referred to a CRS and appeared in the CRS registry. Patients were asked to complete a survey regarding whether or not they had contact with the CRS. Patients were mailed an initial survey on being entered into the CRS registry. Three-month follow-up surveys were sent to all patients who did not refuse the first survey, regardless of whether they returned a completed initial survey or saw a CRS. Surveys were by mail, with telephone follow-up from April 2015 to January 2017. All patients surveyed received a \$2 presurvey incentive and a \$10 incentive for survey completion. We used a standard sequence for survey approach and nonresponder follow-up.

Survey content included the Consumer Assessment of Healthcare Providers and Systems: Patient-Centered Medical Home Items<sup>16</sup>; the Patient Activation Measure (the 6-question version)<sup>17</sup>; physical activity and social isolation questions

adapted from the Behavioral Risk Factor Surveillance System<sup>18</sup>; a single-item health status question<sup>19</sup>; questions about goal setting, action planning, CRS referral, and follow-up; patient-reported use of community programs for health; and satisfaction with the CRS service.<sup>a</sup>

Items presented only at baseline or follow-up have no associated statistical tests and are presented to describe the population that worked with the CRS. Follow-up survey data were restricted to patients who reported working with the CRS. For the cohort that responded at both baseline and follow-up, we used prespecified analyses to detect changes in clinical follow-up rates, average weekly exercise, self-reported health status, and patient activation. Categorical variables were compared by  $\chi^2$  test. Continuous variables were compared using a 2-sample *t*-test with unequal variances.

**Patient Focus Groups**

Two focus groups were conducted at Clinics B and C (4 groups total) with patients who used the CRS service. The aim was assessing patient experience, impact of CRS services on patient behavior and well-being, and patient recommendations for improvement.<sup>a</sup>

The recruitment sample was all patients aged 18 years and older who had worked with a CRS at Clinics B or C at least once in 2015 (n = 227). The CRS at each clinic reviewed the list of potential participants and excluded 11 individuals for reasons that included serious mental illness or physical disability, no contact with the CRS despite appearing in the automated data, or death. The 216 remaining potential participants were invited by letter with a phone number to volunteer or decline; 16 declined or were ineligible. Patients were called until each group had 8 to 12 participants. Participants received a \$75 thank-you. Two research team members (CH and EH) facilitated focus groups, which were audio-recorded and real-time transcribed by a court reporter.

The analysis team included 3 project team members who attended some or all focus groups. A thematic analysis approach<sup>20,21</sup> with iterative rounds of coding was used to develop and finalize codes. Two team members (CH and JB) coded

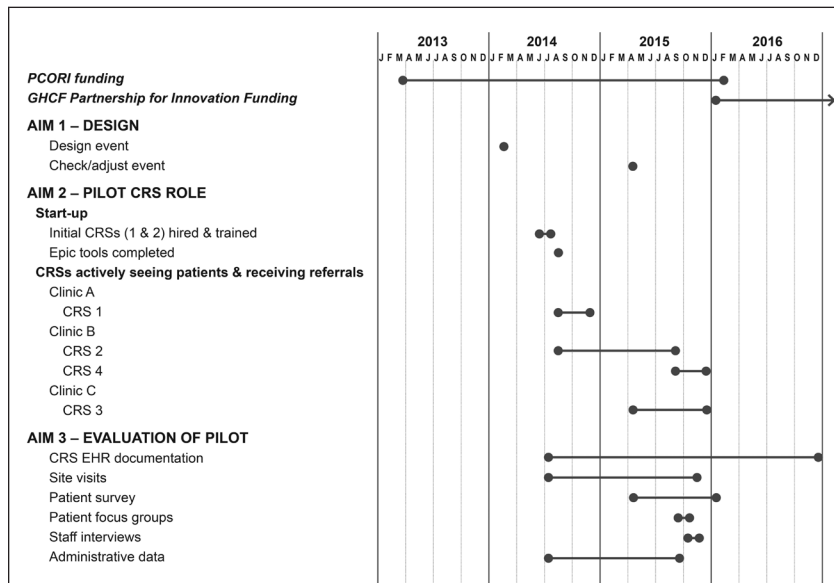


Figure 1. Project timeline.

Abbreviations under years = months; CRS = Community Resource Specialist; EHR = electronic health record (Epic); GHCF = Group Health Community Foundation; PCORI = Patient-Centered Outcomes Research Institute.

all transcripts and reconciled differences, with all transcripts entered in qualitative data analysis software (Atlas.ti, Berlin, Germany).<sup>22-25</sup> Codes were again reviewed by one team member (CH), who identified subthemes and synthesized and summarized the results.

### Staff Interviews

Qualitative interviews in late Fall 2015 assessed staff reactions to the CRS position. Interviewers asked respondents about their experience with CRS implementation, how they felt the role was working in the clinic, how the referral process was working, the extent to which they felt the role was becoming integrated

into clinic workflow, how it affected their work, and their perception of benefits or challenges.

Participants in formal interviews included KPWA organizational leaders with responsibilities relevant to the CRS position; Clinic Managers; and up to 5 purposively selected primary care providers and staff working at Clinics B and C, including physicians, RNs, medical assistants, and social workers. Interviews were 1 hour long, either in person or by phone. Participants provided written consent and were given permission to use work time to participate. All interviews were audio-recorded and transcribed. Informal interviews were conducted with CRSs,

clinic leaders, and staff during regular research site visits. Interview consent was verbal. These interviews were not audio-recorded, but detailed notes were taken. Three research team members conducted interviews (CH, EH, and JM).

Data were analyzed by interviewers and an additional team member (MG) using a thematic analysis approach.<sup>20</sup> One team member (EH) developed an initial code list using themes from review of 3 transcripts. Three team members (CH, EH, and JM) applied the initial code list to 3 transcripts, then reconciled revised codes and clarified definitions. Additional coding comparison finalized the code book and confirmed shared

**Table 1. Key questions and data sources**

Data source	Description of data	Key questions informed by data source
EHR-CRS documentation	<b>Data collection time frame:</b> July 2014-December 2016 <b>Final dataset:</b> 4505 records analyzed for 1182 unique patients	Who was served by the CRS? What services did CRS patients receive? What impact did the CRS have on the patient? What were the key lessons learned?
Site visits/ implementation observations	<b>Data collection time frame:</b> July 2014-November 2015 <b>Final dataset:</b> Clinic A, 3 daylong visits Clinic B, 6 daylong visits Clinic C, 3 daylong visits	Who was served by the CRS? What services did CRS patients receive? What impact did the CRS have on the delivery system? What were the key lessons learned?
Patient survey	<b>Data collection time frame:</b> April 2015-January 2017 <b>Final dataset:</b> Mailed to 518 unique individuals. (Not all patients received both follow-up and a baseline survey because of timing issues.) Baseline surveys were mailed to 354 patients at the time of CRS registry entry. Of these, 169 were completed, 115 refused, 30 were ineligible, and 40 never responded, resulting in a 52% response rate. <sup>a</sup> Follow-up surveys were mailed to 384 patients 3 months after registry entry. Of these, 200 <sup>b</sup> were completed, 71 refused, 16 were ineligible, and 97 never responded, resulting in a 54% response rate. <sup>a</sup>	What impact did the CRS have on the patient?
Patient focus groups	<b>Data collection time frame:</b> September 2015-October 2015 <b>Final dataset:</b> A total of 33 individuals participated in 4 focus groups.	What impact did the CRS have on the patient?
Staff interviews	<b>Data collection time frame:</b> October 2015-November 2015 <b>Final dataset:</b> Participants in formal interviews were Kaiser Permanente Washington (KPWA) organizational leaders with responsibilities relevant to the CRS position (N = 5); clinic managers (N = 2); and clinic staff (N = 10) working at the 2 final pilot clinics, including physicians, registered nurses, medical assistants, and social workers.	What impact did the CRS have on the delivery system? What were the key lessons learned?
Administrative data (EHR, Health Plan, etc)	<b>Data collection time frame:</b> July 2014-September 2015 <b>Final dataset:</b> 420 CRS patients met inclusion criteria: 1) at least 1 full encounter with the CRS, 2) aged 18 years or older, and 3) enrolled at KPWA at time of CRS encounter. A total of 1036 patients served as matched controls. Up to 3 individual controls were matched to every CRS patient. Controls were selected on the basis of having similar 1) health care utilization in the index month, 2) race/ethnicity, 3) duration of enrollment before CRS visit, 4) age, 5) sex, and 6) ACG RUB. Some CRS patients were matched with only 2 controls if a third comparable control could not be identified.	Who was served by the CRS? What impact did the CRS have on the delivery system?

<sup>a</sup> Response rate was calculated by subtracting the ineligible from the total number mailed and using that number as the denominator and the completed surveys as the numerator.

<sup>b</sup> Not all those responding to the survey had a visit with the CRS.

ACG RUB = Adjusted Clinical Group Resource Utilization Band; EHR = electronic health record; CRS = Community Resource Specialist.

understanding and consistent application of codes. Transcripts were coded in Atlas.ti software.<sup>22-25</sup> On the basis of review of coded data, one team member (EH) drafted a coding memo with feedback from the coding team (JM, MG, CH).

**Administrative Data**

Health care utilization was examined using administrative data from the EHR and Health Plan data systems. Data were analyzed using an interrupted time-series design with observations by patient-month. We included anyone who saw the CRS at the 3 pilot clinics who was aged 18 years and older at the intake visit. Individuals contributed data until disenrollment from KPWA or the end of September 2015, whichever came first. To control for temporal trends at KPWA, we matched patients referred to a CRS (“CRS patients”) to as many as 3 control patients at selected KPWA control clinics. Control clinics were geographically close to intervention sites (and therefore had access to similar community resources); were of similar size; and had similar patient demographics, including race/ethnicity distributions. Every CRS patient (as of September 30, 2015) was matched with up to 3 individuals from the corresponding control clinic using these criteria: 1) health care utilization in the index month, 2) race/ethnicity, 3) duration of enrollment before the CRS visit, 4) age, 5) sex, and 6) Adjusted Clinical Group Resource Utilization Bands.<sup>26</sup> In several cases, an individual was matched with only 1 or 2 controls because appropriate controls were not available. Missing clinical outcomes data were accounted for with multiple imputation via chained equations, using 100 imputed datasets. Analyses were conducted in Stata software (Version 15.1, StataCorp LLC, College Station, TX).<sup>27</sup>

We used random-effects models to analyze data, accounting for correlation between observations in the same patient. We used a restricted cubic spline to model the overall temporal trend in KPWA, with a knot placed at the time of the CRS visit and 2 additional knots at 6 months before and after the visit. To identify changes associated with the introduction of the CRS, we included interaction variables of the splines against an indicator variable,

defined as 1 if the patient was in a clinic where the CRS was active at that time. Because the intervention-group patients and the controls may have had slight differences in average utilization rates before the CRS visit, we adjusted for intervention/control status to avoid potential confounding. We present the estimated differences between cases and matched controls at 3 and 6 months after the visit, adjusting for patient characteristics and baseline differences in rates.

**RESULTS**

We present our results organized around 5 key questions: 1) Who was served by the CRS? 2) What services/support did patients receive from the CRS? 3) What impact did the CRS have on the patients they worked with? 4) What impact did the CRS have on the health system? and 5) What were the key lessons learned? Because of our mixed-methods approach, findings were often

**Table 2. Characteristics of patients referred to a Community Resource Specialist with at least 1 complete visit**

Characteristic	Clinic A (n = 59), no. (%)	Clinic B (n = 331), no. (%)	Clinic C (n = 429), no. (%)	All clinics (N = 819), no. (%)
Sex, female	45 (76)	266 (80)	290 (68)	601 (73)
<b>Age, y</b>				
≤ 18	5 (8)	36 (11)	55 (13)	96 (12)
19-34	8 (14)	81 (24)	40 (9)	129 (16)
35-64	29 (49)	120 (36)	115 (27)	264 (32)
≥ 66	17 (29)	94 (28)	219 (51)	330 (40)
<b>Race</b>				
Asian	1 (2)	77 (23)	10 (2)	88 (11)
Black	10 (17)	130 (39)	12 (3)	152 (19)
Hawaiian/Pacific Islander	3 (5)	10 (3)	6 (1)	19 (2)
Native American	2 (3)	10 (3)	9 (2)	21 (3)
Other	2 (3)	19 (6)	13 (3)	34 (4)
Unknown	1 (2)	11 (3)	18 (4)	30 (4)
White	40 (68)	74 (22)	361 (84)	475 (58)
<b>Hispanic ethnicity</b>				
No	54 (92)	296 (89)	387 (90)	737 (90)
Yes	5 (8)	24 (7)	23 (5)	52 (6)
Unknown	0 (0)	11 (3)	19 (4)	30 (4)
<b>ACG RUB (from lowest to highest predicted utilization)</b>				
RUB 0	0 (0)	1 (0)	2 (0)	3 (0)
RUB 1	1 (2)	16 (5)	7 (2)	24 (3)
RUB 2	0 (0)	37 (11)	21 (5)	58 (7)
RUB 3	24 (41)	137 (41)	152 (35)	313 (38)
RUB 4	19 (32)	63 (19)	85 (20)	167 (20)
RUB 5	9 (15)	29 (9)	87 (20)	125 (15)
Missing	6 (10)	48 (15)	75 (17)	129 (16)
<b>Chronic condition</b>				
Congestive heart failure	4 (7)	21 (6)	43 (10)	68 (8)
Depression	23 (39)	81 (24)	165 (38)	269 (33)
Diabetes	18 (31)	66 (20)	91 (21)	175 (21)
Hypertension	33 (56)	143 (43)	220 (51)	396 (48)
Persistent asthma	16 (27)	63 (19)	89 (21)	168 (21)
None of selected conditions	13 (22)	132 (40)	137 (32)	282 (34)

ACG RUB = Adjusted Clinical Group Resource Utilization Band.

based on multiple data sources. Table 1 describes the data sources and the key questions they answer.

**Population Served by Community Resource Specialist**

Overall, 1182 patients were referred to CRSs. Of referred patients, 69% (819) had at least 1 complete visit documented in the medical record; 11% (126) had no CRS interaction but received resource information via mail, phone, or secure messaging; and 20% (237) had no CRS interaction despite referral. Figure 2 summarizes the number of patients referred to the CRS between July 2014 and December 2016 and the disposition of those patients, including whether they received services from the CRS and the outcomes of those services. We also tracked the number of overall encounters and unique individuals seen by the CRS each month between April 2015 and October 2016, a period when the CRS role had been fully implemented, was running smoothly, and had stable staffing. The CRS capacity peaked at approximately 55 to 60 patient visits per month with 40 unique patients during this time frame. The CRS patients were diverse in age and ethnicity but were mostly female (73%, Table 2). The racial and ethnic diversity of the CRS patients roughly reflected the diversity in each pilot clinic (Figure 3). Patients who were referred to a CRS were primarily concentrated in Adjusted Clinical Group Resource Utilization Bands corresponding to moderate or

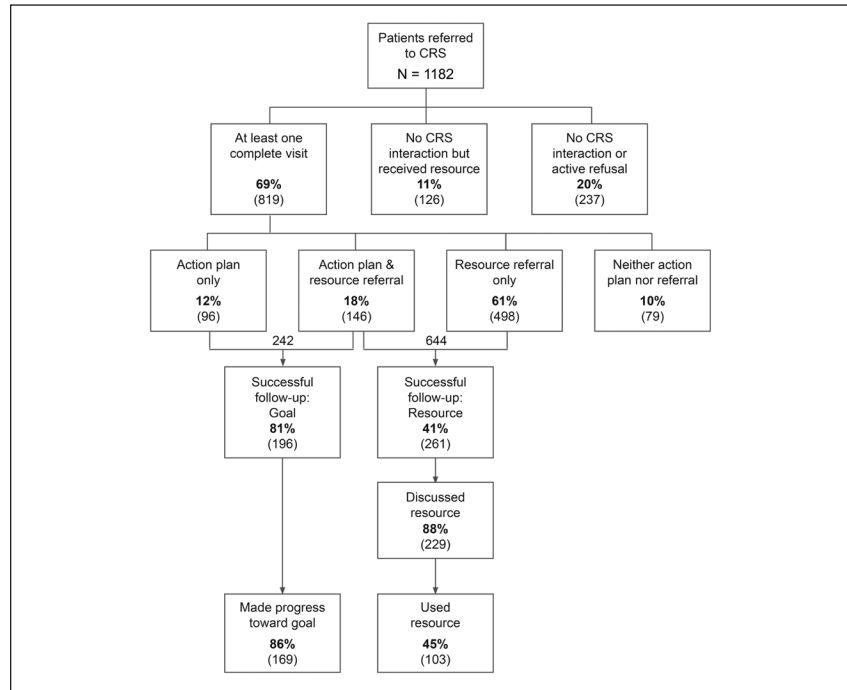


Figure 2. Referrals, level of connection to Community Resource Specialist (CRS), and outcome of interaction.<sup>a</sup> Values in parentheses are numbers of patients.

high health care utilization, which was the desired focus. Most CRS patients (66%) had 1 or more of the 5 common chronic diseases described in Table 2.

**Services/Support Provided by a Community Resource Specialist**

In our analysis of EHR-CRS documentation data, services to patients ranged from providing information about

community resources to developing action plans (tools to elicit and document next steps for patients). Figure 2 shows the numbers of patients receiving specific types of services. Different service types were associated with a different intensity of contact from the CRS. Action planning involved more contacts per client; approximately 60% of clients with action plans had 3 or more contacts.

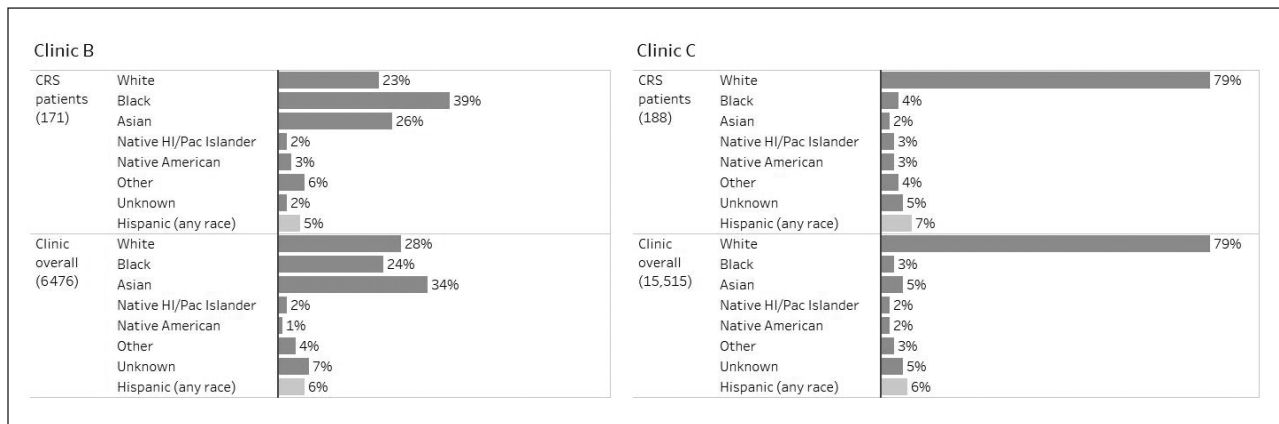


Figure 3. Race/ethnicity for pilot clinics and CRS patients.<sup>a</sup> Data are for 2 of the 3 pilot clinics with CRSs, from administrative data on 420 patients total. Clinic A was excluded because of the small number of CRS patients seen at the clinic during the pilot. Percentages may not total to 100% because more than 1 response was possible. CRS = Community Resource Specialist; HI = Hawaiian; Pac Islander = Pacific Islander.

Of patients with whom the CRS had 1 or more follow-up visits and discussed a resource, almost half reported that they used it (Figure 2). The 5 most frequent CRS referral types to external resources were social services (n = 328), physical activity (n = 199), support groups (n = 62), health care resources outside KPWA (n = 59), and parenting support (n = 50). Referrals to resources within KPWA were also common; 82 CRS patients received referrals to KPWA written or Web site materials, and 29 were referred to KPWA's Living Well with Chronic Conditions class. The CRSs often referred patients to different health care practitioners, including social workers or behavioral health practitioners (n = 66) or primary care providers (n = 47), and other practitioners such as specialists or eye care providers (n = 26). Overall, 45% of patients who were given a resource referral and had a follow-up encounter with a CRS reported using the resource (n = 103, Figure 2). If a patient set a goal, the likelihood of an accompanying action plan was higher. We found that 86% of patients who set a goal and had a follow-up encounter (n = 169) made progress toward their goal, according to analysis of CRS documentation.

**Impact of Community Resource Specialist on Patients**

Three-month follow-up surveys showed high satisfaction with CRS services. Of 106 patients who returned 3-month follow-up surveys who had at least 1 visit with the CRS, 63% (67 patients) marked very satisfied, 29% (31) marked somewhat satisfied, and 8% (8) marked not satisfied when asked about CRS services. Satisfaction levels were similar across all pilot clinics. These survey results were consistent with focus group data, which showed high CRS satisfaction.

A key goal for the CRS role was supporting patients in making changes to increase overall health and wellness. We found no significant differences in patient survey responses between baseline and follow-up for several health status-related questions for respondents who had seen CRSs (data not shown). Focus group data, however, indicated that the subset of patients who came to a focus group felt that working with the CRS contributed

**Table 3. Health care utilization (per 1000 members per month) over time among patients seen by a Community Resource Specialist (CRS; N = 420 from administrative data) and matched controls (N = 1045)**

Utilization	3 months after CRS contact	6 months after CRS contact
<b>Total overall primary care utilization</b>		
CRS patients, no.	523	481
Controls, no.	467	423
Adjusted difference (95% CI)	35.3 (-134, 205)	36.4 (-98, 171)
p value <sup>a</sup>	0.683	0.597
<b>Emergency Department</b>		
CRS patients	23.8	19.8
Controls	16.6	17.1
Adjusted difference (95% CI)	-6.7 (-29.8, 16.5)	-11.2 (-30.5, 8.2)
p value <sup>a</sup>	0.572	0.259
<b>Urgent care</b>		
CRS patients	50.3	51.9
Controls	72.7	71.5
Adjusted difference (95% CI)	-5.6 (-62.2, 51.0)	-2.8 (-49.1, 43.6)
p value <sup>a</sup>	0.847	0.907
<b>Behavioral health</b>		
CRS patients	147	118
Controls	82	74
Adjusted difference (95% CI)	15.1 (-49.1, 79.2)	-6.5 (-67.0, 53.9)
p value <sup>a</sup>	0.646	0.832
<b>Primary care face-to-face</b>		
CRS patients	329	299
Controls	230	227
Adjusted difference (95% CI)	82.7 (15.5, 149)	56.7 (-1.6, 115)
p value <sup>a</sup>	0.016	0.057
<b>Outpatient</b>		
CRS patients	959	853
Controls	847	766
Adjusted difference (95% CI)	166 (-30, 361)	141 (-53, 335)
p value <sup>a</sup>	0.097	0.154
<b>Consulting nurse</b>		
CRS patients	97	90
Controls	117	102
Adjusted difference (95% CI)	-21.7 (-60.9, 19.5)	-13.7 (-47.3, 19.9)
p value <sup>a</sup>	0.312	0.423
<b>Secure messages</b>		
CRS patients	2079	1955
Controls	2010	1878
Adjusted difference (95% CI)	580 (143, 1018)	588 (192, 985)
p value <sup>a</sup>	0.009	0.004
<b>Secure-message threads<sup>b</sup></b>		
CRS patients	1312	1257
Controls	1317	1245
Adjusted difference (95% CI)	313 (36, 589)	330 (73, 586)
p value <sup>a</sup>	0.027	0.012
<b>Telephone</b>		
CRS patients	643	581
Controls	491	436
Adjusted difference (95% CI)	36.4 (-106.6, 179.4)	29.7 (-96.7, 156.0)
p value <sup>a</sup>	0.618	0.645

<sup>a</sup> p value compares intervention and control rates, after adjusting for baseline trends. Baseline values were evaluated at 1 month before the CRS visit.

<sup>b</sup> A series of related messages about a specific issue. CI = confidence interval.



to positive behavior change and/or increased wellness. Focus group participants reported behavior changes mainly related to healthy eating or active living.

*I kind of liked it because the goals were little ones, like I promised I wasn't going to park in the handicapped parking. ... I got to park at the end of the lot and that would give me a little walk. ... It helped me because I did push myself to at least walk a little more. (Patient, Clinic B)*

*[I]t's been like 2 or 3 weeks that I have been going to the gym every day, and the last time I weighed myself it was 248, and today was 238, so I lost 10 pounds. (Patient, Clinic C)*

In addition to changing behaviors, almost all focus group participants reported improved health and well-being. Some improvements were general, such as feeling better, whereas others were specific, such as improved strength, decreased pain, or losing weight.

*I've been in a yoga class now for 11 weeks. I haven't missed at all. I can see and feel how the yoga is making my knee stronger [and] taking the pain away from my shoulders. (Patient, Clinic C)*

Several focus group participants described increased self-efficacy, both in knowing how to access health care and community resources and in increased goal-setting abilities.

*It's lifted my spirits to know that I have the ability to find what I need and that I can go to [the CRS] for that kind of help. (Patient, Clinic C)*

*I think what was really important to me was she taught me to organize my action plan for life ... because, you know, I would talk about it, but I wouldn't specify—actually execute—what I wanted to do. And she really taught me how to motivate myself ... to actually do it. That was really helpful, and that still stays with me. (Patient, Clinic B)*

### Impact of Community Resource Specialist on Health System

A key measure of the impact of the CRS on the delivery system was changes in health care utilization. Table 3 shows changes in utilization measures over time, comparing patients with a CRS encounter vs the matched comparison group (rates are per member per month).

Most measures showed no significant differences between the groups in utilization patterns at 3 and 6 months after CRS contact. However, we did observe increases in both face-to-face visits (adjusted difference in rates per member per month, 82.7 at 3 months) and secure-message utilization (adjusted difference in rates per member per month, 580 at 3 months and 588 at 6 months). Exceptions were face-to-face primary care visits and secure messaging, which showed slightly higher rates among CRS patients; and secure messaging to the health care team, which showed slightly lower rates for CRS patients.

Other indicators of impact on the delivery system were the experiences of primary care team members who were interviewed in fall 2015. Nearly all interviewed staff reported that the CRS role made their jobs easier or saved them time by finding resources they would otherwise have searched for; coaching patients who might have required substantial time with a physician, RN, social worker, or medical assistant; and allowing other staff to deliver care that requires specific licensure.

*[S]he enhances what we can do for the patient, and she saves me time. (Provider, Clinic C)*

Clinic staff also reported that CRSs brought new knowledge and awareness to the primary care team. They acknowledged the importance of knowing factors that affect patients' lives outside the clinic, especially for diverse or low-income populations. The CRS role was described as "eye opening."

*[The CRS and I] learn a lot from each other. ... Sometimes we might know patients for years and years, and there's stuff I didn't know, stuff [that the CRS] found out what's happening in their personal life, and how she's been helpful to them, and I thought it was very, very helpful to me. ... Everything, I think, is positive about this for our clinic. (Staff, Clinic B)*

### Key Lessons Learned

Our data collection and analysis also surfaced a number of lessons learned that were used for formative feedback and improvement. We summarize a few of the key learnings that have broad applications to SDH interventions involving

the addition of a new role to a primary care team.

#### Role Clarity

The CRS was designed as a bridge between medical care and community resources. A number of other roles in health care occupy this interstitial space, including behavioral health workers, social workers, care coordinators, community health workers, *promotoras*, and patient navigators. Clearly articulating what was in and out of scope for the CRS, especially regarding other related positions, such as the team social workers, was a challenge. Clinical and administrative leaders also had different priorities regarding the patient needs that they thought the CRS was best positioned to address, compounding the difficulty in clearly articulating the role. Perhaps because of these challenges, staff were often surprised that the CRS could help patients with a wide variety of issues.

#### Value of Warm Handoffs

Warm handoffs were extremely important for both the CRS patient engagement and job efficiency. Patients who had a warm handoff required fewer outreach attempts to successfully complete their initial visit (Table 4).

#### Community Resource Specialist Visibility

Having the CRSs be physically visible to other primary care team members and personally connected with them was important. When CRSs were not visible, clinical staff often forgot the role existed. Visibility and availability made warm handoffs easier because staff could quickly find and signal the CRS when they had a patient to refer. Visibility to team members proved even more critical than visibility to patients, as we found by experimenting with a CRS desk in the lobby. The lobby desk did not result in any patients using CRS services beyond CRS-initiated offers of resource information; however, we did see differences in referral rates when the CRS was sitting in a location where other members of the primary care team could easily see the CRS's desk.

### DISCUSSION

The LINCC project designed and piloted a new primary care team role—the CRS—in 3 clinics. Most patients who

**Table 4. Contact attempts with and without warm handoff for patients with a documented Community Resource Specialist encounter after May 15, 2015 (N = 272)<sup>a</sup>**

Handoff status	No. of patients	No. of contact attempts	Average attempts per patient
With warm handoff	98	111	1.10
Without warm handoff	174	306	1.76

<sup>a</sup> Time frame was limited because warm-handoff training occurred just before May 15, 2015. A warm handoff was a personal introduction to the Community Resource Specialist by staff.

interacted with the CRS received resource recommendations, and many set personal goals. Of those who set goals and had CRS follow-up documented in the EHR, most made progress. Almost half who received a referral and had a follow-up visit used the resource. In focus groups, patients reported behavior changes and improved health and well-being; however, we found no systematic differences in clinical or health status at the population level using administrative data or patient surveys. Overall, patients were highly satisfied with the services of referral, coaching, and motivational interviewing provided by the CRSs. Other primary care team members reported that benefits of the role included overall improved patient care and the ability to offload work so others could work at the top of their license.

After research funding for the CRS role ended, Clinics B and C chose to fund the position from their own budgets and subsequently, the health system leadership decided to hire a total of 19 full-time CRSs across all 25 KPWA clinics. The CRS role is now fully deployed at KPWA. The system sees this role as critical to the implementation of behavioral health integration because it allows clinic social workers to work at the top of their license, providing behavioral health counseling rather than resource referrals and health coaching. The goal is for the costs of this role to be offset by increasing the productivity of more expensive primary care team roles such as social workers, nurses, and primary care providers. However, the longer-term financial sustainability of this type of role is an ongoing question for KPWA and the field as a whole.

The CRS pilot occurred simultaneously with a proliferation of innovations nationwide addressing SDH in clinical settings, including development of

screening tools,<sup>28-30</sup> use of community health workers for patient navigation and resource referral,<sup>10,14,31</sup> and specialized services such as medical legal aid partnerships,<sup>32,33</sup> and food security interventions.<sup>34-36</sup> Several studies similar to LINCC had promising results related to decreased reported needs and improvement in clinical outcomes such as improved blood pressure or hemoglobin A<sub>1c</sub> measures.<sup>10,14,30</sup> LINCC provides unique documentation of key implementation measures, including patient uptake of services, patient follow-through on accessing resources, and primary care team integration of the new role. The lessons learned provide guideposts for primary care teams interested in introducing a similar role. Our measurement challenges and qualitative findings may provide guidance for researchers interested in testing broadly targeted SDH interventions who struggle to identify appropriate and realistic outcome measures for testing the impact. As shown by our findings, examining patient experience and/or psychological impacts such as sense of well-being and resilience might be a promising approach for evaluation of SDH interventions aimed at a broad set of needs and a diverse patient population. Finally, given the proliferation of programs to address SDH, primary care clinics need not develop these roles and related tools de novo but can use the guidance, resources, and services of organizations already doing work in this area.

This project encountered and overcame challenges inherent in implementing changes in a real-world health care setting. We experienced staff turnover, complexity in developing EHR tools and metrics for clinic use, and a major health care system reorganization. Because we chose not to target a specific subpopulation of patients, the heterogeneous nature

of patients' health issues and resource needs led to diverse clinical outcomes and small subgroup populations (eg, only 89 CRS patients had an indication of diabetes in the EHR, and even fewer had prescriptions or associated laboratory results). These low numbers affected our ability to conduct subanalyses. Also, lack of randomization in CRS referral provided the potential for confounding. Our matching of patients from CRS and control clinics did not produce samples that were comparable in baseline clinical outcome measures. Therefore, we were unable to test whether these measures changed after working with CRSs and could not determine if health care utilization by patients who interacted with CRSs was affected by the poorer health of CRS patients compared with controls. Finally, our survey, focus groups, and staff interview methods were limited by self-report and selection bias. We mitigated these potential biases by ensuring that data collection timing was proximal to the intervention and by surveying all individuals referred to a CRS rather than a sample. Focus group invitations had no restrictions.

Our evaluation of the addition of CRSs to primary care teams explored what type of patients were served by this type of community health worker, the most common services and types of support provided by CRSs, the impact of CRSs on their patients and their primary care team members, and key lessons for delivery systems considering community health workers as links to community resources. Ongoing challenges exist around quantifying the impact of CRSs on patient health outcomes and health care utilization. A related issue is the need to identify appropriate and feasible measures of the impact of community health workers because clinical outcomes may be too long-term and heterogeneous to evaluate programs that serve a broad population of patients in primary care settings. Other measures of impact may be more sensitive and feasible such as patient satisfaction, mental health, and resiliency. Finally, a major challenge for our data analysis was identifying appropriate control groups for this real-world primary care intervention. Recently developed

social-needs screening and assessment tools<sup>28-30</sup> may provide effective means of identifying appropriate control populations. Furthermore, having team members such as the CRS screen for SDH needs, adverse childhood events, and elicitation of patient values may offer new ways to foster a therapeutic relationship between patients and their primary care teams.

## CONCLUSION

We identified requirements for efficiently implementing a primary care team member who specializes in community resources that address SDH. Effective use of the CRS required a relationship with clinic staff, high visibility to providers and staff, and a commitment to warm handoffs. The CRS role had multiple positive impacts. Use of CRSs increased patient satisfaction and sense of well-being, although health changes from this pilot study were not detected in patient survey findings or administrative data. Clinic staff and providers appreciated the ease on their workload that allowed them to work at the top of their licensure. ❖

• Supplemental material is available from the author.

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**Keywords:** community health workers, integrate neighborhoods and clinical care, primary care teams, social determinants of health

## Casting a Stone

I alone cannot change the world,  
but I can cast a stone across the waters  
to create many ripples.

— Mother Teresa, 1910-1997, also known as Saint Teresa of Calcutta,  
Roman Catholic nun and missionary

# Perceptions and Experience of Patients, Staff, and Clinicians with Social Needs Assessment

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## ABSTRACT

**Context:** Assessment of social needs is expanding at Kaiser Permanente (KP), but little is known about how members and clinicians experience the incorporation of social needs into health care.

**Objective:** To assess how KP members and clinicians experience social needs assessments incorporated into care.

**Design:** Qualitative and descriptive analysis of data from member and clinician focus groups, interviews, and surveys among 68 members and family caregivers who had participated in social needs assessment programs and 90 clinicians and staff in the KP Colorado, Georgia, Northern California, Northwest, and Southern California Regions.

**Main Outcome Measures:** Members' and clinicians' perceptions and experiences of social needs assessment.

**Results:** Members and clinicians understood the impact of social needs on health and why a health care system representative would ask about food, housing, transportation, and other social needs. Members and clinicians supported social needs assessment at KP and agreed that KP should help address identified social needs. However, both groups emphasized the importance of assessments yielding actionable information. Members were also concerned about how the information would be used and by whom.

**Conclusion:** Our findings support the continuing assessment of social needs at KP and identify issues that require attention as it expands. Assessment should not outpace organizational capacity to connect members with resources. Careful attention to communications is required because members may be uncertain or concerned about the purpose of the assessment and the dissemination of sensitive information. Messaging should assure members about data use and dissemination and what they can expect after screening.

## INTRODUCTION

Despite substantial improvements in clinical care, disparities in health persist and mounting evidence suggests that traditional clinical care models are insufficient at closing these health gaps.<sup>1</sup> Nonclinical health-related social needs, such as housing instability, food insecurity, financial stress, and transportation limitations, have been shown to influence care utilization and ultimately have an impact on health outcomes.<sup>2-6</sup> Thus, health care systems are increasingly interested in implementing programs to identify and to address social needs,<sup>7</sup> moving care “upstream” to intervene in

nonclinical drivers of population health outcomes. In addition to having the potential to reduce barriers to clinical care, health system interventions to identify and to address social needs can improve clinicians' ability to tailor their care planning through a more holistic understanding of patients' circumstances, to reduce clinician burnout,<sup>8</sup> and to improve linkages with community resources that are best suited to work with patients to address outstanding social needs.<sup>9,10</sup>

Since 2012, there have been at least 3 dozen interventions in Kaiser Permanente (KP) Regions that include the use of questionnaires to screen for and to document social needs, as well as pilots to address identified needs. However, little is currently known about the prevalence and distribution of social needs among KP members. Similar knowledge gaps exist about which needs are best addressed by health care systems in general and about KP member and staff perceptions of more systematic efforts to assess and to address members' social needs.

There is also a paucity of evidence about the effectiveness and acceptability of social needs interventions.<sup>7</sup> Information about patients' perceptions and attitudes about whether social needs affect health and whether health care systems should address social needs is lacking; an exception is a report in the pediatric setting providing evidence of parental willingness to share social needs information with their child's care team.<sup>11</sup> However, there is also evidence that the screening mode may affect patients' and parents' willingness to share.<sup>12</sup> More, albeit still limited, evidence is available about physician perceptions of patients' social needs. In a 2018 survey of 240 physician faculty members in an academic medical center, respondents, on average, believed that social determinants affect health and that benefits of screening for social needs outweighed risks.<sup>13</sup> Olayiwola et al<sup>8</sup> found support for incorporating social needs into care from primary care physicians practicing in 3 delivery systems in San Francisco, CA, where greater clinician belief in the system's ability to address patients' social needs was associated with lower burnout.

The purpose of this project was to assess how KP members and clinicians experience the incorporation of social needs into care.

## METHODS

### Design

Between April 2017 and December 2017, we partnered with the KP Colorado (KPCO), Georgia (KPGA), Northern California (KPNC), Northwest (KPNW), and Southern California

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(KPSC) Regions to understand member and clinician experiences of screening for social needs in programs that incorporated the use of a standardized assessment instrument. The qualitative and descriptive assessment served as an initial evaluation of the feasibility, acceptability, and effectiveness of social needs screening within diverse care settings and informed interregional quality improvement efforts related to social needs.

We assessed 2 interventions to improve care coordination through team-based primary care models for patients with complex health and social needs (Primary Care Plus onboarding for Medicare members in KPCCO and the High Risk Care Coordination program for Medicare members in KPGA), as well as a care coordination intervention that integrated social needs screening into Medi-Cal member onboarding (Model of Care onboarding in KPNC). Additionally, we assessed a patient navigator intervention to screen for social needs and to connect members to community resources in primary care settings and the Emergency Department (ED; Community Health Navigator in KPNW) and a phone-based intervention to screen for and address the social needs of members who were predicted high utilizers of care (Social Needs Screening Toolkit [Health Leads, Boston, MA] in KPSC). Among the included interventions, the most frequently used survey instrument was Your Current Life Situation.<sup>14</sup>

### Data Collection and Analysis

The information we sought varied by regional needs and programmatic opportunities (Table 1). In general, we gathered leadership, member, clinician, and staff attitudes and experience with social needs assessment and social needs referrals and follow-up as well as their general perceptions of how social needs assessment influences care delivery. Key topics included members' perceptions of screening for social needs in the health care

setting, the usability and acceptability of assessment instruments, preferences for modes and timing of screening administration, and experiences and improvement opportunities throughout the process of sharing social needs information, working with community resources to address needs, and collaborating with care teams to adjust care plans depending on identified social needs. Similarly, for clinicians and staff, we focused on assessing perceptions and experiences of incorporating social needs into care, documentation preferences, ideas for program improvement, and the usefulness of available social needs information.

We used a combination of focus groups, journey mapping,<sup>15</sup> member and clinician interviews, and surveys to gather the perspectives of 68 members and family caregivers and 90 clinicians and staff. Members were recruited to participate in focus groups or interviews if they were enrolled in one of the regional programs of interest (Table 1) and had been exposed to a social needs assessment tool. Focus group and interview recruiters contacted members by phone with an invitation to participate in an interview or group at a KP medical center office. In KPGA, where mobility and transportation concerns posed an initial barrier to participation, recruiters offered an in-home interview option.

Clinicians and staff in all participating Regions except KPCCO were recruited for in-person interviews and group discussions via emails from their chiefs and managers, encouraging them to join discussions that typically took place during lunch breaks onsite at their workplaces. At KPCCO, clinicians and staff received emails from their chiefs, managers, and regional leadership, asking them to complete an online survey that was administered to collect feedback and their perceptions of incorporating social needs into care.

When possible, data collection tools, such as interview guides and survey instruments, were standardized across Regions to facilitate interregional learning and comparisons. Responses to

**Table 1. Study Regions, interventions, topics, and data collection methods**

KP Region	Intervention, screening questionnaire	Key evaluation topics	Data collection method, no.
Northern California	Model of Care onboarding for Medicaid members, YCLS	Referral appropriateness resulting from YCLS screening Comfort with administration Ease of accessing resources	Member interviews, 4 Staff group discussions, 21
Southern California	Health Leads (Boston, MA) phone outreach for predicted high utilizers of care, proprietary instrument	Perceptions and expectations of incorporating social needs into care	Member surveys and focus groups, 43 Staff surveys and group discussions, 42
Colorado	Primary Care Plus onboarding for Medicare members with complex needs, YCLS	Usefulness of questionnaire Comfort using responses to inform care Perceptions and expectations of providers and staff	Provider and staff survey, 27
Georgia	High Risk Care Coordination program for Medicare members with complex needs, YCLS	Ease of use reviewing and acting on information Member expectations for information use and experience of having needs met	Member interviews and journey mapping, 10
Northwest	Community Health Navigator program for one Primary Care Physician's panel, modified YCLS	Rescreening preferences Willingness to share social needs information Experience engaging with resources Questionnaire usefulness	Member and caregiver interviews and journey mapping, 11

KP = Kaiser Permanente; YCLS =Your Current Life Situation.

surveys were summarized descriptively. All in-person interviews and focus groups were video-recorded, transcribed, and coded for common themes within each Region. All written findings were aggregated to protect confidentiality, and all participants who were video-recorded consented to sharing their footage for quality improvement purposes.

## RESULTS

### How Members and Clinicians View Social Needs in General

Most interviewed members and clinicians believed that it was important to capture information about members' social needs, that social needs influence health outcomes, and that equipping care teams with information about member social needs could improve care. Clinicians we interviewed in KPSC and surveyed in KPCO believed that social needs were an issue for most of their members with complex needs. Clinicians in KPCO and KPSC reported that they use social needs information in medical decisions and care planning. For instance, surveyed clinicians in KPCO agreed that social needs were an issue for most of their Primary Care Plus patients (average score, 4.2 on a 5-point scale from 1 [strongly disagree] to 5 [strongly agree]) and that they used information about social needs in medical decisions and care planning (mean score, 4.1).

### Prevalence of Social Needs and Types of Member- and Clinician-Reported Needs

In interviews and focus groups with 43 KPSC members, 36 (83%) indicated that they had not experienced any social needs. In contrast, among 140 Medi-Cal patients in KPNC screened for social needs, 74 (53%) were identified as needing support. Among specific needs identified by members or member engagement specialists, difficulty paying for basic living expenses and difficulty paying for healthy food and food insecurity were most frequent. Social isolation and stress were also common. Other social needs reported by members included a lack of transportation to get to work or to medical care, housing problems or homelessness, and difficulty understanding written medical information.

Clinicians identified the same categories of needs but with different frequency. Surveyed clinicians reported members with social needs as most frequently having difficulty with affordable or available transportation and social isolation, followed by difficulty affording basic living expenses. Other reported needs, in decreasing frequency, were difficulty affording healthy food, homelessness or other housing problems, and other needs that included caregiver or mental health support and the inability to afford medications. In discussion groups, clinicians identified patients as being unable to afford the costs of medication, office visits, and basic living expenses, as well as having health problems arising from low literacy.

### What Members and Clinicians Think about Assessing Social Needs

Among members, the majority thought that KP should ask about social needs, including affording healthy food or basic living expenses, housing problems and homelessness, social isolation, difficulty finding or affording transportation to work and medical care, and difficulty understanding written medical information.

Among surveyed KPCO clinicians, the mean score on a 5-point scale for an item assessing if they asked patients about social needs was 2.8, indicating that they are not assessing on average. Data from KPSC clinicians suggested that time and lack of resources were primary reasons that clinicians did not assess social needs. However, in discussion groups, KPSC staff and clinicians reported that assessing social needs was an opportunity to obtain valuable information to inform care decisions and improve communication with their patients. Assessment of social needs would promote a holistic view of members and allow clinicians to tailor care. As one said, "The more you learn about patients and the more comfortable they are, you know exactly what to do for them." Having this information available would also raise awareness among all clinicians of the importance of social needs to members' health.

In discussion groups, KPSC clinicians wanted information on a range of social needs, such as living situation, food insecurity and difficulty with meal preparation, transportation, substance abuse, domestic violence, literacy and learning disabilities, and insurance coverage and copayments. However, they voiced concern about having too much information. They suggested that an easily understood format, such as yes/no questions about difficulty with transportation, paying for medications, and financial concerns would help reconcile this dilemma. Clinicians noted that assessing social needs could not replace clinician-patient discussions. As one explained, "[The information] needs to promote engagement. It needs to be a conversation because, through interactions, not only do you build trust, [you] also set a tone that allows members to better understand the questions."

### How Members Experience Social Needs Assessments

Members and caregivers who completed a social needs screening questionnaire and provided feedback about their experience reported that they welcomed the assistance and that the assessment comprehensively addressed their needs. The discussion with a care coordinator around their needs was generally perceived as friendly and caring; one member said, "I enjoyed the call. I felt like he was getting to know me so he could help, not just check the boxes." Some members found the assessment process reassuring. One member said, "No one has ever called me before just to ask if I need help. That was wonderful." Another said, "He really affirmed for me that it was okay to ask for help and receive and accept services."

On the other hand, members also wanted to know more about how the information would be used and with whom it would be shared. One said, "I was happy to share. I just didn't know where the information was going." Some were concerned about how to update the information when their status changed. One member commented, "I think that information should be used judiciously and should be used properly. Once it's in there [the electronic health record], it's not getting out, and I don't know how to update it once my status changes."

Members who had been screened for social needs suggested doing so earlier. "A lot of the reasons that brought me to the ED could have been remedied a lot sooner, had I had a frank discussion about cause and effect."

Members participating in interviews and focus groups in KPSC described preferences for multiple modes of assessing social needs: Online assessment (kp.org); in-person assessment during a hospital stay, outpatient visit, or ED encounter; and over the phone. Similarly, they preferred multiple ways to access information about addressing social needs and referrals.

### Actionable Information is Key

Both members and clinicians emphasized the importance of social needs assessments leading to actionable information. As one member said, "I need to know what's going to be done or where to start. I don't want to just have a conversation."

Clinicians wanted to be able to respond effectively to information about social needs. One clinician said, "We do not want to ask questions we do not have the answers to." Surveyed clinicians were generally aware of resources to address patients' social needs. Another clinician indicated the need for an accurate and current list that could be used to connect patients directly with resources. "We need something immediate that we can address right there ... someone who can engage and get the process started." Another clinician noted that responsibility for addressing social needs needed to be clear: "We need a better point of contact, so they aren't shifting members from one person to another or waiting weeks to open a case. If it's not clearly identified who is going to do the work, then it's not going to be done."

### Connection to Resources

Between March 2016 and February 2017, approximately 1.5% of the 300 members who were onboarded in KPNC received a referral to a Health Care Coordinator. Of these, 31% received a total of 295 resources; 77 (29%) addressed undefined social needs, food insecurity, and housing.

Members who were connected to resources in KPNW and KPGA identified enablers and barriers to making successful resource connections. Direct help accessing resources enabled successful connections, as did having a trustworthy person available to educate and support members in addressing their needs. Said one member, "I never feel like I'm getting in [the Care Coordinator's] way. She makes it easy for me to pick up the phone and ask for help if I need it." However, members also found it challenging to follow through on plans to access resources for a variety of reasons, including misplaced information, scheduling difficulties, impersonal handoffs, and processes that were simply too burdensome.

### Challenges of Screening for Social Needs

When asked how the assessment could be improved, some members noted opportunities to clarify question wording, reduce repetition, and minimize confusion about choosing the appropriate response. Members were also concerned about the sensitivity of the information collected. Said one, "I would like to be asked if it was okay [for my clinician] to share this information with the next person on my care team." Another noted that it was important that clinicians not make assumptions on the basis of the information provided: "I would just ask that the team use this information to know more about me, not make assumptions about me."

Another challenge is identifying the population to be screened. When asked who should be screened, surveyed clinicians identified varying populations: All members, predicted or actual high utilizers of care, members with complex clinical conditions, and those with one or more chronic conditions.

## DISCUSSION

Surveys, interviews, and focus groups with members and clinicians in 5 KP Regions revealed that they understood the relationship of social needs to health and why a representative of the health care system would ask about food, housing, transportation, and the like. Members and clinicians supported social needs assessment at KP and agreed that the health care system has a role in addressing social needs. However, that role is not without limits; members and clinicians emphasized the importance of assessments that yield actionable information. Members were also concerned about how the information about their social needs would be used and by whom.

Strengths of our analysis include that it is the first, to the best of our knowledge, to assess the experiences of patients and clinicians with social needs assessment. It includes both members' and clinicians' experiences of social needs assessment integrated into usual care and their perceptions about how that experience could be improved.

Several limitations deserve mention. Our analysis drew on a relatively small number of individuals at a few sites; had we included more members and clinicians at more sites, our findings might have been different. A similar limitation is the likelihood that member and clinician experience with social needs assessment depends on the context in which it occurs. Assessing social needs in the ED or via an unanticipated telephone call is likely to differ from the same assessment conducted as part of an ongoing relationship with a health care clinician. We did not include enough members and clinicians in varying contexts to elucidate the nature of these differences. The novelty of social needs assessment may have affected our findings; as members and clinicians accumulate experience that includes both assessing needs and subsequently addressing them, their perspectives may change. Finally, our findings may not be generalizable to other settings.

Our findings have several implications. They provide strong support for continuing social needs assessment throughout KP, using the resulting information to tailor treatment plans to available resources and connect members to needed services in their local communities. Our findings also provide some cautionary notes. Members and clinicians alike expressed a clear desire for social needs assessment that leads directly to meaningful follow-up to help members address identified needs; as social needs assessment activities expand, they must not outpace organizational capacity to connect members with resources. Finally, social needs assessment is categorically different from gathering health status data, such as blood pressure; members may be uncertain or concerned about the purpose of the assessment and dissemination of information they view as sensitive. Related communications should assure members about how the data will be used and what they can expect after screening.



## CONCLUSION

Future research should identify the population most likely to benefit from social needs assessment. It should also focus on the appropriate timing for follow-up assessments after social needs screening and test the effectiveness and acceptability of various modes of administering social needs screening assessments: In person, by phone, and online. Members' concerns about privacy and stigma should be explored, as should the relationships between having social needs, wanting help from KP to address them, and sharing decision making about prioritizing multiple needs. ❖

## Disclosure Statement

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

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Keywords: disparities in health, financial stress, food insecurity, health outcomes, physician burnout, social determinants of health, social needs screening

## Humanity

Humanity in physicians manifests itself in ... services to the poor.

— Benjamin Rush, 1746-1813, physician, politician, social reformer, humanitarian, educator, and signer of the Declaration of the Independence

# Professional Medical Association Policy Statements on Social Health Assessments and Interventions

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## ABSTRACT

**Background:** Evidence demonstrating the link between social and economic needs and health outcomes and a concurrent shift toward value-based payment models have incentivized health care delivery system leaders to explore social and economic risk-related screening and intervention programs. This study was designed to elucidate the ways in which professional medical associations (PMAs) encourage these activities in organizational policy statements and practice guidelines.

**Methods:** We extracted publicly available policy and position statements and clinical guidelines from 42 US PMAs that featured themes related to screening for or addressing patients' social determinants or social needs in health care delivery settings.

**Results:** Among the 42 PMAs included in this study, 9 (21%) published 39 relevant statements. Fourteen of these statements referred to clinic-based social or economic health screening activities, 34 referred to clinical interventions to promote social or economic health, and 3 referred to strategies for financial support for these activities. Thirty-six of the 39 statements (92%) were published after 2008.

**Discussion:** PMAs are releasing public statements related to social needs screening and interventions in clinical settings with increasing frequency. Disciplines such as pediatrics, family medicine, and psychiatry are policy leaders in this area. Statements released by PMAs representing these disciplines include detailed information about social and economic needs screening and interventions that can be adopted by clinical care systems.

**Conclusion:** Findings in select medical disciplines indicate that social health assessments and interventions are gaining acceptance.

## INTRODUCTION

An expanding literature explores ways in which social and economic risk factors contribute to persistent inequities in population health and well-being.<sup>1-7</sup> These findings are grounded in a body of work that demonstrates how race/ethnicity and class differences manifest in uneven access to and quality of education, employment, and wealth, which contributes to disparities in access to material goods such as housing and food; stress; and health behaviors such as smoking, physical activity, and nutrition.<sup>8-14</sup> As the literature that links upstream social and economic risk factors and downstream health inequities has expanded, the health care financing focus has shifted from rewarding volume to rewarding positive clinical outcomes.<sup>15</sup> These developments have incentivized some health care system leaders to explore concrete ways to

recognize and improve social and economic conditions as one part of a comprehensive strategy to improve health outcomes.<sup>16</sup> In clinical settings, these innovations largely have focused on identifying and addressing patients' basic material needs by strengthening bridges between medical and social service organizations.

Despite the evolving evidence demonstrating that targeted programs may improve well-being for people with socioeconomic barriers to health care,<sup>16-19</sup> there is little awareness of the extent to which screening for social and economic risks and related interventions actually has been adopted across the health care sector.<sup>20,21</sup> Existing patient, practitioner, or payer survey findings are limited by small numbers of respondents, restricted to particular medical disciplines, or focused on unique clinical settings.<sup>22-29</sup> Statements from professional

medical associations (PMAs), which may reflect or elevate new professional practice standards, provide a unique gauge of the degree of engagement surrounding social health assessments and interventions. Although PMA policies do not always precede widespread clinical practice, they can pave the way for practice mainstreaming.<sup>30-32</sup> An advantage of using PMA statements to measure practice diffusion is that PMAs represent a wide range of medical disciplines, many of which have not been surveyed in other health services research. We reviewed policies and guideline statements from 42 PMAs with the goal of understanding ways in which social health assessments and interventions are endorsed across specialty groups.

## METHODS

Between January 1, 2018, and March 31, 2018, we reviewed the Web sites of the American Medical Association and all PMAs listed as members of the Council of Medical Specialty Societies. From the 42 sites, we extracted publicly available policies, position statements, and clinical guidelines that related to assessing for or intervening on patients' social needs in health care settings. Articles were included if they referenced assessment or intervention activities for social determinants of health, social risk, social health or related topics such as food, housing, financial security/poverty, employment, or education/numeracy/literacy.

Exclusion criteria were applied if articles referenced "care management" or "extraclinical services" without specifying social health assessments or medical and social/community service links to health care. Statements also were excluded when clinician advocacy or clinical education related to social health was described without

reference to clinic-based screening or interventions. Articles referencing screening for or interventions related to intimate partner violence or substance abuse were excluded because these topics already have been examined by the US Preventive Services Task Force.<sup>33-35</sup> References to efforts to decrease discrimination in clinical care settings based on race/ethnicity, sexual orientation, or other patient characteristics were not included in this analysis. All extracted statements were reviewed by 2 authors (GG, LG) for relevance to the primary topic, and content was classified into screening, intervention, and financing categories; articles could be included in more than 1 category (Table 1). Other PMA publications such as press releases, letters to Congress, or affirmations of other PMA guidelines, even if publicly available, were not reviewed.

## RESULTS

Thirty-nine statements published by 9 of 42 PMAs (21%) met our inclusion criteria (Table 2). Of these statements, 21 (53%) were published by the American Academy of Pediatrics or the American Academy of Family Physicians. Fourteen statements referred to clinic-based social

or economic health screening activities, 34 discussed clinical interventions to promote social or economic health, and 3 addressed strategies to finance the related activities. Of the 39 statements, 92% were published after 2008, 75% were published after 2012, and 50% were published after 2014.

The 14 statements promoting social health screening in clinical settings varied in content and specificity. Although all 14 statements encouraged practitioners to screen for social risk factors that could affect health, details regarding which social domains should be covered or how screening should be conducted were not uniformly included. For example, one American Academy of Family Physicians statement recommended, "Screening patients to identify patients' socioeconomic challenges should also be incorporated into the practice."<sup>36</sup> In contrast, 3 American Academy of Pediatrics statements<sup>37-39</sup> and 1 statement from the American College of Obstetricians and Gynecologists<sup>40</sup> referred both to specific screening tools (eg, a specific food security screening tool) and screening data storage/tracking approaches (eg, electronic health record-based tracking). Most PMA statements

referred to screening generally for a range of social needs (eg, housing, nutrition, etc), whereas several statements referenced only domain-specific screening (eg, for human trafficking<sup>41</sup> or food security<sup>38</sup>) or encouraged screening in specific populations such as immigrant children.<sup>39</sup>

Most PMA statements featured text that encouraged practitioners to assess and also intervene when social needs were identified. Intervention recommendations included making referrals, building stronger partnerships with social service providers, and providing social services within clinical settings. These recommendations varied substantially in terms of content and specificity; 35% of PMA statements provided guidance such as encouraging coordination with certain types of service providers such as housing or transportation organizations, referring to specific social service programs (eg, Women, Infants and Children or the Supplemental Nutrition Assistance Program) or promoting colocation of services at the clinic site such as medical-legal partnerships.<sup>37,39,42</sup> The remaining statements made general recommendations such as "partner with community

**Table 1. Sample PMA statements by statement category**

Category	Definition	Sample PMA statement
Screening	A call for patient social health (including risk and/or resilience) assessments, such as for housing stability or nutrition	"Use individual clinical encounters as opportunities to screen and address the social, economic, educational, environmental, and personal-capital needs of the children and families they serve."—AAP <sup>1</sup>
Intervention	Referrals to off-site agencies: A call for clinic-based referrals to social services to reduce social risks	"Maximize referrals to social services to help improve patients' abilities to fulfill these [social] needs."—ACOG <sup>2</sup>
	Service coordination: A call for clinics and/or practitioners to better coordinate with social service providers or community organizations that reduce social risks	"... clinical and community partnerships, enabled by digital advances, offer a way to maintain the clinical integrity and continuity in managing obesity."—ACPM <sup>3</sup>
	On-site service delivery: A call for clinics and/or practitioners to provide services to reduce social risks	"Medical-legal partnerships should be supported to help immigrant families with these issues."—AAP <sup>4</sup>
Financing	A call for health care funding to cover clinic-based social health-related interventions	"Managed care organizations ... must be able to coordinate interaction with other social services, such as nutrition programs. Capitation rates would reflect the additional cost of providing specialized services and the savings from reduced emergency department and other hospital costs."—ACP <sup>5</sup>

AAP = American Academy of Pediatrics; ACOG = American College of Obstetricians and Gynecologists; ACP = American College of Physicians; ACPM = American College of Preventative Medicine; PMA = professional medical association.

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**Table 2. Professional medical association social prescribing statement characteristics**

PMA, year	Type	Topic	Screening	Intervention	Financing
AAFP, 2013 <sup>1</sup>	P	Social determinants of health	X	X	
AAFP, 2015 <sup>2</sup>	P	Population health		X	
AAFP, 2016 <sup>3</sup>	P	Health equity		X	
AAFP, 2015 <sup>4</sup>	PS	Poverty	X	X	
AAFP, 2017 <sup>5</sup>	P	Human trafficking		X	
AAFP, 2015 <sup>6</sup>	PS	Incarceration and health		X	
AAFP, 2015 <sup>7</sup>	PS	Primary care and public health		X	
AAFP, 2015 <sup>8</sup>	P	Violence		X	
AAP, 2010 <sup>9</sup>	P	Health equity and children's rights	X		
AAP, 2016 <sup>10</sup>	P	Poverty and child health	X	X	
AAP, 2015 <sup>11</sup>	P	Food security	X	X	
AAP, 2013 <sup>12</sup>	P	Immigrant children	X	X	
AAP, 2013 <sup>13</sup>	P	Community pediatrics		X	X
AAP, 2017 <sup>14</sup>	P	Team-based care		X	
AAP, 2014 <sup>15</sup>	P	Care coordination		X	
AAP, 2011 <sup>16</sup>	P	Family support programs		X	
AAP, 2002 <sup>17</sup>	P	Medical home		X	
AAP, 2013 <sup>18</sup>	P	Homeless youth		X	
AAP, 2012 <sup>19</sup>	P	Childhood adversity	X		X
AAP, 2018 <sup>20</sup>	P	Advocacy for nutrition		X	
AAP, 2016 <sup>21</sup>	P	School readiness		X	
ACC, 2015 <sup>22</sup>	P	Team-based care		X	
ACC, 2012 <sup>23</sup>	P	Patient-centered care		X	

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(Table continued on next page)

resources.”<sup>43</sup> Among the statements that recommended interventions, 44% focused on subpopulations such as patients who were homeless or elderly or children with complex medical needs. Three statements included recommendations for social intervention funding strategies,<sup>44-46</sup> but only the American College of Physicians recommended a specific source that called for managed care organizations to include the costs of “specialized services” such as transportation or social service coordination in capitation rates.<sup>44</sup>

**DISCUSSION**

We searched 42 PMA Web sites for publicly available policy statements and clinical guidelines and found 39 statements published in 2002 or later that were related to social needs screening and interventions in clinical settings. This work, which explores the extent to which PMAs recommend social needs assessment and interventions, complements other efforts to examine the prevalence of social needs assessments and interventions across health care settings.<sup>23-29</sup>

As measured by their organizational policy and practice statements, pediatrics, family medicine, and psychiatry PMAs have been pioneers in this area. The organizations’ statements included details about which social domains to include in screening, interventions that can accompany screening, and, to a lesser extent, ways to finance those programs. Although it has not been established that PMA policy statements or clinical guidelines are ideal indicators of either current or future practice norms, our findings suggest that

(Table continued from previous page)

PMA, year	Type	Topic	Screening	Intervention	Financing
ACEP, 2018 <sup>24</sup>	P	Resource guidelines		X	
ACEP, 2018 <sup>24</sup>	P	Geriatric Emergency Department		X	
ACEP, 2018 <sup>24</sup>	P	Human trafficking	X	X	
ACOG, 2018 <sup>25</sup>	CG	Social determinants and cultural awareness	X	X	
ACOG, 2016 <sup>26</sup>	CG	Team-based care		X	
ACOG, 2013 <sup>27</sup>	CG	Homeless women		X	
ACP, 2017 <sup>28</sup>	P	Medically underserved people		X	X
ACPM, 2016 <sup>29</sup>	PS	Weight management		X	
AMA, 2015 <sup>30</sup>	P	Human trafficking		X	
AMA, 2016 <sup>31</sup>	P	Obesity		X	
APA, 2017 <sup>32</sup>	P	Serious mental illness	X	X	
APA, 2017 <sup>33</sup>	P	Displaced persons		X	
APA, 2004 <sup>34</sup>	CG	PTSD evaluation	X		
APA, 2015 <sup>35</sup>	CG	Psychiatric evaluation of adults	X		
APA, 2010 <sup>36</sup>	CG	Depression	X		
APA, 2003 <sup>37</sup>	CG	Suicide	X		

AAFP = American Academy of Family Physicians; AAP = American Academy of Pediatrics; ACC = American College of Cardiology; ACEP = American College of Emergency Physicians; ACOG = American College of Obstetricians and Gynecologists; ACP = American College of Physicians; ACPM = American College of Preventative Medicine; AMA = American Medical Association; APA = American Psychiatric Association; CG = clinical guideline; P = policy; PMA = professional medical association; PS = position statement; PTSD = posttraumatic stress disorder.

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social health assessments and interventions are increasingly part of the PMA dialogue.

Few specialty associations include social health assessment or intervention recommendations in their public statements. Exceptions include the American College of Obstetricians and Gynecologists and the American College of Cardiology. Future work exploring the implementation and dissemination of social needs assessments and related interventions could focus on discipline-specific opportunities and barriers to assessing and addressing social needs (including available workforce resources, quality measures, and payment models). New uniform value-based payments and integrated care delivery models may help reduce discrepancies in social needs activities across disciplines.

This study has several limitations. First, we limited our study sample to the American Medical Association and the 41 PMA members of the Council of Medical Specialty Societies. Although there are other types of medical professional organizations such as the National Academy of Medicine and the Institute for Healthcare Improvement and organizations representing nonphysician practitioners such as nurses and social workers, we could not locate a representative list. Future work might examine policy statements from other professional health care organizations to reflect a wider range of practitioners. Also, there are important differences in how PMAs develop, format, and present public statements. Although PMA statements may reflect current or evolving practice norms, policy statements and clinical guidelines often are developed by small groups of experts primarily on the basis of members' knowledge or interest in a particular area. Some statements are formatted as short declarations whereas others are extensive reports; some PMAs routinely make their statements publicly available and others rarely release their statements to the public. In our study, we found that PMAs offering the most publicly available content generally were more likely to produce social health-related statements; these statements often were quite detailed. At least 4 PMAs limited the number of publicly available statements on their Web sites, although other statements may have been accessible behind member-only

firewalls. These differences in statement development and availability limited our ability to fully understand the degree to which PMA statements reflect practice. Finally, in some cases, PMA statements were reendorsements of earlier publications. These reendorsements appeared relatively uncommon, however, which suggests that the number of social health-related statements in the PMA literature is increasing.

## CONCLUSION

We found a wide range of published statements from PMAs related to social health assessments and interventions. A small subset of organizations representing professional medical specialties including the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Psychiatric Association published the majority of these statements. Since our original search was completed, a 2018 statement from the American College of Physicians that was consistent with others included in this review recommended that all health professionals "should be knowledgeable about screening and identifying [social determinants of health] and approaches to treating patients whose health is affected by social determinants throughout their training and medical career."<sup>47</sup> The number and content of the PMA statements identified in this study support other health services research<sup>13,48,49</sup> indicating that social health assessments and interventions are gaining acceptance in select medical disciplines. ❖

## Disclosure Statement

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

## Author Contributions

*Geoff Gusoff, MD, led the professional medical association review and drafted the initial manuscript. Laura M Gottlieb, MD, MPH, conceptualized, helped write, and edited the manuscript. Caroline Fichtenberg, PhD, helped conceptualize and edit the manuscript.*

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Keywords: food security, health policy, social determinants of health, social interventions, social needs screening

# Using Neighborhood-Level Census Data to Predict Diabetes Progression in Patients with Laboratory-Defined Prediabetes

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## ABSTRACT

**Context:** Research on predictors of clinical outcomes usually focuses on the impact of individual patient factors, despite known relationships between neighborhood environment and health.

**Objective:** To determine whether US census information on where a patient resides is associated with diabetes development among patients with prediabetes.

**Design:** Retrospective cohort study of all 157,752 patients aged 18 years or older from Kaiser Permanente Northern California with laboratory-defined prediabetes (fasting plasma glucose, 100 mg/dL-125 mg/dL, and/or glycosylated hemoglobin, 5.7%-6.4%). We assessed whether census data on education, income, and percentage of households receiving benefits through the US Department of Agriculture's Supplemental Nutrition Assistance Program (SNAP) was associated with diabetes development using logistic regression controlling for age, sex, race/ethnicity, blood glucose levels, and body mass index.

**Main Outcome Measure:** Progression to diabetes within 36 months.

**Results:** Patients were more likely to progress to diabetes if they lived in an area where less than 16% of adults had obtained a bachelor's degree or higher (odds ratio [OR] = 1.22, 95% confidence interval [CI] = 1.09-1.36), where median annual income was below \$79,999 (OR = 1.16 95% CI = 1.03-1.31), or where SNAP benefits were received by 10% or more of households (OR = 1.24, 95% CI = 1.1-1.4).

**Conclusion:** Area-level socioeconomic and food assistance data predict the development of diabetes, even after adjusting for traditional individual demographic and clinical factors. Clinical interventions should take these factors into account, and health care systems should consider addressing social needs and community resources as a path to improving health outcomes.

## INTRODUCTION

Up to one-third of Americans have prediabetes,<sup>1</sup> a state of elevated blood glucose levels that increases the risk of development of Type 2 diabetes. Clinical trials such as the Diabetes Prevention Program have shown that lifestyle changes and initiation of metformin therapy in patients with prediabetes can prevent or delay the onset of Type 2 diabetes<sup>2-4</sup> and that these prevention efforts may be cost-effective and improve health outcomes.<sup>5-6</sup>

Understanding the potential predictors for development of diabetes and other chronic conditions can help clinicians and health care systems design interventions and target clinical responses to patients at elevated disease risk.<sup>7-9</sup> However, most

studies of diabetes risk focus on individual patient-level factors<sup>10-17</sup> and do not consider patient social context. Recent research suggests a relationship between the characteristics of where individuals reside and their short-term and long-term health outcomes,<sup>18-20</sup> specifically diabetes risk and development.<sup>21,22</sup> Most of the neighborhood information collected in these studies is from data sources that are not readily available on a national scale such as regional or small-scale national surveys, or it involves additional computational analysis such as geographic information system mapping. The systematic use of census-level data, which is readily available for linkage at the patient level in Kaiser Permanente (KP) and other

health care systems, is rarely leveraged in predicting patient health risk and is often not incorporated into diabetes prediction tools used in primary care practice.<sup>23</sup> The importance of census block-level and tract-level data in predicting diabetes risk is largely unknown.

The purpose of this study is to determine whether US census data on where a patient resides is associated with the development of diabetes in a prediabetes population after adjustment for traditional demographic and clinical factors.

## Research Design and Methods

This retrospective cohort study analyzed data from KP Northern California (KPNC), a large integrated health care delivery system with more than 4 million members. The primary data source was the integrated electronic health record (EHR), which combines diagnosis, utilization, pharmacy, and laboratory records. We identified all patients aged 18 years and older with laboratory-defined prediabetes (fasting plasma glucose [FPG] of 100 mg/dL-125 mg/dL and/or glycosylated hemoglobin [HbA<sub>1c</sub>] of 5.7-6.4) diagnosed between January 1, 2006, and December 31, 2010.<sup>24-27</sup> To create an incident prediabetes cohort, we then excluded all patients who had tested in this range in the 2 years prior, those with a preexisting diagnosis of diabetes or prediabetes during this period, and those whose prediabetes converted to diabetes within the first 6 months. Patients were required to have at least 2 years of continuous Health Plan enrollment before the index laboratory date (ie, first elevated FPG or HbA<sub>1c</sub> value) and for 36 months after the index date. Further information on this cohort is available elsewhere.<sup>26,27</sup> These laboratory values

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were obtained from the KPNC EHR, along with other patient demographic and clinical characteristics.

The primary source for the census data used in this study is the American Community Survey 5-year Summary File for 2006 to 2010. The American Community Survey is conducted as part of the US Census Bureau's Decennial Census Program, which is designed to provide demographic, socioeconomic, and housing data on the US population for geographic areas in the US, including Puerto Rico.<sup>28</sup> A subset of these variables is included in the KP Virtual Data Warehouse and is available for epidemiologic and health services research and quality improvement in all KP Regions. We included Virtual Data Warehouse census block-level variables from the 2010 census on the education level of the adult population (aged  $\geq 25$  years) and median household income. We also included Virtual Data Warehouse census tract-level data on the percentage of households receiving food assistance through the US Department of Agriculture's Supplemental Nutrition Assistance Program (SNAP). These census variables were chosen for inclusion on the basis of research suggesting a relationship between access to food and diabetes outcomes.<sup>29-33</sup>

### Statistical Analyses

To examine the relationship between demographic, clinical, and census variables with diabetes progression, we used logistic regression to obtain estimates of odds ratios (ORs) with 95% confidence intervals (CIs). The logistic regression model included patient age, sex, race/ethnicity, body mass index (BMI), and index FPG or HbA<sub>1c</sub> laboratory result, census block-level median household income, census block-level percentage of adults with a bachelor's degree or higher, and census tract-level percentage of households receiving SNAP benefits. We also estimated a model without the census variables, using only age, sex, race/ethnicity, BMI, and index blood glucose laboratory results to compare the C statistic of this pared-down model with that of the main model described. All analyses were performed using SAS Version 9.3 (SAS Institute, Inc, Cary, NC). This study was approved by the KPNC institutional review board.

### RESULTS

The cohort included 157,752 patients with prediabetes, with a mean age of 57 years (standard deviation = 14 years),

50% of whom were women, and 59% were non-Hispanic white (Table 1). An average of 4.1% of households received food assistance through SNAP, with a

**Table 1. Characteristics and progression to diabetes of patients with laboratory-defined prediabetes**

Characteristic	Total (N = 157,752)	Did not progress to diagnosis within 36 months (n = 151,857)	Progressed to diagnosis within 36 months (n = 5895)
Age, years, mean (SD)	57.22 (13.64)	57.23 (13.66)	56.98 (13.22)
Male, %	50	50	49
Race/ethnicity, %			
Asian	14	14	17
Black	6	6	10
Hispanic	13	13	17
American Indian/Alaskan Native	< 1	< 1	< 1
Native Hawaiian/Pacific Islander	1	< 1	1
Race missing/unknown	6	6	4
White	59	60	51
BMI, kg/m <sup>2</sup> , %			
< 25: Normal	23	24	11
25-29: Overweight	38	38	29
30-34: Obese level 1	22	22	28
35-39: Obese level 2	9	9	17
$\geq 40$ : Obese level 3	6	5	14
Missing/unknown	2	2	1
All patients, mean (SD)	29.25 (6.06)	29.12 (5.99)	32.53 (6.92)
Laboratory test results in prediabetes range, %			
FPG: 100-109 mg/dL	70	71	38
FPG: 110-119 mg/dL	16	15	33
FPG: 120-125 mg/dL	3	3	16
HbA <sub>1c</sub> : 5.7%-5.9%	8	9	5
HbA <sub>1c</sub> : 6.0%-6.2%	3	2	5
HbA <sub>1c</sub> : 6.3%-6.5%	< 1	< 1	3
Census block level: Adults with bachelor's degree or higher, %			
< 16%	15	15	20
16%-30%	27	27	31
31%-45%	26	26	26
> 45%	32	32	23
All patients, mean (SD)	36.56 (20.16)	36.73 (20.18)	32.14 (19.01)
Census block level: Median household income, US \$, %			
< 50,000	17	17	21
50,000-79,999	36	36	39
80,000-119,999	34	34	31
$\geq 120,000$	13	13	9
All patients, mean (SD)	81,789 (33,991)	82,024 (34,072)	75,745 (31,231)
Census tract level: Households receiving SNAP, %			
0%	17	17	13
1%-2%	38	38	33
3%-9%	35	35	39
$\geq 10\%$	10	10	15
All patients, mean (SD)	4.09 (4.93)	4.06 (4.90)	5.05 (5.55)

BMI = body mass index; FPG = fasting plasma glucose; HbA<sub>1c</sub> = glycated hemoglobin; SD = standard deviation; SNAP = Supplemental Nutrition Assistance Program.

higher proportion receiving assistance in the group in whom diabetes developed in the 36-month observation window (5.1%). In the logistic regression model (Table 2), those aged 40 years and older had statistically significantly higher ORs for diabetes development compared with those aged

18 to 29 years. Black/African American, Asian, Hispanic, American Indian/Alaska Native, and Native Hawaiian/Pacific Islander patients all had statistically significantly higher ORs for developing diabetes compared with whites. Overweight/obesity or an index FPG value above 110

mg/dL or HbA<sub>1c</sub> greater than 6.0% also were independently and significantly associated with diabetes developing within 36 months of prediabetes identification.

After adjustment for these patient-level characteristics, patients with prediabetes were also more likely to progress to diabetes if they lived in an area where 45% or less of the adult population had obtained a bachelor's degree or higher (eg, OR = 1.22; 95% CI = 1.09-1.36 for block groups with < 16% obtaining a bachelor's degree or higher). Patients with prediabetes living in areas where median household incomes were \$50,000 to \$79,999 had higher odds of progression to diabetes compared with those living in areas with median incomes of \$120,000 or more (OR = 1.16; 95% CI = 1.03-1.31). Our results also showed that patients living in an area where SNAP benefits were received by 10% or more of households had higher odds of progression to diabetes within 36 months (OR = 1.24, 95% CI = 1.10-1.41). The C statistics for the models, including the census information, indicated that these models offered slightly higher predictive value compared with the models with age, sex, BMI, blood glucose, and race/ethnicity only (0.77 vs 0.76, data not shown).

**Table 2. Estimated odds ratios (ORs) and 95% confidence intervals (CIs) from logistic regression model predicting progression to diabetes within 36 months (N = 157,752; no. of events = 5895)**

Variable	OR (95% CI)
Male	1.01 (0.96-1.07)
Age category, years (reference: 18-29 years)	
30-39	1.26 (0.99-1.61)
40-49	1.40 (1.11-1.77)
50-59	1.47 (1.17-1.85)
60-69	1.69 (1.34-2.14)
70-79	1.88 (1.48-2.39)
≥ 80	1.96 (1.52-2.54)
Race/ethnicity (reference: White)	
Asian	2.10 (1.94-2.28)
Black	1.48 (1.34-1.64)
Hispanic	1.41 (1.31-1.53)
American Indian/Alaskan Native	1.73 (1.18-2.54)
Native Hawaiian/Pacific Islander	2.50 (1.90-3.29)
Missing/unknown	0.81 (0.71-0.93)
BMI category, kg/m <sup>2</sup> (reference: < 25 kg/m <sup>2</sup> : Normal)	
25-29 (Overweight)	1.67 (1.52-1.83)
30-34 (Obese Level 1)	2.72 (2.46-3.00)
35-39 (Obese Level 2)	4.02 (3.61-4.49)
≥ 40 (Obese Level 3)	5.29 (4.71-5.94)
Missing/unknown	1.63 (1.29-2.07)
Laboratory test result (reference: FPG 100-109 mg/dL)	
FPG: 110-119 mg/dL	3.76 (3.53-4.01)
FPG: 120-125 mg/dL	10.01 (9.20-10.89)
HbA <sub>1c</sub> : 5.7%-5.9%	0.94 (0.83-1.07)
HbA <sub>1c</sub> : 6.0%-6.2%	3.08 (2.71-3.50)
HbA <sub>1c</sub> : 6.3%-6.5%	9.77 (8.14-11.73)
Census block level: % of adults with bachelor's degree or higher (reference: < 45%)	
< 16%	1.22 (1.09-1.36)
16%-30%	1.18 (1.08-1.29)
31%-45%	1.17 (1.08-1.27)
Census block level: median household income, US \$ (reference ≥ \$120,000)	
< 50,000	1.14 (0.99-1.30)
50,000-79,999	1.16 (1.03-1.31)
80,000-119,999	1.11 (0.99-1.24)
Census tract level: % of households receiving SNAP (reference: 0%)	
1%-2%	1.06 (0.97-1.16)
3%-9%	1.13 (1.03-1.25)
≥ 10%	1.24 (1.10-1.41)

BMI = body mass index; FPG = fasting plasma glucose; HbA<sub>1c</sub> = glycated hemoglobin; SNAP = Supplemental Nutrition Assistance Program.

## DISCUSSION

Most studies that examine predictors of diabetes risk focus exclusively on individual-level demographic and clinical factors. Area-level socioeconomic characteristics are rarely included, despite evidence that the socioeconomic characteristics of a person's residential area are strong determinants of health status. Prior research that addressed the impact of neighborhood factors on health and diabetes risk derived information from small and nonrepresentative data sources that are not readily available on a large scale and/or that involve additional computational analysis such as geographic information system mapping.<sup>18-22,29,31,32</sup> Our study added socioeconomic and food assistance information from the US census to traditional predictors of diabetes progression and found that education, income, and receipt of SNAP benefits were all significant predictors of progression to diabetes within 36 months. This finding suggests that leveraging readily available census data may improve the

ability to predict diabetes progression, and help physicians and Health Plans target prevention strategies to those who need it most. Other research has suggested that using EHR-based information as a tool for targeting diabetes prevention outreach can improve preventive care.<sup>34</sup> Findings of this study's analysis, based on EHR data and other administrative data readily available on KP patients, support the assertion that these data can be used to identify patients who may be at high risk of diabetes development. These results also suggest that adding census data readily available to Health Plans in addition to their EHR data may add useful information to these efforts.

More than 3 trillion dollars are spent on health care in the US each year, representing 18% of the country's gross domestic product.<sup>30</sup> Most of these resources invested in health care are traditionally focused on providing direct medical care, with less spent on addressing patients' social and economic needs or environmental conditions that contribute to health status.<sup>30</sup> Recent research has postulated that rebalancing some of these resources to address social needs may improve health care and health equity in the US.<sup>30</sup> Results of our study, which show that socioeconomic factors and food assistance needs are directly associated with worse health outcomes, suggest that directing health care resources toward social needs may ameliorate the health of the US population.

Previous research findings suggest that food insecurity (defined as a limited access to nutritious food based on cost) is associated with a wide range of chronic diseases and their complications, and that increasing access to healthy foods may improve the health of patients and their families.<sup>29-33,35</sup> We found that the percentage of households receiving SNAP benefits in a patient's neighborhood is significantly related to that individual patient's risk of diabetes developing independently of other factors, including neighborhood income and educational attainment. This finding suggests that addressing food needs and food insecurity may reduce diabetes risk as well.

Health care systems may have a direct role to play in addressing these community and individual social needs. The UK

National Health Service was founded in part on the idea that preventing disease required a holistic approach that incorporated attention to environment, well-being, diet, housing, and clinical care.<sup>36</sup> The UK National Health Service currently allows its general practitioners to employ "social" prescribing for direct provision of healthy foods and other nonnutritional services as well.<sup>37</sup> Research evidence has shown that social prescribing of healthy foods, fruits, and vegetables through patient discounts on fruit and vegetable purchases reinforces the link between food intake and health.<sup>38</sup> Health care policy leaders in the US have recently suggested that a "place-based" approach that makes health care delivery and public health systems accountable for improving population health might be a promising avenue for American health care policy as well.<sup>39</sup> Our current findings underscore the important effect of place on individual patient disease risk. Efforts by US health care systems to directly address food insecurity and increase access to healthy eating resources may be important strategies for improving population-level disease prevention and care.

This study has limitations that should be noted. Although the inclusion of census variables on education, income, and food assistance increased the predictive power of the logistic regression model predicting progression to diabetes among patients with prediabetes, it did so by a relatively small amount. It is possible that individual-level socioeconomic data and social needs data would have increased the predictive power of these variables for diabetes progression. Future research should work to collect more refined measures of both individual and community-level socioeconomic indicators, social needs, and resource measures on a systematic basis; to further understand the relationship between place of residence and socioeconomic factors; and to incorporate them into planning patient care. Although prior work has suggested that lower neighborhood "walkability" may also be a place-based variable related to lower rates of diabetes incidence,<sup>40</sup> this variable was not available for inclusion in our analysis. We limited our inclusion of census data to 3 variables on the basis of the current literature; it is possible

that other census variables may also be significantly associated with diabetes progression as well.

Furthermore, our findings are from a single health care delivery system within 1 state (California), which may limit generalizability. The percentage of people in a census tract in our sample (4.09%) was less than the percentage of those receiving SNAP assistance in the State of California as a whole (7.4%, with a margin of error of 0.1%)<sup>41</sup>; this may limit generalizability as well. Finally, our results show the statistical significance of including census data in a model for only 1 outcome (diabetes progression). Future research and quality improvement efforts should test the predictive power of using census data and other information on social and resource needs on a wider range of patient-centered health outcomes.

## CONCLUSION

Census information on socioeconomic status and receipt of public food assistance predict diabetes development in patients with prediabetes, even after adjusting for traditional individual demographic and clinical factors. Clinical interventions should take these factors into account, and health care systems should consider addressing social needs and community resources as a path to improving individual and population-level health outcomes. ❖

## Disclosure Statement

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

## Author Contributions

*Julie A Schmittiel, PhD, supervised all aspects of conceptualizing the study design and data analysis and wrote the first draft of the manuscript. Cassandra J Marshall, DrPH, MPH, contributed to creating the conceptual framework, interpreting the analysis results, and drafting the manuscript. Wendy T Dyer, MS, performed all data analysis and assisted in drafting the manuscript. Roberta Bivins, PhD, contributed to creating the conceptual framework, interpreting the analysis results, and drafting the manuscript. All authors approved the final version of the manuscript submitted.*

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**Keywords:** census data, diabetes risk, prediabetes, risk prediction, social needs

# Universal Screening for Social Needs in a Primary Care Clinic: A Quality Improvement Approach Using the Your Current Life Situation Survey

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## ABSTRACT

**Context:** Kaiser Permanente's Care Management Institute created a screening tool, Your Current Life Situation (YCLS), which primarily is used to identify social needs for populations at risk of high health care utilization.

**Objective:** This frontline improvement project was designed to address key stakeholder concerns about implementing universal screening for social needs using the YCLS in a primary care clinic.

**Methods:** I conducted a rapid stakeholder analysis through informal conversations to identify the most important concerns. Four Plan-Do-Study-Act cycles were conducted to answer stakeholder questions and address concerns.

**Results:** Stakeholders expressed concerns including YCLS length and low screening acceptability and the possibility that too few or too many patients may have social needs. Throughout the project's duration, 125 office visits occurred and 111 patients were screened. Among the patients for whom findings were positive, 27% requested help. Of the 14 patients who were not screened, only 1 patient opted out of screening. Practitioners and medical assistants stated that administration of the YCLS screening tool did not disrupt clinic workflow.

**Conclusion:** By using a frontline improvement approach, these investigators could answer questions and address concerns most important to local operational stakeholders when implementing screening for social needs. When practitioners conduct universal social needs screening and more fully understand social needs prevalence in a primary care clinic, resources can be tailored more effectively to accommodate patient needs.

## INTRODUCTION

Social and economic factors profoundly influence health and can affect up to 40% of health outcomes.<sup>1-3</sup> Until recently, however, health care organizations rarely identified and addressed nonmedical factors because of financial incentives that led to an emphasis on procedure and visit volume rather than outcomes. With the enactment of the Affordable Care Act,<sup>4</sup> value-based payment systems proliferated and prompted many health care systems to look beyond patients' medical needs and address social determinants of health ("social needs").<sup>5-6</sup>

The importance of addressing social needs has been established, but many health care systems lack clear guidance on ways to screen for and identify social needs.<sup>7</sup> Despite the availability of multiple social needs screening tools,<sup>8</sup> many health care

practitioners do not routinely screen for social needs during primary care clinic encounters.<sup>9</sup>

Kaiser Permanente's (KP) Care Management Institute (CMI) created a social needs screening tool, Your Current Life Situation (YCLS; see Sidebar: Your Current Life Situation (YCLS) Item Sources) through a process that included stakeholders within KP, public health researchers, and community-based organizations.<sup>10</sup> The YCLS has been used in several KP Regions to identify social needs in populations at risk of high health care utilization, such as dual-eligible beneficiaries who qualify for both Medicare and Medicaid benefits, but it has not yet been used as a universal screening tool in primary care clinics. At KP Washington (KPWA, formerly Group Health), primary care clinics do not systematically screen, identify, and address social needs.

This frontline improvement project used minimal resources to address key stakeholder concerns regarding implementation of universal social needs screening using the YCLS in a primary care clinic. The intent was to gather as much data as necessary to increase confidence in the intervention and to help operational leaders make decisions.

## METHODS

### Context

Burien, WA, is a suburban community with a population of about 50,000. Median household income is \$54,546, and about 17% of the population lives below the poverty line. Census records show the racial makeup of the city is 63.5% white (52% non-Hispanic white), 10.9% Asian, 7.6% two or more races, 6.4% African American, 1.6% American Indian, and 1.2% Pacific Islander.<sup>11</sup>

Group Health, and now as KPWA, has served Washington since 1947 and has more than 700,000 members throughout the state. The KPWA Burien Medical Center is a primary care clinic and a National Committee for Quality Assurance level 3 patient-centered medical home. The clinic has a patient panel of 21,295 with more than 30,000 office visits annually, and it houses a laboratory, pharmacy, Radiology Department, and short-term counseling services. The Medical Center staffs 6 residents, 12 family medicine physicians, 2 advanced practice practitioners, 1 pediatrician, and 1 general internist, and the support staff includes 3 nurses, 2 licensed practical nurses, 1 clinical pharmacist, and 1 licensed independent clinical social worker.

At KPWA primary care clinics including the Burien Medical Center, the social worker functions as an on-site behavioral

**Your Current Life Situation (YCLS) Item Sources****Core YCLS Questionnaire items**

1. **Living situation:** This is a Kaiser Permanente (KP)-created item that is a slight modification of a question on the Medicare Total Health Assessment.
2. **Concerns about living situation:** This is adapted from the Health Begins social needs assessment screening questionnaire.
3. **Financial hardship:** This is a KP-created item.
4. **Food insecurity:** This is the food insecurity item used by KP Colorado and Hunger Free Colorado.
5. **Transportation:** This is a slight adaptation of the transportation item from the PRAPARE Social Determinants of Health risk assessment.
6. **Enough help with activities of daily living:** The KP item has been created for the Medicare Total Health Assessment.
7. **Help desired checklist:** This is a KP-created item.
8. **Who answered these questions:** This was a KP-created question similar to the Medicare Total Health Assessment question used to document whether a member (or parent of child) provided the responses or someone else.

**Supplemental/optional items that will be available in the YCLS Item Bank**

- **Current marital/relationship status:** This KP-created item is used to assess potential social support and people who possibly should be brought into the care plan. Note: There also is a field for marital status in the KP electronic medical record.
- **Educational attainment:** This KP-created item is used to assess potential health literacy issues. The research shows that people with a high school education or less education are more likely to have difficulty understanding health information, instructions, etc.
- **Food insecurity (healthy food):** These items are taken from California Medicaid Adult Stay Healthy Questionnaire.
- **Caregiver responsibilities:** This is a KP-created item.
- **Trouble getting medications at the time needed:** This KP-created item is modeled after the Institute of Medicine-recommended financial hardship question.
- **Instrumental social support (someone can call):** This KP-created item also is used in the Medicare Total Health Assessment.
- **Health literacy:** This Single Item Health Literacy Screening has shown to perform moderately well at ruling out limited reading ability in adults.<sup>2</sup>
- **Stress:** This item is adapted from the 1998 NHIS Adult Prevention Supplement.
- **Interpersonal violence:** This KP-created item is used to screen for intimate partner violence, caregiver abuse, and abuse or threats from someone else known to a person.
- **Loneliness/social isolation:** This was modified from an item in the PROMIS Item Bank v 1.0-Emotional Distress-Anger-Short Form 1 and the AARP overall loneliness item from the AARP survey about loneliness in older adult.
- **Social connection:** This item was taken from the PRAPARE SDOH assessment that combines the original Institute of Medicine-recommended Berkman-Syme Social Connection Index into 1 item.
- **Preventive dental care:** This is a KP-created item.
- **Health confidence:** This item was taken from the Dartmouth Primary Care Cooperative Research Network questionnaire.<sup>3</sup>
- **Financial abuse:** This item was used in a KP Northern California Division of Research survey of high utilizers.
- **Overall rating of health:** These items are from the PROMIS Global 10 scale and are also used in the Medicare Total Health Assessment.

1. Hager ER, Quigg AM, Black MM, et al. Development and validity of a 2-item screen to identify families at risk for food insecurity. *Pediatrics* 2010 Jul;126(1):e26-32. DOI: <https://doi.org/10.1542/peds.2009-3146>.

2. Morris NS, MacLean CD, Chew LD, Littenberg B. The Single Item Literacy Screener: Evaluation of a brief instrument to identify limited reading ability. *BMC Family Practice* 2006 Mar 24, 7:21. DOI: <https://doi.org/10.1186/1471-2296-7-21>.

3. Wasson J, Coleman EA. Health confidence: An essential measure for patient engagement and better practice. *Fam Pract Manag* 2014 Sep-Oct;21(5):8-12.

AARP = American Association of Retired Persons; NHIS = National Health Interview Survey; PRAPARE = Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences; PROMIS = Patient-Reported Outcomes Measurement Information System; SDOH = social determinants of health.

health specialist to address mental health needs. S/he conducts psychosocial assessments, diagnoses mental health conditions, and provides short-term counseling to address substance-use disorders and behavioral health concerns.

Because the social worker's responsibility at KPWA did not include addressing patients' social needs, KPWA patients codesigned the community resource specialist (CRS) role in the Learning to Integrate Neighborhoods and Clinical Care project in 2012.<sup>12</sup> The CRS addressed social needs by linking patients to community resources and internal organizational resources, helping patients set goals, and developing contacts in the local community. At the time of this project, KPWA had 2 CRSs staffed in 2 Medical Centers but no CRS at the Burien Medical Center. Consequently, the social worker at Burien Medical Center agreed to help address social needs identified through screening.

**Stakeholder Identification**

First, I conducted a rapid stakeholder analysis to identify people who had high interest in addressing social needs and power to effect change at Burien Medical Center.<sup>13</sup> These stakeholders were a Burien Medical Center family medicine physician, the Burien Medical Center clinic manager, a KPWA Research Institute researcher, the KPWA behavioral health services manager, and the 2 CRSs. The KPWA behavioral health services manager also led implementation of the CRS role at KPWA.

Through one-on-one conversations, I informally interviewed stakeholders about implementing universal screening using the YCLS and using Plan-Do-Study-Act (PDSA) cycles to address questions and concerns. These questions and concerns were used to set the objective for the PDSA cycles.

**The Survey**

KP's Care Management Institute created the 32-item comprehensive social needs screening tool, YCLS. They also created a brief 6-item questionnaire to assess these domains: Living situation, concerns about living situation, financial hardship, food insecurity, transportation, and help with activities of daily living. This form also included 2 questions to assess patients' wanted help addressing their social needs and to document who answered the questions. The KP Care Management Institute defined the included domains and answers that resulted in a positive screening result on the YCLS. An additional "item bank" with questions from other domains was also available if practitioners, clinics, or organizations wish to tailor the tool for a specific purpose (see Appendix online at: [www.thepermanentejournal.org/files/2018/18-189-Suppl.pdf](http://www.thepermanentejournal.org/files/2018/18-189-Suppl.pdf)).

**Plan-Do-Study-Act Cycles**

The first PDSA cycle was conducted between July 24, 2017, and July 27, 2017, and the other PDSA cycles were conducted in 2-week increments between July 31, 2017, and August 14, 2017 (PDSA 2); August 28, 2017, and September 11, 2017 (PDSA 3); and September 25, 2017, and October 9, 2017 (PDSA 4). Patients were excluded from screening if they were non-English-speaking or had advanced dementia and no present

**Table 1. Plan-Do-Study-Act cycle objectives and changes made following each cycle**

PDSA cycle	Objective	Changes
1	To assess if the YCLS form can be used to screen for social needs in a primary care office visit without affecting standard workflow by screening all patients of Practitioner 1 between July 24, 2017, and July 27, 2017	YCLS endorsed by stakeholders and local clinic staff; CRS in other medical centers to start using YCLS form for assessing referred patients
2	To understand prevalence of social needs at the Burien Medical Center by screening all patients of Practitioner 2 with the YCLS form between July 31, 2017, and August 14, 2017	Changed "Debt" to "Debt causing financial distress" on YCLS form; added question regarding "social isolation" and "lack of access to healthy food" from the YCLS item bank to YCLS form for screening
3	To understand prevalence of social needs at the Burien Medical Center by screening all patients of Practitioner 2 with the modified YCLS form between August 28, 2017, and September 11, 2017	Added question to YCLS form about desiring help to address social isolation
4	To understand prevalence of social needs at the Burien Medical Center by screening all patients of Practitioner 3, a practitioner with a higher number of patients on Medicare, with the modified YCLS form between August 28, 2017, and September 11	Plans to incorporate YCLS into the EMR

CRS = community resource specialist; EMR = electronic medical record; PDSA = Plan-Do-Study-Act; YCLS = Your Current Life Situation.

caregiver. Caregivers completed forms for children younger than age 12 years. The objectives of each PDSA cycle are detailed in Table 1. During each cycle, universal screening was conducted on each practitioner's patients using the screening process shown in Table 2. For all patients, the medical assistant (MA) obtained verbal informed consent, and patient anonymity was retained by removing all patient identifiers before collating data outside of the medical record.

The MA handed the YCLS form to each patient after assisting patient to the exam room, obtaining vitals, reviewing their preventative care needs, and recording the data in the electronic medical record. The MA described the form and told patients they could opt out of screening if they desired, left the room, and allowed patients to self-administer the form. When the practitioner was ready for the clinical encounter, s/he entered the room and reviewed the completed form with the patient. The practitioner and MA did not alter their workflow; if any needs were identified, the practitioner referred the patient to the clinic's social worker.

The Burien Medical Center's family medicine physician (Practitioner 1, a key clinic stakeholder) conducted the first PDSA cycle. The second and third PDSA cycles were conducted on the patient panel of Practitioner 2, a family medicine resident physician. The fourth PDSA cycle was conducted on another family medicine physician's panel (Practitioner 3) to address concerns raised during the third PDSA cycle. Practitioner panel data are shown in Table 3.

### Analysis

Measures were chosen to address the objective of each PDSA cycle and to add minimal burden to staff conducting cycles. For PDSA 1, the practitioner-MA dyad measured the number of incomplete YCLS forms at the time the practitioner entered the room. For all other PDSA cycles, the practitioner-MA dyad collected the completed YCLS forms and calculated the number of office visits, number and percentage of patients screened, number and percentage of positive screens, and number and percentage of patients requesting help. I collected

the forms, collated the data without patient identifiers in Excel, and summarized the data in a PowerPoint presentation. I calculated the aggregated needs types that were identified during PDSA cycles 2 to 4 by percentage and elicited open-ended feedback from each practitioner in PDSA 1 and PDSA 4 and from each MA participating in all PDSA cycles about things that went well and needed improvement. I shared the results with the key stakeholders identified at the beginning of this project and used stakeholder feedback to create aims for subsequent cycles.

## RESULTS

### Stakeholder Concerns

During one-on-one conversations and group discussions, stakeholders expressed numerous concerns, including the YCLS form may be too lengthy to administer before a clinic visit and may disrupt the practitioner; patients may refuse to fill out forms assessing for social needs; too few patients may have social needs; and too many patients may have social needs.

**Table 2. Universal screening process overview**

Step	Process
1	The dyad MA called the patient from the waiting room and roomed the patient according to standard clinic procedural process.
2	The MA used a script to describe the YCLS form and, with an opt-out process, explained the organization's vision to care for the total health of the patient.
3	The MA exited the room and allowed the patient to self-administer the form.
4	The practitioner entered the room, acknowledged the responses, and, if results were positive, referred the patient to the CRS. If no CRS was available, the practitioner referred the patient to the social worker.
5	At the end of each PDSA cycle, the practitioner-MA dyad provided feedback regarding the process.
6	The feedback was reviewed and used to develop the aim for the subsequent PDSA cycle.

CRS = community resource specialist; MA = medical assistant; PDSA = Plan-Do-Study-Act; YCLS = Your Current Life Situation.

**Table 3. Each Practitioner’s panel size and patient characteristics**

Practitioner	Full-time equivalent adjusted panel size	Ages 0-18, no. (%)	Ages 19-64, no. (%)	Ages 65 and older, no. (%)	Medicare, no. (%)
1	1868	206 (11%)	1382(74%)	280(15%)	336 (18%)
2	1594	143(9%)	1307 (82%)	144 (9%)	159 (10%)
3	1999	80 (4%)	1339 (67%)	580 (29%)	640 (32%)

The Burien Medical Center practitioner, identified as a key stakeholder at the beginning of the project, was concerned the YCLS form may be too long; she worried that if the form was intended to be self-administered after the patient was roomed, the patient could still be filling out the form when the practitioner reentered the room. In this instance, the practitioner might not have time to address the clinical agenda.

Although screening for social needs in primary care settings generally is associated with high levels of acceptability by patients (especially when screening is self-administered rather than during face-to-face contact),<sup>14-16</sup> multiple stakeholders raised concern about low acceptability of social needs screening at KP because KP is a unique system that only serves insured members who may be of higher socioeconomic status and who refuse to fill out surveys about social needs.

Lastly, stakeholders said there were no data on the prevalence of social needs in the KP patient population and expressed concern. Few patients may have social needs, making screening “not worth it,” or many patients may have social needs and consequently “overwhelm the system.”

**Social Needs Prevalence**

During the course of this project, 125 office visits occurred, 111 patients were screened, 38 patients screened positive for social needs, and 30 patients (27%) requested help to meet their social needs. Of the 14 patients who were not screened, only 1 patient opted out. All others were not screened by the medical team because of unintentional omissions of survey administration. The percentage of patients with positive screening findings who wanted help addressing their social needs during each PDSA cycle is illustrated in Figure 1. The aggregated types of needs identified during PDSA cycles 2 through 4 by number are shown in Figure 2. Although the question that screened for social isolation was added only during PDSA cycles 3 and 4, more patients screened positive for social isolation than any other need during this project.

**Plan-Do-Study-Act Findings**

During the first PDSA cycle, all of Practitioner 1’s patients were screened to determine if the YCLS was “too lengthy” and could not be completed before the beginning of an office visit. During the course of 2 days, 18 patients were screened and every patient was able to complete the YCLS form before the practitioner entered the room to begin the clinic visit. The practitioner stated that as long as the form was filled out before she entered the room, it did not affect her workflow; the MA also stated that the screening did not affect her standard workflow. These findings were disseminated to the stakeholders,

which alleviated the concern that the YCLS could not be administered before an office visit. The CRS team reviewed the YCLS form and appreciated its structure. The team advised leadership to consider endorsing the form with the item bank for complete social needs evaluation of all referred patients at their home primary clinic.

The second PDSA cycle was conducted to better understand the prevalence of social needs in the clinic and to gauge screening acceptability. During the course of 2 weeks, 29 patients were screened, 12 patients had positive findings, and 9 (31%) requested help for the social needs identified. Those who requested help were referred to the social worker who contacted patients at a later time to address their needs. Also, 8 of the 9 patients screened positive for debt. The social worker believed that the positive screens for “debt” were false positives, however. Patients who screened positive for debt had reported student loan and mortgage payments that did not cause financial distress, so a revision to screening tool wording from “Debt” to “Debt causing financial distress” was suggested. The MA stated that employees at other clinics were enthusiastic after hearing about this work, which built momentum and energy around the project. The MAs requested that the forms be available for use outside of the project. These findings were disseminated to the clinic and shared with a larger stakeholder group at KPWA, including the manager for screening and outreach programs.

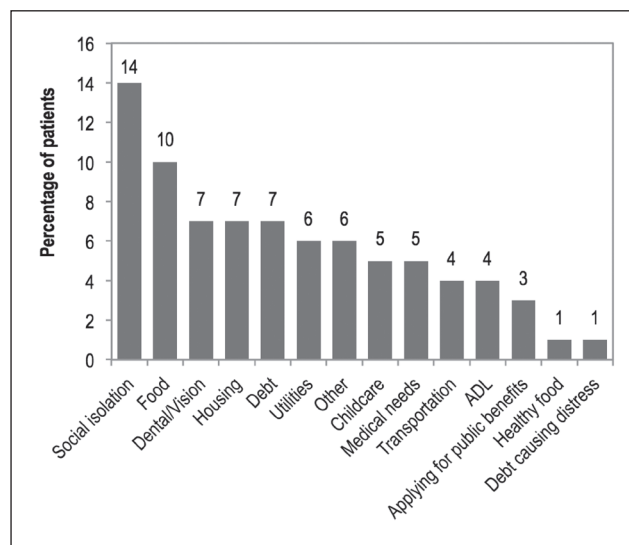


Figure 1. The types of needs by percentage of patients with positive screening findings who wanted help addressing their social needs. ADL = activities of daily living.



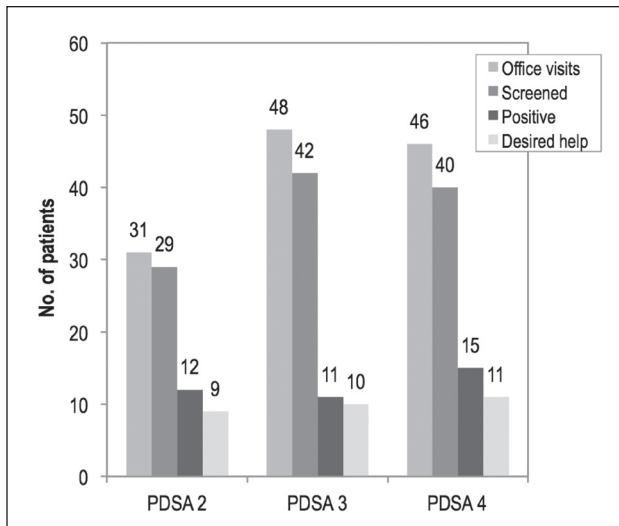


Figure 2. Aggregated need types identified during Plan-Do-Study-Act (PDSA) cycles 2 to 4.

Two additional topics were identified by stakeholders who shared initial findings of Medicare's Health Outcomes Survey, which showed a strong negative correlation between social isolation and health outcomes. A CRS reported underutilization of the Fresh Bucks Program, which provided electronic benefits transfer cardholders with funds to purchase fresh produce at participating markets. The feedback was acknowledged, the YCLS was modified, and 2 questions from the item bank were added to screen for social isolation and lack of access to healthy food.

The third PDSA cycle was conducted to better understand the prevalence of social needs in the clinic using the modified YCLS form and to gauge screening acceptability. During the course of 2 weeks, 42 patients were screened, 11 patients had positive results, and 10 patients (24%) requested help. After modifying question verbiage from "Debt" to "Debt causing financial distress," only 1 patient screened positive for debt (28% during PDSA cycle 2 vs 2% during PDSA cycle 3). Seven patients screened positive for social isolation by stating that they "sometimes" or "often" felt socially isolated. The MA believed the screening was well received by patients and other staff members but also stated that the YCLS form did not provide an area in which to request help for social isolation. Findings were shared with the stakeholders, and the clinic manager contended that screening may work with Practitioner 1 and Practitioner 2's panel but may not be feasible if a practitioner had a "more geriatric" panel. The clinic manager believed older patients may have more social needs and disrupt the clinic workflow. To address this concern, Practitioner 3 (a practitioner with a higher proportion of Medicare patients) was asked to participate in the fourth (final) PDSA cycle, which was conducted to better understand the prevalence of social needs in the clinic through use of the modified YCLS form.

During the course of 2 weeks, 40 patients were screened, 15 patients had positive results, and 11 patients (28%) requested

help with needs identified. The percentage of office visits with Medicare patients was 46%. The dyad appreciated the structure with which to screen for social needs and felt it did not disrupt standard workflow. Practitioner 3 stated that the YCLS format made it difficult to scan the questionnaire before the clinic visit, understand needs, and customize care recommendations. She also shared that she enjoyed using the YCLS form to screen and identify social needs, which she had not done consistently during clinical encounters before the project launch. Findings were disseminated to stakeholders, and the clinic manager was reassured that universal screening for social needs could be conducted without disrupting clinic workflow.

## DISCUSSION

During the course of this project, 111 of the clinic's patients were screened using the YCLS form. Of the patients screened, 27% screened positive for a social need. Of the 14 patients not screened, only 1 patient opted out of screening.

Project findings addressed key stakeholder concerns. First, findings from the initial project phase demonstrated that the YCLS can be completed before a practitioner begins an office visit. Second, by using opt-out criteria for screening as a proxy for social acceptability, this project helped inform opinions about screening acceptability among the KP Burien Medical Center patient population. Although patients may have acquiesced, stakeholders and medical staff found it reassuring that they would not overwhelmingly refuse to participate in screening for social needs. Third, although the true prevalence of social needs in a primary care clinic patient population could not be ascertained with this project design, this work generated data that could serve as an anchor for discussions about whether there are too many or too few social needs in the KPWA Burien Medical Center population to justify the need for universal screening.

Universal screening for social needs was not continued at the end of this project because electronic medical record support was lacking. Integration of the survey into the electronic medical record and electronic tracking of who had already been screened and who needed to be screened was not achieved for several reasons. First, leadership had not achieved consensus on the best screening tool with which to identify patients' social needs at KPWA. Multiple tools are currently being evaluated for social needs screening, including the Medicare Total Health Assessment,<sup>17</sup> a survey that is offered to all KPWA Medicare Advantage members, and The Accountable Health Communities Health-Related Social Needs Screening Tool created by the Center for Medicare & Medicaid Innovation.<sup>18</sup> Second, the KPWA Information Technology team had already committed its resources to other projects and did not have the capacity to support this project. Lastly, during this project, KPWA implemented universal screening of all members for depression and alcohol use disorder to better integrate behavioral health care in the primary care clinic. This initiative took precedence over social needs screening because both depression and alcohol use disorder screening are endorsed by the US Preventive Services Task Force. Electronic medical record support for social needs screening likely can be built at KPWA after achieving consensus

among leadership regarding the best screening tool for KPWA, confirming dedication of more information technology resources, and completing the behavioral health integration initiative.

Although this was not a primary clinic role, the social worker agreed to address the needs of patients who screened positive for a social need on the YCLS survey during this project. While the project was conducted, there were plans to expand the CRS role to all primary care clinics including the Burien Medical Center. The role of the CRS is to focus on addressing patients' social needs by connecting them to internal organizational resources and external community resources, but the staffing ratio for the CRS was designed as only 1 CRS for every 20,000 patients. Because there was no universal screening for social needs and the demand for the CRS was unknown, the staffing ratio was determined at leadership's discretion. By conducting more PDSA cycles and by better understanding the prevalence of social needs using universal screening, the CRS staffing ratio can be better tailored to match the demand of the primary care clinic.

This project's strength was its ability to use minimal resources and existing workflows to rapidly address concerns of operational leaders. By using a frontline improvement approach, this project could focus on the psychology of change and combat skepticism of top-down initiatives. This was shown when Practitioner 3 shifted perspective on the possibility to address social needs in a primary care clinic, MAs requested that YCLS forms be used outside of the project, and CRSs endorsed use of YCLS in their social needs assessments.

The simplicity and the minimal costs and trade-offs associated with this project maximize its ability to be replicated in other contexts. Because this project was conducted within the KP system, it involved unique advantages that likely are not present in all organizations. Because of KP's integrated health system model, financial incentives are aligned to address patients' social needs, myriad stakeholders are accessible, and frontline innovation is valued.

Several project findings may help direct research, practice, and policy. The 6-item YCLS form was created with these domains: Living situation, concerns about living situation, financial hardship, food insecurity, transportation, and help with activities of daily living. During the PDSA iterations, several domains were added after receiving feedback from stakeholders. If universal screening is conducted, it is unclear which social needs domains should be included. Although ideally the domains would be chosen according to rigorous research findings demonstrating an ability to change outcomes, this research is not currently available. As the momentum of screening for and addressing social needs builds, it may be more feasible to choose screening domains that correlate with outcomes and measures valued by operational leaders.

## CONCLUSION

This project focused on universal screening, but many organizations focus on screening patients at risk of high health care utilization because of cost savings. Cost savings are most apparent when treating populations at risk of high health care utilization because the decrease in inpatient, outpatient, and emergency services is

most pronounced.<sup>19-20</sup> Focusing only on cost savings subverts the competing priorities of a health organization such as KP, whose mission also consists of achieving health equity, providing appropriate clinical care, and acting as an anchor institution in a community. Referring ad hoc to community resource specialists or targeting only populations at risk of high health care utilization is an approach tainted by implicit and explicit bias, which leads to inequitable care. If an organization only targets high-risk individuals who often comprise the top 1% or 5% of high users, it would be likely that only a portion of the 27% of patients whose social needs were revealed in this project would be identified. This would undermine the ability of the care team to tailor care plans and decisions that take into account every patient's social situation and would affect KP's ability to understand its patient population and appropriately invest in the community. Universal screening is needed so organizations and clinics can best understand their patients' social needs, leverage business finances, and align missions with the community to achieve better health. ❖

## Disclosure Statement

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

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Keywords: community resource specialist, front-line improvement, psychosocial issues, quality improvement, screening, social determinants of health

## Citizen Advocates

[Poverty] is basically a political problem, whose radical solution will require a return to distributive justice. Why write about it in a medical journal? Because doctors are also citizens; they have opportunities to observe and perhaps to mitigate the effects of poverty; and they should be, in Virchow's words, "the natural advocate of the poor."

— Douglas Andrew Kilgour Black, 1913-2002, Scottish physician and medical scientist who played a key role in the development of the National Health Service

# Measuring Patients' Basic Resource Needs: The Role of a Small Survey to Guide Operational Decisions

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## ABSTRACT

**Introduction:** Increasingly, health care systems use systematic surveys of their patients to identify basic resource needs such as food insecurity. Surveys of small patient samples can help these systems improve existing instruments and explore new measures.

**Methods:** In response to operational concerns with an existing food insecurity measure, we surveyed 110 older adult members (60% response rate) from Kaiser Permanente Colorado (KPCO); 96 (87%) of these individuals completed a 3-month follow-up survey. The survey compared measures of food insecurity, assessed coexisting basic resource needs, explored trade-offs between those needs, assessed changes over time, and described the use of community food resources.

**Results:** A well-validated, 2-item food insecurity measure had fewer false-positive responses than a previously used single-item measure. Individuals with food insecurity commonly reported concurrent difficulties paying for housing, transportation, utilities, and cost-related medication nonadherence. These basic resource needs persisted during a 3-month period. Participants commonly reported reciprocal trade-offs in paying for basic resource needs; 47.4% had delayed paying for food to pay for housing, and 22.0% had delayed paying for housing to pay for food ( $p < 0.001$ ). Although 51.8% of participants reported receiving assistance from KPCO in obtaining food and 25.5% reported assistance with medical costs, fewer than 5% received assistance with other basic resource needs.

**Conclusion:** This survey informed operational decisions about measure selection and survey timing, and helped leaders and researchers understand the relationships among basic resource needs. Such surveys can help learning health systems improve their capacity to assess these fundamental human needs.

## INTRODUCTION

Patients in clinical practice often have basic resource needs such as food insecurity, inadequate housing, or financial resource strain. These needs are associated with adverse health outcomes<sup>1-3</sup> and are potentially modifiable through interventions within health care systems.<sup>4-6</sup> To identify basic resource needs systematically, health care systems can conduct screening surveys of their entire patient population or focused surveys in high-risk subgroups.<sup>7</sup> As systems gain experience with these survey instruments, they may identify problems such as excessive

length, ambiguous wording, omission of important topics, or items that do not produce actionable information. Although operational leaders can unilaterally make changes in the survey to address these problems, a specifically designed survey administered to a small number of patients provides a more rigorous approach to continuous improvement.

Since 2012, older adult members of Kaiser Permanente (KP) Colorado (KPCO) have been offered a survey, the Medicare Total Health Assessment (MTHA), as part of Medicare Annual Wellness Visits.<sup>8</sup> This survey included a single item

that assessed food insecurity.<sup>9</sup> Between January 2012 and December 2015, a total of 50,097 KPCO members aged 65 years or older (39% of all older adult members) completed the MTHA, of whom 5.7% reported food insecurity.<sup>10</sup> When KPCO staff followed-up with patients who reported food insecurity on the MTHA survey, many members indicated that they had never had food insecurity, and had no other basic resource needs. Staff members and operational leaders concluded that the single MTHA food insecurity item had a high rate of false-positive responses.

As part of a quality improvement initiative, operational leaders collaborated with KPCO researchers to design and to conduct a small survey that would assess alternative measures of food insecurity for the MTHA. The survey also addressed operational questions about the coexistence of food insecurity with other basic resource needs, changes in basic resource needs over time, and outreach by KPCO to members with food insecurity. Researchers also used this opportunity to pilot test more extensive measures of basic resource needs that might be useful in subsequent studies<sup>2</sup> and to develop new questions that assessed trade-offs among basic resource needs. Consistent with the principles of a learning health system,<sup>11</sup> the survey was designed to provide information that was sufficiently accurate and timely to inform operational decisions, even if it was too small to answer these questions conclusively. This article reports the findings of this small survey and discusses how these findings affected subsequent decisions.

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## METHODS

### Study Setting

In 2016, KPCO provided health insurance and clinical care to approximately 120,000 members aged 65 years and older, of whom 86.0% received insurance coverage through the Medicare Part C (Medicare Advantage) program, 2.5% had dual Medicare and Medicaid coverage, and 11.5% had a private insurance plan or received traditional Medicare benefits. When basic resource needs were identified during a clinic visit or through screening, KPCO community specialists, social workers, nurse care managers, and registered dietitians helped connect older adult members to social services in the community.<sup>12,13</sup> This project was approved by the KPCO institutional review board.

### Participants

We identified all KPCO members who completed the MTHA between September 1, 2016, and December 31, 2016. We have previously described the content and administration of the MTHA survey and the characteristics of survey respondents.<sup>10</sup> For the current survey, members were eligible if they 1) reported food insecurity

using the single item on the MTHA<sup>9</sup>; 2) resided in the Denver-Boulder, CO, metropolitan area; 3) were age 65 years or older on September 1, 2016; 4) spoke English as their first language; 5) had not previously opted out of research; and 6) lived independently (vs in a skilled nursing facility or hospice) at the time of recruitment.

### Assessment of Food Insecurity in Clinical Practice

The single-item measure of food insecurity in the MTHA was derived from the Nutrition Screening Initiative checklist, a 10-item set of questions about nutritional issues in the elderly.<sup>9</sup> The food insecurity item in this measure had not been independently validated, and the decision to include it in the MTHA was made in 2011, before the use of other brief measures of food insecurity became widespread.

The gold standard for assessment of food insecurity is an 18-item survey developed by the US Department of Agriculture (USDA) that is administered annually to assess food insecurity in the US.<sup>14</sup> Six-item<sup>15</sup> and 2-item<sup>16</sup> screening measures that use a subset of USDA items have

been developed for clinical and research use, and have been validated through comparison with the 18-item measure. The 2-item measure, referred to as the Hunger Vital Sign, has rapidly gained acceptance in clinical settings,<sup>17</sup> even though brief measures of food insecurity demonstrate lower specificity (ie, a higher false-positive rate) than the 18-item survey.<sup>18</sup> The 1, 2, and 6-item food insecurity measures are described in Table 1.

### Survey Design and Measures

We designed baseline and 3-month follow-up surveys to address questions of operational and research importance including: 1) the prevalence of food insecurity using the 2-item and 6-item measures (Table 1); 2) the prevalence of other basic resource needs (housing, transportation, utilities, and medication costs) in members with food insecurity; 3) the stability of basic resource needs during the 3-month interval between surveys; 4) assistance from KPCO or other sources in meeting basic resource needs; and 5) trade-offs between paying for competing basic resources. These surveys included items from existing KP

**Table 1. Short measures of food insecurity<sup>a</sup>**

Measure and references	Number of items	Wording of items (response options)	Responses indicating food insecurity
Medicare Total Health Assessment (MTHA) <sup>a,9,10</sup>	1	"Do you always have enough money to buy the food you need?" (Yes/No)	No
Hunger Vital Sign <sup>b,c,16</sup>	2	"Within the past 12 months, we worried whether our food would run out before we got money to buy more." (Often true, Sometimes true, Never true) "Within the past 12 months, the food we bought just didn't last and we didn't have enough money to get more." (Often true, Sometimes true, Never true)	Often or sometimes true to either statement
USDA short form <sup>b,c,15</sup>	6	"In the past 12 months, did you or other adults in your household ever cut the size of your meals or skip meals because there wasn't enough money for food?" (Yes/No) If answered yes to previous question: "How often did this happen?" (Almost every month, Some months but not every month, In only 1 or 2 months) "In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money to buy food?" (Yes/No) "In the last 12 months, were you ever hungry but didn't eat because you couldn't afford enough food?" (Yes/No) "The food we bought just didn't last, and we didn't have money to get more." (Often true, Sometimes true, Never true) "We couldn't afford to eat balanced meals." (Often true, Sometimes true, Never true)	≥ 2 affirmative responses

<sup>a</sup> The MTHA was developed and is in use in Kaiser Permanente. The single food insecurity survey item is derived from the Nutrition Screening Initiative checklist for nutrition assessment in older adults.<sup>9</sup>

<sup>b</sup> The time frame for recall varies from 3 to 12 months in different settings. The survey reported here used a 3-month time frame to assess changes during the 3 months between baseline and follow-up surveys. The time frame described here is from the references cited.

<sup>c</sup> The Hunger Vital Sign and USDA 6-item short form both use items derived from an 18-item USDA survey, the Household Food Security Scale.<sup>14</sup> USDA = US Department of Agriculture.

surveys, previously validated items from the literature, and newly developed items. The domains and item sources are shown in Table 2 (available online at: [www.thepermanentejournal.org/files/2018/18-098-T2.pdf](http://www.thepermanentejournal.org/files/2018/18-098-T2.pdf)). The final surveys are available on request.

On our baseline survey, we assessed the prevalence of food insecurity using the Hunger Vital Sign. Although we did not repeat the MTHA food insecurity item, we believed that the time gap between the MTHA and our survey was sufficiently short that individuals who did not report food insecurity on the Hunger Vital Sign were likely to represent false-positive responses to the original MTHA. On the follow-up survey, we repeated the Hunger Vital Sign to assess changes since baseline and added the 6-item USDA survey to compare with the Hunger Vital Sign and to assess its association with other basic resource needs. Although prior studies typically used a 12-month recall period,<sup>15,16</sup> we chose a 3-month recall period for all measures to reflect the time between baseline and follow-up surveys.

At baseline, we also collected sociodemographic information, including age, sex, race/ethnicity, marital status, education, living situation, employment, household income, and caregiver of a child younger than age 18 years. Furthermore, we assessed health status using the Patient-Reported Outcomes Measurement Information System (PROMIS) measures of general health and quality of life,<sup>19</sup> a measure of social isolation,<sup>20</sup> and the 2-item Patient Health Care Questionnaire (PHQ-2) depression scale,<sup>21</sup> as well as information about health behaviors, specifically tobacco use, alcohol use, and illegal drug use. We included a question from another KP instrument, the Your Current Life Situation Survey, that inquired about difficulty paying for 6 basic resources (food, housing, utility bills, child care, medical needs, and debts).<sup>7,22</sup> We also asked more detailed questions about housing concerns (4 items) and transportation barriers (5 items) from the Your Current Life Situation Survey, and we included a 4-item measure of cost-related medication nonadherence.<sup>23</sup>

The primary purpose of the follow-up survey was to assess changes in basic

resource needs during the 3 months since the baseline survey. We also included more extensive measures of housing, transportation, and energy expenses from prior research and a slightly different measure of cost-related medication nonadherence, to explore their utility for subsequent research.<sup>2</sup> To assess trade-offs between food insecurity and other basic resource needs, we developed 3 new pairs of questions with the general form: "How often did you put off paying for food in order to pay for (housing, transportation, medical costs?)" and "How often did you put off paying for (housing, transportation, medical costs) in order to pay for food?" Response options were never, rarely, sometimes, or often. These questions allowed us to assess whether members consistently prioritized paying for one resource need over another or whether they juggled their financial demands by paying for different basic resources at different times.<sup>24,25</sup> Although we did not solicit open-ended responses, we recorded any written comments on paper surveys or verbal comments on telephone surveys to gain a narrative perspective on the needs of the respondents.

We conducted cognitive interviews to assess the wording, comprehension, response sets, and functionality of the initial version of the baseline survey and recruitment materials.<sup>26</sup> These cognitive interviews lasted approximately 45 minutes. We recruited 10 KP members (5 who reported food insecurity and 5 who did not) from a sample of 50 adults aged 65 years and older who had completed the MTHA earlier in 2016. After members gave informed consent, 2 trained staff conducted an in-person interview with each member. The interviewers completed field notes and analyzed recordings using qualitative methods (content analyses and identification of themes). On the basis of results of these interviews, we revised the baseline survey. Participants in the cognitive interviews were not included in the final survey sample.

### Survey Administration

Between September 1, 2016, and December 31, 2016, a total of 210 KP members reported food insecurity on the MTHA. Of these individuals, 4 (1.9%) had opted out of research and 19 (9.0%)

were not living independently. Of the remaining 187 individuals, 6 lived in the same household as another eligible member. We randomly excluded 3 of these individuals (1.4%), resulting in a final sample of 184 (87.6% of the total). These individuals received a mailed survey packet, between December 2016 and June 2017, that included a \$20 gift card. Members could opt out of the survey by calling or sending an email to study staff. Participants could return the survey by prepaid mail or could request telephone administration. Individuals who neither responded nor opted out were contacted by project staff, who administered the survey by phone to those who gave verbal consent. The baseline survey was completed a mean of 120 days (standard deviation = 38 days, range = 46-221 days) after the member reported food insecurity on the MTHA. Members who completed the baseline survey received a follow-up survey 3 months later, with a second \$20 gift card.

### Statistical Analysis

Questions about assistance from KP and other organizations with basic resource needs other than food had 7% to 15% missing responses, but missing responses were below 5% for other items. We compared characteristics and survey responses between participants who reported food insecurity at baseline on the 2-item Hunger Vital Sign and those who did not using *t*-tests for normally distributed continuous variables, Wilcoxon rank tests for nonnormally distributed continuous variables, and  $\chi^2$  tests or Fisher exact test for categorical variables. McNemar tests for paired data were used to examine changes between baseline and follow-up surveys. We calculated the sensitivity, specificity, positive predictive value, and negative predictive value of the 2-item Hunger Vital Sign compared with the 6-item scale using standard cutoffs for each measure, with exact 95% confidence intervals.<sup>15-17</sup> All analyses were conducted using SAS software version 9.4 (SAS Institute Inc, Cary, NC).

### RESULTS

Of the 184 eligible KP members, 110 (59.8%) completed the baseline survey. Of these, 98 (89.1%) completed the

survey by mail and 12 (10.9%) by telephone interview. Ninety-six of these 110 members (87%) completed the follow-up survey, 94 (98%) by mail and 1 each by email or telephone.

Table 3 compares the characteristics of the 81 members (73.6%) who reported food insecurity on the Hunger Vital Sign at baseline with those of the 29 members (26.4%) who did not report food insecurity on the baseline survey but previously reported food insecurity on the MTHA. Members who consistently reported food insecurity had a significantly lower household income, were less likely to be married or living with a partner, reported worse general health or quality of life, and were more likely to feel lonely or isolated than those who were not food insecure.

### Measurement of Food Insecurity

On the follow-up survey, 94 respondents completed the 2-item Hunger Vital Sign and the 6-item USDA survey. Forty-six individuals (48.9%) reported food insecurity on both measures, 29 (30.9%) did not report food insecurity on either measure, 19 (20.2%) reported food insecurity on the 2-item but not the 6-item measure, and none reported food insecurity on the 6-item but not the 2-item measure. Compared with the 6-item scale, the sensitivity of the 2-item scale was 100% (95% confidence interval [CI] = 92.3%-100%), negative predictive value was 100% (95% CI = 88.1%-100%), specificity was 60.4% (95% CI, 45.3%-72.2%), and positive predictive value was 70.8% (95% CI = 58.2%-81.4%). The prevalence of other resource

needs was comparable between individuals identified with food insecurity on the 2-item and 6-item measures (data not shown). The prevalence of food insecurity and other basic resource needs did not change significantly between the baseline and 3-month follow-up surveys (Figure 1).

### Coexistence of Basic Resource Needs

As shown in Table 3, individuals with food insecurity also reported more difficulty paying for basic resources, housing, and transportation and were more likely to report cost-related medication nonadherence (70.4% vs 20.7%,  $p < 0.001$ ). Table 4 extends this finding by demonstrating that 22% to 47% of members reported putting off paying for a basic resource to pay for another. Only 37 of the 96 participants

Characteristic	Overall (N = 110)	No food insecurity (n = 29, 26.4%)	Food insecurity (n = 81, 73.6%)	p value
Mean age at survey, years (SD)	72.4 (6.3)	73.2 (7.6)	72.1 (5.8)	0.83
Female sex	78 (70.9)	17 (58.6)	61 (75.3)	0.09
<b>Race/ethnicity</b>				
Hispanic/Latino	16 (14.5)	3 (10.3)	13 (16.0)	0.19
White	66 (60.0)	22 (75.9)	44 (54.3)	
Black	13 (11.8)	1 (3.4)	12 (14.8)	
Other	15 (13.6)	3 (10.3)	12 (14.8)	
<b>Education</b>				
Less than high school graduate	15 (13.6)	3 (10.3)	12 (14.8)	0.47
High school graduate or GED	30 (27.3)	7 (24.1)	23 (28.4)	
Some college or 2-year degree	42 (38.2)	10 (34.5)	32 (39.5)	
College graduate or higher	23 (20.9)	9 (31.0)	14 (17.3)	
<b>Living situation</b>				
Independently	68 (61.8)	22 (75.9)	46 (56.8)	0.11
With relative or friend	29 (26.4)	7 (24.1)	22 (27.2)	
Senior, retirement, or assisted living	8 (7.3)	0 (0)	8 (9.9)	
Other	5 (4.5)	0 (0)	5 (6.2)	
Marital status (living with spouse or partner)	33 (30.0)	16 (55.2)	17 (21.0)	0.001
<b>Employment</b>				
Working	12 (10.9)	1 (3.4)	11 (13.6)	0.15
Retired	73 (66.4)	24 (82.8)	49 (60.5)	
Disabled	23 (20.9)	4 (13.8)	19 (23.5)	
Other	2 (1.8)	0 (0)	2 (2.5)	
<b>Household income per year, US dollars</b>				
< 14,999	46 (41.8)	3 (10.3)	43 (53.1)	< 0.001
15,000-24,999	30 (27.3)	7 (24.1)	23 (28.4)	
25,000-49,999	23 (20.9)	13 (44.8)	10 (12.3)	
≥ 50,000	4 (3.6)	3 (10.3)	1 (1.2)	
Missing/prefer not to answer	7 (6.4)	3 (10.3)	4 (4.9)	
Primary caregiver of child < 18 years of age	5 (4.9)	0 (0)	5 (6.8)	0.15

(table continued on next page)

who responded to these items (38.5%) reported that they never made such trade-offs. Members were significantly more likely to put off paying for food to pay for housing or utilities than they were to put off paying for those resources to pay for food ( $p < 0.001$ ). They were equally likely to put off paying for food and medical needs ( $p = 0.39$ ).

**Organizational Follow-up for Basic Resource Needs**

Among all 110 baseline respondents, 52% indicated that KP had contacted them to offer food assistance through referral to community organizations and 29% reported assistance from other sources (Table 5). Approximately 25% reported that KPCO had offered assistance

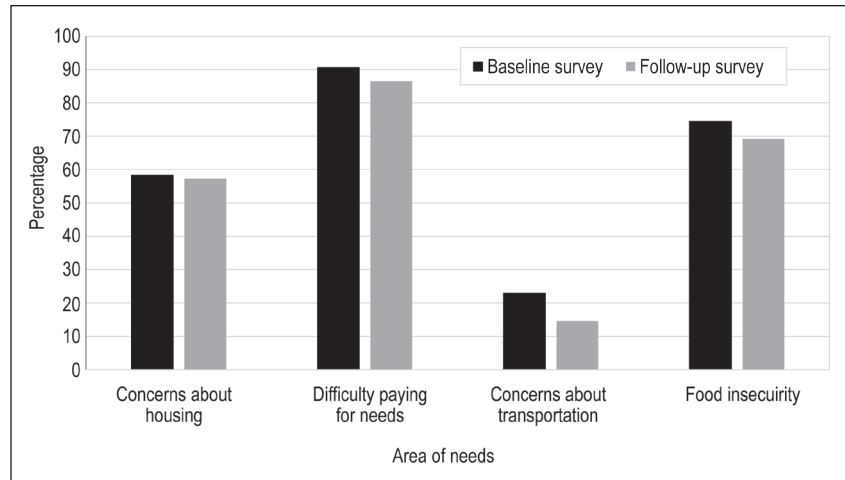


Figure 1. Self-reported basic resource needs at baseline (N = 110) and 3-month follow-up (N = 96) among older adult members of Kaiser Permanente Colorado.<sup>a</sup>

<sup>a</sup> Food insecurity was assessed using the 2-item Hunger Vital Sign.<sup>17</sup> No differences were statistically significant.

(table continued from previous page)

Characteristic	Overall (N = 110)	No food insecurity (n = 29, 26.4%)	Food insecurity (n = 81, 73.6%)	p value
<b>Insurance at survey</b>				
Medicaid (standard or SNP)	30 (27.3)	3 (10.3)	27 (33.3)	0.02
Medicare or commercial	80 (72.7)	26 (89.7)	54 (66.7)	
<b>Health status</b>				
General health (excellent or very good)	29 (26.4)	12 (41.4)	17 (21.0)	0.05
Quality of life (excellent or very good)	26 (23.6)	14 (48.3)	12 (14.8)	0.001
Physical health (excellent or very good)	24 (22.0)	12 (41.4)	12 (15.0)	0.002
Mental health (excellent or very good)	48 (43.6)	17 (58.6)	31 (38.3)	0.09
Feel lonely or isolated (sometimes, often, or always)	55 (50.0)	9 (31.0)	46 (56.8)	0.02
Have someone to call for help	102 (92.7)	28 (96.6)	74 (91.4)	0.36
Depression (on PHQ-2)	22 (20.4)	3 (10.7)	19 (23.8)	0.14
<b>Tobacco use</b>				
Current	19 (17.3)	5 (17.2)	14 (17.3)	0.19
Quit	50 (45.5)	17 (58.6)	33 (40.7)	
Never	41 (37.3)	7 (24.1)	34 (42.0)	
<b>Alcohol and substance use</b>				
Never	73 (66.4)	15 (51.7)	58 (71.6)	0.07
Moderate	32 (29.1)	11 (37.9)	21 (25.9)	
Heavy	5 (4.5)	3 (10.3)	2 (2.5)	
Never use illegal drugs	104 (94.5)	28 (96.6)	76 (93.8)	0.58
<b>Difficulty paying for basic resources (6 items)</b>				
Mean no. of concerns (SD)	3.37 (1.63)	2.17 (2.00)	3.80 (1.23)	< 0.001
≥ 1 concern	98 (89.1)	19 (65.5)	79 (97.5)	< 0.001
<b>Housing (4 items)</b>				
Mean no. of concerns (SD)	1.13 (1.21)	0.48 (0.83)	1.36 (1.24)	< 0.001
≥ 1 concern	64 (58.2)	9 (31.0)	55 (67.9)	0.001
<b>Transportation (5 items)</b>				
Mean no. of concerns (SD)	0.64 (1.42)	0.17 (0.93)	0.80 (1.53)	0.008
≥ 1 concern	24 (21.8)	1 (3.4)	23 (28.4)	0.005
<b>Medication adherence</b>				
Cost-related nonadherence, 4 items	63 (57.3)	6 (20.7)	57 (70.4)	< 0.001

<sup>a</sup> Respondents were defined as having food insecurity if they responded "sometimes, often, or very often" to either question in the 2-item Hunger Vital Sign<sup>16</sup> on the baseline survey.

Data are number (percentage) unless otherwise indicated.

GED = General Equivalency Diploma; PHQ-2 = Patient Health Questionnaire-2<sup>21</sup>; SD = standard deviation; SNP = Special Needs Program.



with medical costs, but less than 5% reported assistance with other basic resource needs. At follow-up, the proportion of participants reporting contact was generally lower, although only the declines in contacts from KP for food assistance ( $p = 0.01$  vs baseline) and contacts from others for housing assistance ( $p = 0.02$  vs baseline) were statistically significant.

The Sidebar: Open-Ended Comments on Food Insecurity Surveys provides spontaneous comments from written surveys or telephone interviews that illustrate how participants experienced basic resource needs in the context of their social circumstances and biomedical health concerns.

## DISCUSSION

We conducted this survey in a small sample of 110 KPCO members to address pragmatic questions from clinical and operational leaders about the basic resource needs of KPCO members and to develop new methods to assess those needs. Such interactions between organizational leaders and researchers exemplify the work of learning health systems, which requires a compromise between the desire for generalizable knowledge and the need for “directionally correct” information to inform operational decisions and rapid action.<sup>11</sup>

Before our survey, members who reported food insecurity on the MTHA often failed to confirm this or other basic resource needs when they were offered assistance by KPCO staff. These staff members concluded that many older adults erroneously reported food insecurity using the single-item measure on the MTHA.<sup>9</sup> Confirming staff concerns, we found that only 74% of participants who initially reported food insecurity on the MTHA later reported food insecurity on our baseline survey. Because a mean of 4 months elapsed between the initial MTHA response and the baseline survey, needs could have changed in the intervening period. We believe this was unlikely, however, because members rarely reported changes in other basic resource needs over that interval (Figure 1), and because individuals who reported food insecurity using the Hunger Vital Sign had substantially higher rates of other basic resource needs than those who did not (Table 3). Operational leaders were dissatisfied with

the prevailing MTHA measure; therefore, they chose to include the 2-item Hunger Vital Sign in a revision of the MTHA because of its brevity and despite its potentially higher false-positive rate than the 6-item USDA measure.

For the 26% of participants who did not report food insecurity on the baseline survey, we compared their other basic resource needs with those of participants who confirmed that they were food insecure. Such resource needs were substantially more common in the latter group (Table 3). This information reaffirmed the need for clinical staff to inquire about other basic resource needs during follow-up and convinced organizational leaders to include questions about other basic resource needs in the revised MTHA.

Because food insecurity was generally identified through the MTHA survey rather than at the point of care, operational leaders wanted to determine whether KPCO staff consistently followed-up with members to assist in addressing

food needs. Only 52% of members who indicated food insecurity on the MTHA reported that KPCO staff had offered such assistance. Although members commonly had other basic resource needs, KPCO staff rarely contacted them to help address those needs (Table 5). Staff outreach may have been unsuccessful in some cases and members may have forgotten earlier conversations with staff, but this finding suggested that periodic tracking and follow-up might help KPCO members connect to community resources.

Once health care systems commit to identifying basic resource needs, they must determine how often to reassess their patients. Frequent assessments are resource-intensive and could be perceived as intrusive or redundant, whereas insufficiently frequent assessments might overlook new, critical needs. Our finding that basic resource needs did not change substantially during a 3-month period (Figure 1) suggested that surveys could be administered at longer intervals.

### Open-Ended Comments on Food Insecurity Surveys

“Being cold and sleeping in my car. Paying storage on my household belongings and medical premiums and meds. No family in Denver [and] do not have the money to move.”

“[Housing] not kept clean on consistent basis. Sharing bathrooms, showers, kitchens with male and female roomers. Roach problem. Have small refrigerator but do not want to keep food or drink in my room. Rooming house all I can afford right now.”

“Member does not pay utilities; she lives in a hotel room. She says it’s troublesome not having a microwave or refrigerator. She uses a hot plate to cook or warm things, and her son uses an ice chest to keep things cold and has to keep changing the ice. The cost to rent the hotel room changes every day. She has worried for her safety; there was a shootout and patrons were asked to stay inside their rooms. Member panhandles to make extra money for living expenses and pay for the hotel room and for medication for herself and children [to supplement] Social Security check. All 3 have diabetes.”

“Two great-granddaughters moved in with me because their father has no housing.”

“I am on medical financial assistance from Kaiser [Permanente], and this is a real life-saver. I am so thankful. No problem right now because of this [financial assistance]. Just worried about the future.”

“Member is worried that if the owner decides to sell the property, she won’t be able to afford to move. She has no savings. She cannot afford to pay a deposit and first and last months’ rent.”

“My roommate covers most of the money for food costs in exchange for care I’ve given. I can only work 9 hours a month, or I lose Medicaid. I cohabit with a friend who was going through chemoradiation, as a caregiver. [If] the situation changes, I will not be able to support myself for food and housing.”

“It is not practical to go to the food bank. The produce is no good; most of it has already turned brown. The cases of grated cheese and yogurt are too much for anybody to consume before it goes bad. They don’t give people the basics.”

**Table 4. Tradeoffs between paying for food and other basic resource needs, follow-up survey (N = 96)**

Put off paying for food to pay for other need	Percentage	Put off paying for other need to pay for food	Percentage	p value <sup>a</sup>
Put off paying for food to pay for housing	45 (47.4)	Put off paying for housing to pay for food	20 (22.0)	< 0.0001
Put off paying for food to pay for utilities	45 (47.4)	Put off paying for utilities to pay for food	29 (30.5)	0.0009
Put off paying for food to pay for medical needs	34 (36.2)	Put off paying for medical needs to pay for food	30 (31.9)	0.38

<sup>a</sup> Exact p values using McNemar test.

**Table 5. Self-reported assistance in obtaining basic resources from Kaiser Permanente Colorado and other sources**

Resource need <sup>a</sup>	KP ever offered assistance, % <sup>b</sup>			Other sources ever offered assistance, %		
	Baseline (N = 110)	Follow-up (n = 96)	p value <sup>c</sup>	Baseline (N = 110)	Follow-up (n = 96)	p value <sup>c</sup>
Food	51.8	33.7	0.01	29.4	26.6	> 0.99
Housing	4.6	4.8	> 0.99	11.1	1.1	0.02
Utility bills	4.6	3.7	0.69	7.4	1.1	0.06
Medical needs	25.5	25.3	0.82	15.6	10.1	0.46
Debts	2.8	2.4	> 0.99	6.5	1.1	0.06

<sup>a</sup> The survey also inquired about KP contacts to help obtain child care; because the need for child care was rare, this question is omitted here.

<sup>b</sup> Missing values ranged from 1% to 15% for these items.

<sup>c</sup> Exact p values using McNemar tests.

KP = Kaiser Permanente.

The survey also allowed KPCO researchers to test new survey measures. In clinical practice, patients often state that they postpone paying for some resource needs to pay for other needs, but existing studies have focused only on trade-offs between medical costs and other basic resources.<sup>24,25</sup> We tested pairs of survey questions to determine whether participants made trade-offs between paying for food and housing, utilities, or medical needs. Our finding that this practice was common (Table 4) deserves further study.

Despite the small size of our survey, its findings confirmed prior research. Others have found that the Hunger Vital sign had a high sensitivity and moderate specificity compared with 6-item or 18-item USDA measures.<sup>16,17,27</sup> Other studies also reported associations between food insecurity and marital status<sup>28,29</sup> or self-reported health status.<sup>1,28</sup> Prior research has consistently found a high prevalence of other basic resource needs among individuals with food insecurity.<sup>2,30,31</sup>

In addition to its impact on operational decisions, the project had several

strengths. We used formal cognitive interviews of KPCO members to improve our baseline instruments and recruitment materials. Measures were largely drawn from existing surveys and the published literature (Table 2, available online at: [www.thepermanentejournal.org/files/2018/18-098-T2.pdf](http://www.thepermanentejournal.org/files/2018/18-098-T2.pdf)). Baseline and follow-up surveys achieved a satisfactory response rate, with few missing data for most items. Although we did not systematically elicit narratives from KPCO members about their challenges in obtaining basic resources, we recorded several compelling stories (see Sidebar: Open-Ended Comments on Food Insecurity Surveys) that complement our quantitative findings.

The survey had several limitations that were inherent to its pragmatic design. First, the survey was limited to older adults who had previously indicated that they had food insecurity on the MTHA. Thus, these findings do not reflect the prevalence of social needs in the broader KPCO membership or in other settings. Additionally, food needs may have

resolved in the mean of 120 days between the MTHA survey and our smaller study. The new items included in this survey require further testing, psychometric analysis, and validation. Missing data for some items exceeded 10%, suggesting the need for additional exploration with respondents through cognitive interviews. Finally, the survey was small, and statistical power to detect differences was limited.

## CONCLUSION

This small survey illustrates a continuous improvement process that had several operational consequences for measurement and interventions to address basic resource needs. First, organizational leaders resolved the trade-off between measurement accuracy and respondent burden by deciding to revise the MTHA to include a 2-item measure of food insecurity. Second, the survey showed that basic resource needs remained stable during a 3-month period, suggesting that longitudinal screening could take place at longer intervals. Third, our findings ratified the importance of assessing other basic resource needs in older adult KPCO members who reported food insecurity. Finally, the finding that many members with basic resource needs did not report outreach from KP or community organizations emphasized the need to develop better tracking processes for referrals and their outcomes in KP and in the community organizations. Despite their limitations, such surveys can promote organizational learning and help health care systems more effectively address the basic resource needs of their patients. ❖

## Disclosure Statement

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

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Keywords: cost-related nonadherence, food insecurity, learning health systems, social determinants of health, survey design

**Investment**

There is no finer investment for any community than putting milk into babies.

— Sir Winston Churchill, 1874-1965, British politician, army officer, writer, and Prime Minister of the United Kingdom, 1940-1945

# Health Care Steps Up to Social Determinants of Health: Current Context

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## ABSTRACT

As the articles in this Supplement demonstrate, the social determinants of health are a major focus for Kaiser Permanente and the broader US health care system. Mounting evidence of the impact of social determinants on people's health has stimulated a surge of activity among policymakers, health systems, and a growing number of social entrepreneurs to integrate health and social services and to find novel ways to finance those efforts. The question is no longer whether there is an appropriate role for the US health care system in addressing the social determinants of health, but what that role is, how to create the right policy context for innovation and how health care can partner more effectively with providers of social services to meet patients' most pressing needs given the fragmented, typically underresourced nature of the social sector.

## INTRODUCTION

The landmark Whitehall study published in 1978, by Sir Michael Marmot<sup>1</sup> provided early, compelling evidence of the dose-response relationship between socioeconomic status and health outcomes in the British civil service. Since then, our understanding of the extent to which social, economic, behavioral, and environmental factors influence people's health has continued to grow. We now know that upwards of 70% of health outcomes are driven by factors beyond health care<sup>2</sup> and that poverty is associated with more years of lost life than smoking and obesity combined.<sup>3</sup>

Following on the work by McGinnis and Foege,<sup>4</sup> who calculated the "actual causes of death,"—factors such as smoking, poor diet, and inactivity, which drive disease-related causes of death—Galea et al<sup>5</sup> quantified the number of deaths attributable to social factors. They estimated that in the year 2000, approximately 423,000 deaths in the US were attributable to poverty, 245,000 were attributable to low educational status, 162,000 to low socioeconomic support, and 119,000 to income inequality.<sup>5</sup> To a large extent, social and economic stressors also drive the so-called "diseases of despair": Suicide, alcohol abuse, and opioid addiction. These diseases are creating pain and suffering for millions of American families and leading to declines in life expectancy for certain segments of the population.<sup>6</sup>

On the front lines of the US health care system, clinicians experience every day how unmet social and economic needs serve as a barrier to adherence, limit treatment options, and shape the flow of clinical interactions. Prioritizing one's health

can be difficult under the best of circumstances, but it can be so much harder when people struggle with so many more pressing issues—challenges such as affording a safe place to live, tenuous employment, difficulty paying for healthy food, social isolation, and the stress of being a caregiver.

As a society, we seem to be misallocating our resources by underinvesting in social care. Bradley and colleagues<sup>7</sup> have demonstrated how in the US, health care investments have displaced spending on social services, despite the higher health return on investment associated with the latter. The US is at the bottom of the pack of industrialized nations in terms of most measures of population health, but we are at the top in terms of how much we spend on health care relative to social services. In other words, we spend more and get less than countries who invest a smaller share of their total economic output on health care. The same holds true in the US at the state and county level. The good news is that public policy and the marketplace are both shifting to bring more attention and resources to addressing the social determinants of health in multiple ways—a shift that may have a profound impact on affordability, health, and well-being in the years to come.

## POLICY CONTEXT

Public policy has encouraged health care organizations to focus on social determinants of health. Although there is a long history of policy efforts to encourage health plans and health systems "to go upstream," passage of the Affordable Care Act (ACA)<sup>8</sup> in 2010 created an inflection point. First and most importantly, the ACA has extended coverage to more than 27 million Americans and reduced the uninsured rate to a historic low. This has allowed health systems, public health departments, and other stakeholders to focus additional resources and creativity on addressing the social determinants of health rather than filling gaps in coverage, and to move beyond disease management as the sole focus of their population health improvement efforts.

The ACA included provisions to shift payments from fee-for-service to value-based care, including bundled payments, capitation, and penalties for unnecessary readmissions. The ACA also created Accountable Care Organizations (ACOs) that facilitate the sharing of financial risk and accountability for patient outcomes among groups of health care providers. Collectively, these arrangements created incentives for treating the whole patient across broad episodes of care and over time. In so doing, they challenged

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health care providers to focus beyond specific conditions or diseases to provide more value to patients and public payers alike.

By authority established in the ACA, the Center for Medicare and Medicaid Innovation also established the Accountable Health Communities Model, developed specifically to test approaches to integrating health and social services. To date, 31 Accountable Health Communities demonstration sites have been funded. Each must screen and address a core set of 5 social needs: Housing instability, food insecurity, transportation needs, utility assistance, and domestic violence.<sup>9</sup> Similar Accountable Health Communities initiatives have been launched by state governments in Vermont, Massachusetts, and California, where the state has been joined by private funders. The California Accountable Communities for Health Initiative explicitly requires funded efforts to incorporate complementary policy, systems, and environmental change strategies into their interventions.<sup>10</sup>

Under both new and existing statutory authority, state Medicaid agencies and Medicaid managed care plans have also been granted increased flexibility by the Centers for Medicare and Medicaid Services (CMS) to address enrollees' social and nonmedical needs. States have used this flexibility to classify social services as covered benefits under state Medicaid plans; launch Whole Person Care pilots; use incentives, "withholds," and value-based payments to encourage health plan investments in social interventions; and integrate social needs activities into quality improvement efforts.<sup>11</sup> This flexibility has also extended to Medicare managed care plans. Most recently, CMS issued guidance allowing Medicare Advantage plans to include some types of social services into supplemental benefit plans.<sup>12</sup> This follows an earlier change in payment rules that allows physicians to bill for assessing their patients' social needs as part of enhanced payments for coordinating the care of patients with chronic illnesses.<sup>13</sup>

Beyond new payment incentives, the ACA also required non-profit hospitals to conduct community health needs assessments and to develop community benefit implementation strategies every 3 years. These assessments are intended to guide hospital community benefit investments, which currently exceed \$63 billion.<sup>14</sup> As intended, this requirement has fostered increased engagement between hospitals, public health departments, and community-based organizations. These community health needs assessments have surfaced a range of community conditions beyond traditional biomedical diseases, such as food insecurity, community violence, and economic insecurity, that are of critical importance to individuals in the community and that many hospitals had not previously addressed in a major way.

The architects of the ACA expected that, as more Americans received coverage, hospital charity care spending would decrease, thereby allowing hospitals to reallocate community benefit investments to prevention and efforts to address social, economic, and behavioral needs. A shift of community benefit dollars to these types of activities has been confounded, however, by counterpressure from the ACA's tethering of subsidized exchange policies to plans whose high cost-sharing requirements drive up nonprofit hospital charity care spending. Reallocation of community benefit dollars away from charity care has also been limited by low Medicaid payment rates in many states.

## DELIVERY SYSTEM AND INDUSTRY RESPONSES

Addressing social determinants has always been the focus of community health centers and many mission-based health systems. In the 1960s, Jack Geiger, the father of the community health center movement, famously wrote prescriptions for food for patients who presented with malnutrition.<sup>15</sup> The chronic care model developed by Ed Wagner and colleagues identified a role for community resources and patients' social and economic context, factors that became more prominent in subsequent articulations of that model.<sup>16</sup> Social determinants became mainstream in health care with 2 contemporaneous developments. The first was the growing use of "hot-spotting," an approach to identifying geographic clusters of patients with high levels of health care utilization and the socioeconomic factors driving those outcomes.<sup>17</sup> The second development was the spread of the Institute for Healthcare Improvement's Triple Aim,<sup>18</sup> a model for health care transformation that focuses on the concurrent achievement of lower costs, better experience of care, and, most relevant here, improved population health.

The evolving policy environment only accelerated health care's focus on social determinants. According to one recent survey, health systems adopting value-based care models were more likely to report undertaking social needs-related activities such as social needs screening and connecting patients to community resources; the more value-based care activities hospitals reported undertaking, the more social needs activities they reported undertaking.<sup>19</sup> As referenced in the article by Gusoff et al (page 22), the health care sector's broadening focus on social determinants is evidenced by the American Academy of Pediatrics' endorsement in 2015 of universal screening for food insecurity, the adoption of Z codes for documenting potential hazards owing to social circumstances in the International Classification of Diseases, Tenth Revision (ICD-10) coding system in 2016, and the recent policy statement on social needs from the American College of Physicians. Just this year, the American Hospital Association began its "Redefining the H" initiative, a campaign that endeavors to associate the ubiquitous blue and white "H" sign identifying a nearby hospital with communitywide efforts to address health more broadly.

As hospitals and other health care settings implement social determinants interventions, a common approach is social prescribing.<sup>20</sup> These interventions include several core elements: Screening patients for unmet social needs; connecting patients who screen positive to a navigator, community health worker, or some other person who helps the patient set goals and identify needed resources; referral of the patient to community-based resources or public programs; and tracking to ensure resolution of the need. These core elements are incorporated in the care continuum for basic resource needs described by Steiner and colleagues (page 53).

Beyond these common features, health care interventions to address social needs vary along several key dimensions.<sup>21</sup> First, some interventions focus on high-risk patients such as predicted high utilizers or complex needs populations, whereas others focus on universal screening. Second, some interventions focus on addressing multiple needs and others target a single need

such as food insecurity or housing. Third, programs vary by the extent to which they focus solely on individual-level interventions or whether they include a focus on policy or system-level changes. For instance, the food insecurity intervention in Kaiser Permanente (KP) Colorado (KPCO)<sup>22</sup> focused on connecting food-insecure patients to food programs and enrolling them in public benefits such as Supplemental Nutrition Assistance Program (SNAP) and Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). That KPCO program also used aggregate-level data on food insecurity and patient stories to successfully advocate for a simplification of the state's SNAP application form, a change that helped drive up the percentage of Colorado's eligible patients who are enrolled in the program. Finally, social prescribing programs vary by the extent to which the health system builds internal capacity to perform these functions or relies on vendors with dedicated capabilities and specialized expertise.

As the health care sector has ramped up its activity in this area and as public policy and private payers increasingly incentivize or require such efforts, a large and dynamic set of organizations has emerged to meet this demand. Of special interest is the emergence of social needs intermediaries that serve as a bridge between health care organizations and community-based social service providers. Butler describes several different types of intermediaries.<sup>23</sup> *Data intermediaries* share data on the social needs of patients and households with health care organizations and social service providers to support intervention design and cross-sector coordination. Some of these firms also focus on the development of models using both clinical and nonclinical data to predict patients who may benefit from social needs interventions, thereby allowing health systems to better target their screening and intervention resources. *Embedded extenders* are organizations that health systems or health plans engage to screen patients for social needs and to connect them to community resources. In some cases, these intermediaries also develop narrow networks of social care providers that exchange data and share financial risk with health care providers. Finally, so-called *budget blenders* include backbone organizations serving Accountable Health Communities that braid and blend different sources of funding and pull together diverse organizations in a variety of collective impact models to deploy those resources.

Most intermediaries in this rapidly evolving component of the social needs sector curate local community resources. Using a combination of Web scraping (Internet data mining), call centers, machine learning, and user feedback, these vendors are replacing the static spreadsheets, word processing documents, and sticky pad notes affixed to computer screens that have long been used by frontline clinician to identify community resources. These vendors may also offer case/client management systems, advanced analytics and reporting, and integration with electronic health records.

Although this sector has primarily been occupied by niche players seeded by philanthropic investments, highly capitalized technology companies such as Alphabet Inc (Mountain View, CA), the parent company of Google, and IBM (Armonk, NY) have recently launched subsidiaries that may reorder the

marketplace. Meanwhile, Benetech (Palo Alto, CA), a nonprofit technology intermediary, is working with information and referral providers including county 211 systems and competing private vendors that curate competing community resource databases. The goal of the ServiceNet Initiative is to develop a collaborative approach to refreshing social service resource data, thereby lowering the costs and increasing the quality of that data, promoting community-level aggregation of social needs data to identify gaps and to design policy- and system-level interventions, and freeing resources and entrepreneurial energy to focus on other value-added services.

As the marketplace continues to evolve and a new set of actors enters the field, the social sector continues to be fragmented and inadequately funded. The organizations providing the bulk of social services today are, by and large, public or nonprofit agencies that do not typically have access to sufficient capital or ongoing revenue streams needed to play the role being asked of them. As these organizations seek to build their capabilities, there remains a risk of demand outstripping supply, with health care organizations putting substantial stress on the organizations on the receiving end of social needs referrals.

### KAISER PERMANENTE'S APPROACH TO ADDRESSING SOCIAL NEEDS

The research reported in this supplement, and the organizational activity it represents, reflects a growing commitment in KP and other community-based delivery systems to address patients' social determinants of health. For health care providers, this commitment often begins with addressing unmet social, economic, and behavioral needs. KP's focus on social determinants is compelled by an organizational structure that integrates care, health insurance coverage, and community health functions, and a business model that creates economic incentives for prevention and upstream investments in health. In many respects, KP is a precursor to the current ACO movement, the "the original ACO."

KP's commitment to social interventions is heavily influenced by the organization's history. From its origins as an occupational health program in the shipyards dotting the West Coast during World War II, KP saw itself as a provider of social care, providing on-site child care and access to affordable healthy food and workforce housing. These investments reflected the imperatives and orientation of an employer intently focused on keeping its workforce healthy and productive. It also reflected the composition of its wartime workforce, which was heavily populated by women taking care of families and African Americans who had recently migrated to the West Coast from the South and Midwest. Addressing this population's social needs was a workforce health imperative, and it was vital to the success of America's war effort.

Over the years, KP's history, structure, and values promoted innovative approaches to clinical prevention and a broad definition of health. These approaches included early adoption of multiphasic health assessments, incorporation of health education as a standard Health Plan benefit, and, more recently, pioneering work in population health. These same drivers have led to the

deployment of community health initiatives that focus on health-promoting policy, systems, and environmental changes,<sup>24</sup> and an anchor strategy that leverages KP's major business assets to create healthy, thriving local economies. These initiatives have resulted in population-level improvements in food and physical-activity behaviors and other health-promoting community changes.<sup>24</sup>

This orientation, along with the fact that approximately 30% of its 12.2 million members have household incomes less than 250% of the federal poverty level, have sharpened KP's focus on addressing members' social needs and the social determinants of health more broadly. In 2017, Health Plan and Medical Group leaders endorsed a vision statement declaring that "In partnership with communities, addressing members' most pressing human needs is an integral part of health care quality." Four key capacities were identified as being necessary to execute this vision: 1) a standardized approach to screening for social need and integration of that approach into appropriate workflows and care processes; 2) deployment of a nationwide, locally adapted social service resource locator to connect members to community resources; 3) partnerships with select community-based social needs providers and others to address the social determinants of health; and 4) a strategy to evaluate and scale social interventions when those interventions prove to be effective.

Most of the studies reported in this issue were produced by KP investigators associated with the Social Needs Network for Evaluation and Translation (SONNET). SONNET was developed by KP in 2017 to advance organizational learning about social needs interventions and to inform KP strategy in this area as well as in the field. Other articles in this supplement were written by members of the Social Interventions Research and Evaluation Network (SIREN). Housed at University of California, San Francisco and funded by KP and the Robert Wood Johnson Foundation, SIREN aims to bring together leading social needs researchers from across the country to help identify and close evidence gaps through collaborative research projects and to build consensus on common measures, metrics, and methods.

## LOOKING FORWARD

Although the momentum to address social determinants of health is strong and growing, we are still in the early days of answering fundamental questions whose answers will be key to effectively and efficiently scaling social interventions in health care. These questions include: Which social needs interventions being delivered by health systems are working, and by what measures? Which patient populations should we focus on with what levels of resources to address people's unmet social needs, and what kind of outcomes is it reasonable to expect? What are the best roles for health care organizations and for their community partners in addressing those needs? What do we own as a health care system, when do we partner with others, and where is our best, highest purpose to advocate and support changes in systems or in public policy?

The articles in this supplement provide some early answers to these questions, as a stimulus to further evaluation and research

in this important area. They also reflect a concerted effort by KP and its partners to build the evidence base in this area, even as caregivers feel a compelling and urgent need to respond to the pressing human needs they see day in and day out. Indeed, this special issue is a fulfillment of noted community-based research expert Larry Green's dictum that "if you want more evidence-based practice, you need more practice-based evidence." ♦

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## Your Brothers are Here

Even if it's a little thing, do something for those who have need of a man's help—  
something for which you get no pay but the privilege of doing it.  
For, remember, you don't live in a world all your own. Your brothers are here, too.

— Albert Schweitzer, OM, 1875-1965, French-German theologian, philosopher, and physician



# Interventions to Address Basic Resource Needs in Kaiser Permanente: A Care Continuum and an Outcomes Wheel

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## ABSTRACT

As Kaiser Permanente develops interventions to help members address basic resource needs such as food, housing, utilities, and transportation, the organization is concurrently developing a framework for program implementation, outcomes assessment, and interventions dissemination. This framework combines a care continuum, adapted from population-based care management strategies for chronic diseases, with an outcomes wheel, which reflects a broad range of health outcomes that are relevant to patients, valued by diverse stakeholders, and potentially modifiable through interventions.

The resource-needs care continuum has 5 steps: 1) *plan* new interventions to generate evidence of effectiveness, 2) *assess* basic resource needs in broad or targeted membership groups, 3) *connect* individuals to community organizations that can fulfill basic resource needs, 4) *improve* health outcomes through these interventions, and 5) *spread* effective programs to other settings. Each step has multiple subcomponents that support implementation and evaluation. Although all stakeholders agree that interventions should assess fulfillment or mitigation of underlying basic resource needs, patients, clinicians, and organizational leaders often have different priorities for assessment of other health outcomes. The outcomes wheel identifies health outcomes at the individual, clinical, social, and system levels that can address these different priorities.

The resource-needs care continuum and outcomes wheel can assist operational leaders in designing and implementing new interventions, evaluating their effectiveness, and planning dissemination. Early collaboration with evaluators and researchers helps ensure that programs select appropriate measures of basic resource needs and health outcomes, adopt rigorous evaluation designs, and are sufficiently large to support decisions about effectiveness and spread.

## INTRODUCTION

Social factors are critical determinants of health outcomes in individuals and populations.<sup>1-3</sup> Although skilled clinicians have long recognized that they must understand their patients' social, environmental, and behavioral context when making clinical recommendations, large health care systems have only recently begun to identify and address social and economic risk factors systematically.<sup>4-6</sup> These efforts are intended both to improve care for individual patients and to increase the effectiveness of population management, care coordination, quality improvement, and risk adjustment.<sup>7,8</sup> Health systems that care for disadvantaged and vulnerable patients, such as safety-net institutions and

the US Department of Veterans Affairs, have emerged as leaders in this area.<sup>9,10</sup> Recent Medicare and Medicaid initiatives<sup>5,11</sup> have prompted private-sector health systems to develop similar programs.

Once a system commits to addressing the social and economic needs of its members or patients, it must determine which concerns to assess, establish processes to identify those needs, refer patients to appropriate resources, and track changes in those needs and related health outcomes over time. Many health systems are developing programs to assess basic resource needs such as food, housing, utilities, and transportation.<sup>12</sup> Although some systems have developed internal programs such as food pharmacies to address specific

needs,<sup>13</sup> most rely on partnerships with community organizations that have expertise in connecting individuals with basic resources. Building collaborations between clinic and community requires careful planning to share essential information, to track referrals, and to assess outcomes of importance to both organizations.

Stakeholders in a health system may have different expectations about the outcomes that can be achieved through interventions to address basic resource needs. Patients and clinicians often assert that addressing these fundamental needs is simply the right thing to do from an ethical and humanitarian perspective. Frontline clinicians and quality leaders may add that an awareness of basic resource needs, even if they cannot be fulfilled, can help individualize care, improve clinical outcomes and quality, and reduce health disparities. For example, a clinician who becomes aware of her patient's transportation barriers may convert medication prescriptions to mail-order delivery, which can improve adherence.<sup>14</sup> Operational leaders attuned to the bottom line may care most about the effect of these programs on patient satisfaction, utilization of services, and costs of care.

Because programs to address basic resource needs cross traditional boundaries between health care and community and their success can be gauged from many perspectives, a comprehensive framework is necessary to guide program development and evaluation. In this article, we describe the evolving framework for implementation, outcomes assessment, and dissemination of interventions to mitigate basic resource needs in Kaiser Permanente (KP). This framework combines a *care continuum* for basic resource needs, adapted from population-based management strategies

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for chronic health conditions, with an *outcomes wheel* that articulates the broad range of potential outcomes of importance to different stakeholders. Although this framework has been developed for programs that identify basic resource needs (primarily housing, food, energy/utilities, and transportation), a similar framework may apply to other programs that connect health systems with community organizations, such as diabetes prevention or postpartum home visitation programs.<sup>15,16</sup>

## GENERAL PRINCIPLES OF A CARE CONTINUUM

To attain optimal biopsychosocial outcomes,<sup>17</sup> to support treatment adherence,<sup>18,19</sup> or to improve the quality of care,<sup>20</sup> health systems must develop multidisciplinary programs that cross organizational reporting lines. Each step in this process is part of a larger continuum of care. In 2011, Gardner and colleagues<sup>17</sup> described a continuum of care for individuals and populations with HIV infection that began with screening to identify HIV infection; continued through linkage to HIV care, retention in care, treatment with antiretroviral

medications, and treatment adherence; and culminated in viral suppression. This care continuum framework has been adopted as the strategy for diagnosis and treatment of HIV infection in the US population.<sup>21</sup> With subsequent refinements, this model has guided HIV quality improvement interventions in the US and other countries since 2012.<sup>22,23</sup> Similar care continua have been defined for other chronic diseases, including depression, hypertension, diabetes, and hepatitis C.<sup>24-27</sup>

Each step in a care continuum depends on successful completion of prior steps. Pictorially, these steps are often represented as a downward cascade<sup>17</sup> or as progressive “voltage drops.”<sup>20</sup> Even if decrements in quality at each step are small, they can accumulate to undermine accomplishment of care goals at the population level. For example, in a hypothetical care continuum with 5 independent steps, a 10% relative decline at each step would result in achievement of the desired outcome in 59% of the population, whereas a 20% relative decline, common in clinical settings, would result in only 33% achieving that outcome. Simple estimates<sup>17</sup> or simulation

studies<sup>25</sup> can identify specific steps in the care continuum at which interventions might optimize outcomes.

Once each step in a care continuum is defined and its importance is quantified, targeted interventions can address specific facilitators and barriers. Because chronic health problems or basic resource needs can rarely be resolved definitively, cycles of intervention and outcome assessment can identify individuals who do not complete a step in the continuum so that they can be reengaged in care.

## DEVELOPMENT OF A CARE CONTINUUM FOR BASIC RESOURCE NEEDS

KP is an integrated health care system that provides preventive care, primary care, and specialty care to more than 12 million individuals in 8 geographic Regions across the US (Northern California, Southern California, Colorado, Georgia, Hawaii, the mid-Atlantic States and Washington, DC, Northwest [Oregon and southwest Washington], and Washington State). In 2016, leaders in the Kaiser Foundation Research Institute and KP Care Management Institute conducted interviews with 18 KP leaders who assessed the design, scale, and value of existing programs to address social, economic, and behavioral needs within KP. These leaders developed a preliminary intervention model for programs to link KP clinical activities with community organizations. They also identified the need for greater rigor and consistency in planning, evaluation, and dissemination of these programs.

In response, KP’s national Community Health program established the Social Needs Network for Evaluation and Translation (SONNET) in 2017. SONNET is a network of experienced KP researchers and external academic colleagues with expertise in health services research, implementation science, and clinical medicine.<sup>28</sup> SONNET first identified more than 35 interventions across KP Regions that addressed 1 or more basic resource needs. Then SONNET investigators and staff examined the development and implementation of selected early programs and confirmed the impression of organizational leaders that few of the programs had used a systematic framework to guide design, implementation, or evaluation.

### Steps in Care Continuum for Basic Resource Needs

#### 1. Plan an approach to assessment and intervention for basic resource needs

- Elicit patient priorities and concerns.
- Develop partnerships with community organizations that provide basic resources.
- Elicit clinician and staff priorities and concerns.
- Identify domains and measures to assess basic resource needs.
- Identify survey formats (online, automated, in person) acceptable to patients and staff.
- Define health outcomes of importance to diverse stakeholders.

#### 2. Assess basic resource needs

- Identify populations or high-risk subgroups for systematic assessment.
- Assess basic resource needs systematically in targeted groups or individuals.
- Store information to be accessible for clinical and operational use.

#### 3. Connect individuals with basic resource needs to community organizations

- Build referral workflows for frontline clinicians and staff.
- Complete referrals to community organizations.
- Share secure information between health systems and community organizations.
- Monitor patient use of community resources.

#### 4. Improve health outcomes (the “outcomes wheel”)

- Fulfill basic resource needs.
- Assess impact on personal health outcomes (eg, physical and mental health status, self-care, satisfaction).
- Assess impact on clinical outcomes (eg, chronic disease outcomes).
- Assess impact on social and community health (eg, health disparities, neighborhood health).
- Assess impact on health system performance (eg, member retention, service utilization, costs of care).

#### 5. Spread effective programs and approaches

- Spread within the health system.
- Share findings to promote spread across health systems.

Measures of basic resource needs or outcomes were often unstandardized, rigorous evaluations were rare, and few programs had spread beyond their initial site.

To address these concerns, SONNET proposed a resource-needs care continuum for basic resource interventions in KP. The Sidebar: Steps in Care Continuum for Basic Resource Needs identifies the 5 steps in this care continuum and defines some of the decisions and actions necessary at each step. Figure 1 illustrates these steps as an upward progression toward a set of goals rather than as a downward cascade.<sup>17,20</sup> The components that we list for each step derive from the ongoing experience of program developers and evaluators. Although we use the word *should* to describe these components, it must be recognized that these recommendations are generally based on expert opinion rather than established evidence.

## STEPS IN RESOURCE-NEEDS CARE CONTINUUM

### Step 1: Plan

In Step 1 (“Plan”), clinical and operational leaders should collaborate with patients to prioritize their most pressing basic resource needs. They should build partnerships with community organizations that can help mitigate these heterogeneous needs. Leaders should also work with frontline clinicians and staff to identify barriers

to addressing basic resource needs in their daily work. As part of this process, leaders should assess the community resource landscape to ensure that capacity exists to address resource needs identified through clinical care or screening. Leaders should then select survey domains and measures to assess high-priority needs. They should develop alternative formats to facilitate survey completion (eg, online, telephone-assisted, tablet computer, or paper administration) in different physical settings (eg, home, waiting room, or examination room). Because patient resource needs, health system priorities, and community capacity are all dynamic, plans for periodic reassessment should be developed. Finally, leaders should anticipate Step 4 of the resource-needs care continuum (“Improve”) by identifying health outcomes that can assess the effectiveness of their interventions, and by developing plans to measure those outcomes.

### Step 2: Assess

In Step 2 (“Assess”), operational leaders identify priority groups of members/patients for assessment of basic resource needs, and administer surveys to those groups. They may decide to assess an entire demographically defined population, such as families with small children or the elderly.<sup>29,30</sup> Alternatively, they may limit assessment to subgroups with a

high presumed or proven prevalence of needs,<sup>31</sup> such as medically complex patients or low-income patients receiving insurance through Medicaid. Survey responses should be stored in the electronic health record so that they are accessible to clinicians, staff who conduct population health activities, program evaluators, and researchers. Strategies should also be developed to assess additional social, economic, or behavioral health needs in patients who identify a “sentinel” basic resource need during screening.

### Step 3: Connect

In Step 3 (“Connect”), workflows should be developed to refer patients/members to community organizations. These workflows must allow clinicians and staff to integrate assessment of basic resource needs with other care goals. Collaborative planning with community organizations can standardize referral processes and ensure secure, bidirectional transmission of protected health information. Tracking of referrals enables frontline clinicians, population health managers, and community organizations to determine whether referrals have been completed. Patients may require ongoing support from clinical or community navigators, social workers, or care managers to complete the referral process and obtain resources to mitigate their needs. Community organizations should also track the resources that patients receive and should develop outcome reports for their own use and for the referring health systems.

### Step 4: Improve

Step 4 (“Improve”) is based on a 5-part “outcomes wheel” (Figure 2). This outcomes wheel encompasses individual, clinical, social, community, and health system goals for interventions to mitigate basic resource needs, and identifies potential measures to assess program effectiveness. The first “spoke” in the outcomes wheel is improvement in the underlying basic resource need. In Figure 2, resource needs are located at the top of the outcomes wheel to signify their pervasive importance to stakeholders. The ability to demonstrate that patients do obtain basic resources is critical to establish the credibility of these programs and sustain them in the face of competing operational demands.

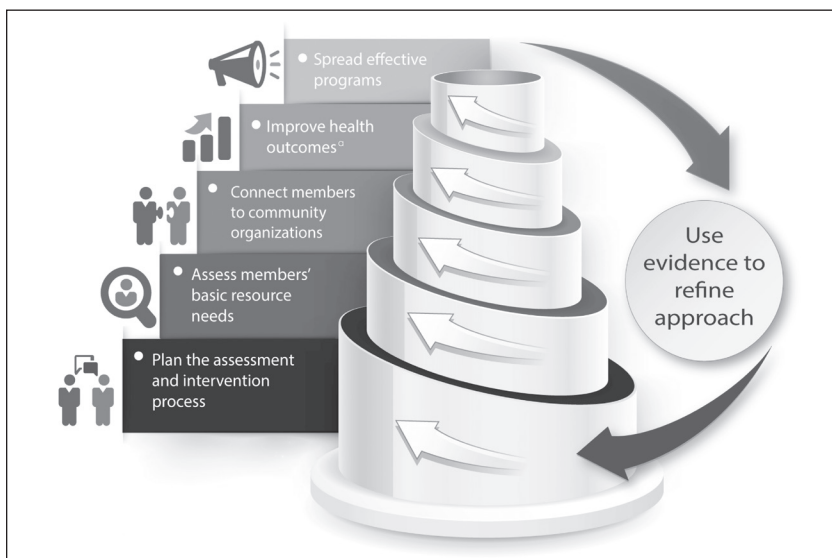


Figure 1. A care continuum for basic resource needs. The continuum consists of 5 steps that are necessary to accomplish the goals of programs designed to mitigate basic resource needs.

\* See health outcomes wheel in Figure 2.



Figure 2. Health outcomes wheel. Each of the 5 “spokes” of this wheel includes a set of health outcomes that can be used to assess the effectiveness of interventions to mitigate basic resource needs.

Identification of individuals whose basic needs have not been fulfilled despite connection to these resources in Step 3 of the care continuum can prompt further exploration of factors that limit their ability to utilize community resources, and can also identify gaps in community and governmental programs that address basic resource needs.<sup>32</sup> If individuals do not obtain sufficient resources, leaders can reexamine prior steps in the resource-needs care continuum and develop quality improvement efforts.

Interventions to mitigate basic resource needs affect a broad array of other health outcomes.<sup>3,33</sup> Personal health outcomes, the second “spoke” of the outcomes wheel, might include measures of health status and well-being, mental health, satisfaction with care, or self-care behaviors. Clinical outcomes could include use of preventive care services such as cancer screening or immunizations, adherence with health care visits and medications, or chronic disease outcomes. Social and community outcomes could include reductions in health inequities between social groups, collateral health effects on household members, or changes in neighborhood-level measures of health. System performance outcomes might include staff satisfaction, member retention, utilization of primary care, specialty and acute care services, or costs of care.

The relationship between these outcomes can be complex, and no program should be expected to measure or attain all of them. Rather, the outcomes wheel

is intended to help program developers clarify their goals; choose outcome domains and measures that address the concerns of their stakeholders; and establish evaluation criteria for spreading, refining, or terminating their initiatives.

### Step 5: Spread

Step 5 (“Spread”) is an essential consideration in geographically dispersed organizations such as KP, where interventions are commonly developed and evaluated in a single clinical site. Successful single-site programs often benefit from impassioned local leadership, committed staff, and well-established relationships with mature community organizations. Because these attributes may be difficult to replicate at other sites, interventions should be designed for dissemination.<sup>34</sup> Considerations in designing a program for dissemination include incorporating stakeholders into development and testing of interventions, using established frameworks and theories to promote spread, characterizing barriers and facilitators to spread in the local “ecosystems” where an intervention is first implemented, and developing strategies to share evaluation findings with clinical and operational audiences.<sup>34</sup> Publications based on rigorously designed evaluations and research can also facilitate spread within and between health systems. Survey instruments, referral forms, and computer codes to extract and manage data can also be shared within the health care system and to other settings.

### LIMITATIONS OF THE CARE CONTINUUM FRAMEWORK

The KP resource-needs care continuum framework has 5 important limitations: 1) Although the model can guide decisions about program design and evaluation, it inevitably oversimplifies complex processes in the health system and the community. Thus, it requires adaptation to each local context. 2) Patients’ ability to complete each step can be affected by clinical, behavioral, and social forces that codetermine the outcomes of interest. These moderators of effectiveness should be measured as part of evaluation efforts. 3) Frontline clinicians and staff face competing organizational priorities that may undermine the effectiveness of programs to address basic resource needs.

4) Community organizations that help mitigate basic resource needs are often inadequately funded and thus dependent on volunteer staff. They may lack robust information technology, internal quality improvement programs, or the ability to assess their own outcomes. As a result, they may have limited capacity to meet increased demand from KP and other health systems. In response, KP and other health systems are collaborating to strengthen the resource landscape in those communities. 5) To date, no KP programs to address basic resource needs have fully characterized the “voltage drops” at each step of the continuum, although some facilitators and barriers have been identified.<sup>35</sup> Thus, this care continuum will be refined as evidence accumulates from increasingly rigorous internal research and evaluations.

Experienced evaluators or researchers should be included in planning for new interventions. They can introduce the framework of the resource-needs care continuum and outcomes wheel, help develop measures to assess outcomes of importance, and estimate the number of participants necessary to demonstrate operationally significant changes in those outcomes. Rigorous evaluation designs such as randomized controlled trials or quasi-experimental studies with concurrent comparison groups can increase confidence in the effectiveness of these programs.<sup>36</sup> The planning process should also anticipate unintended consequences so that they can be avoided or addressed in program design. For example, asking overworked frontline clinicians and staff to add social needs assessments to their daily work may jeopardize other important care goals unless appropriate workflows are developed.

### CONCLUSION

As the resource-needs care continuum framework is introduced in KP, we anticipate that it will prove to be useful for planning, implementation, and evaluation of interventions to mitigate the basic resource needs of KP members. Its inherent logic and specification of the steps necessary to develop and test interventions have already made it appealing to organizational leaders. The continuum also specifies evaluation and research questions that must be addressed during implementation and spread. If the

intended outcomes of an intervention are not achieved, the continuum provides a structure for qualitative and quantitative investigations to identify steps that require quality improvement interventions. We expect that the care continuum for basic resource needs and the outcomes wheel will continue to evolve as KP gains operational experience and generates evidence from these important programs. ❖

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**Keywords:** care continuum, food insecurity, health outcomes, learning health systems, managed care, social determinants of health

# Uses and Misuses of Patient- and Neighborhood-level Social Determinants of Health Data

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## ABSTRACT

Health care leaders in the US are actively exploring strategies to identify and address patients' social and economic hardships as part of high-quality clinical care. The result has been a proliferation of screening tools and interventions related to patients' social determinants of health, but little guidance on effective strategies to implement them. Some of these tools rely on patient- or household-level screening data collected from patients during medical encounters. Other tools rely on data available at the neighborhood-level that can be used to characterize the environment in which patients live or to approximate patients' social or economic risks. Four case examples were selected from different health care organizations to illustrate strengths and limitations of using patient- or neighborhood-level social and economic needs data to inform a range of interventions. This work can guide health care investments in this rapidly evolving arena.

## INTRODUCTION

It is increasingly clear that social and economic contexts are integral determinants of both child and adult health and well-being.<sup>1-9</sup> Emerging literature reveals how social determinants of health (SDH)<sup>10</sup> may affect health outcomes and health care costs.<sup>11-39</sup> As a result, there is growing consensus from professional medical organizations that in collaboration with patients and communities, the health care sector should consider new roles for itself around identifying and strengthening SDH as one part of a comprehensive strategy for improving population health.<sup>40-42</sup> Despite mounting interest and experimentation, no clear consensus has emerged about what strategies health care systems should assume in this arena. Risk and strength assessment and interventions around patients' social and economic contexts vary widely across organizations, often dependent on institutional leadership, resources, and patient populations.<sup>21,22,33,38,39,43-52</sup>

To identify SDH affecting patients, some health care settings have systematized the collection of SDH data by using standardized social screening questionnaires, including those endorsed by organizations such as the National Academy of Medicine, the National Association of Community Health Centers, and the Centers for Medicare and Medicaid Innovation.<sup>53-55</sup> Obstacles to patient-level screening include logistic barriers (eg, cost/time) to adding screening activities in busy clinics<sup>56,57</sup> and concerns about whether and how identified needs can subsequently be addressed.<sup>58-64</sup>

As an understanding of the feasibility, actionability, and potential returns of patient-level social screening evolves and best practices

emerge in this area,<sup>65-69</sup> other health care organizations are also exploring ways to use neighborhood-level data to characterize patients' social and economic contexts.<sup>70</sup> In these instances, area-level data are being used as proxies for individual social and economic status while also being potentially reflective of unique contextual risk factors. To inform future efforts to incorporate SDH data into health care decision making, we describe specific examples in which delivery systems have opted to use patient- or neighborhood-level SDH data to guide intervention investments; we also discuss the strengths and limitations of these different approaches.

## METHODS

We selected 4 examples from practices across the US to highlight different approaches to SDH data collection and application. These examples may help to inform decisions by clinical and population health leaders as they explore ways to more systematically incorporate patients' SDH information into care delivery. The first 2 examples highlight different ways in which *patient-level* data can inform social intervention development and deployment. These examples differ in that the first involves a program specifically designed to collect patient SDH data by adding new responsibilities to the health care team; the resulting intervention is directed at the patient level. The second example relies on existing patient-level data in the electronic health record collected for other purposes; the data then contribute to shaping a neighborhood-level intervention.

An additional 2 examples highlight interventions in which health care organizations use *neighborhood-level* social and economic data to tailor work around SDH. These cases highlight how a surge in the availability of area-level information—such as the availability of supermarkets, the number of liquor stores, or the prevalence of violent crime—and a growing capacity to integrate data sources create new opportunities to identify populations that may benefit from either patient- or neighborhood-level interventions.

## Examples: Social Determinants of Health Data Uses Patient-Level Data Inform Patient-Level Interventions

Health Leads is a national nonprofit organization in Boston, MA, that advises health care systems across the country on approaches to SDH screening and navigation, with the goal of connecting patients and caregivers with community resources.<sup>71</sup> Some health care systems have elected to work with partners like Health Leads to facilitate patient-level screening and interventions. Although approaches vary from centralized call centers<sup>72</sup> to clinic-based programs,<sup>37,47</sup> most begin with health care system staff

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gathering information on social and economic hardships through patient-level screening, which can help uncover challenging patient or household circumstances related to topics such as threatened eviction, food insecurity, or limited transportation access. Staff review screening responses with patients or caregivers, collaboratively select which needs to address, and develop an action plan. Staff offer support and facilitate connections to relevant community resources (patient-level intervention), and track referral status and patient-reported progress toward relevant goals.<sup>37,73</sup> For example, staff may support patients to connect with free legal services, to obtain food from a local food pantry, or to obtain discounted public transportation passes. Studies on the effectiveness of the program model have demonstrated both social hardship and health effects.<sup>37,73</sup>

**Patient-Level Data Inform Neighborhood-Level Interventions**

Between 2009 and 2010, Cincinnati Children’s Hospital Medical Center in Cincinnati, OH, and their partners at the Legal Aid Society of Greater Cincinnati aggregated addresses of patients hospitalized with asthma (patient-level data) from 2 primary care practices. The process led to identifying 16 housing units in 6 local building complexes with a common owner where children were experiencing disproportionately high rates of asthma-related morbidity.<sup>44,74</sup> Once the cluster was verified quantitatively, the team worked with individual tenants and a collective tenants’ association from the housing complex to advocate for building-wide repairs (neighborhood-level intervention). These activities lowered the numbers of asthma triggers (eg, mold, cockroaches) for those patients that initially prompted cluster identification. Activities also extended across the building complexes, resulting in complexwide repairs.

**Neighborhood-level Data Inform Patient-level Interventions**

As part of Cincinnati Children’s Hospital Medical Center’s commitment to decreasing health inequities, the hospital has selected 2 local neighborhoods in which to focus disparity-reducing activities. Neighborhoods were chosen on the basis of census and other area-level data showing disproportionately high rates of both all-cause morbidity and underlying risks related to poverty, such as housing instability and poor transportation access (neighborhood-level data). Each morning, a multidisciplinary team of physicians, nurses, social workers, and community engagement consultants receives an alert from the electronic health record identifying any child hospitalized from these high-risk neighborhoods. This prompts in-depth chart review and a bedside huddle focused on the potential preventability of the hospitalization, identifiable care gaps (eg, need for vaccinations, overdue for primary care follow-up), and transition needs. When appropriate, patients are connected with additional supports during the hospitalization (eg, social work consultation, connection to a community health worker) and/or specialized transition-related service delivery such as postdischarge nurse home visits, medication delivery, or school-based outreach programs (patient-level intervention).

**Neighborhood-level Data Inform Neighborhood-level Interventions**

Kokua Kalihi Valley Comprehensive Family Services runs 9 federally qualified community health centers in Honolulu, HI.<sup>75</sup> The organization’s mission involves serving all community residents, not only clinic patients. As a result, new program development is based on the needs and strengths of the entire community. Neighborhood-level data on food security, safety, and employment help inform these neighborhood-level interventions.

Table 1. Strengths and limitations of patient- and neighborhood-level social determinants of health data applications		
Health data	Patient-level interventions	Neighborhood-level interventions
Patient-level data	<p><i>Strengths:</i> Screening data collected directly from patients are likely more sensitive and specific to condition. Screening and intervention are both in context of shared clinical decision making, so can more closely tie interventions to patients’ priority needs.</p>	<p><i>Strengths:</i> Using a patient lens may increase the health care system’s engagement in upstream activities. Data may be more quickly accessible and aggregated.</p>
	<p><i>Limitations:</i> Cost of screening entire clinical population. Sampling bias and social desirability bias may affect patients’ responses to health care practitioners. High cost of intervening at individual level to address neighborhood-level issues (eg, housing inadequacy, food deserts).</p>	<p><i>Limitations:</i> Sampling bias and social desirability bias may affect patients’ responses to health care practitioners. Subject to “exception fallacy”: Patients from health care system may not reflect neighborhood population adequately.</p>
Neighborhood-level data	<p><i>Strengths:</i> Increases health care system’s engagement in upstream, neighborhood-level activities. Potential to focus on entire population facing health consequences, which could enhance value of interventions.</p>	<p><i>Strengths:</i> Uses a population-level lens; may be more “objective.” More capacity to affect population-level change.</p>
	<p><i>Limitations:</i> Subject to “ecological fallacy”: Some patients in this neighborhood may not be at higher risk. Lack of timely and detailed data limits depth of understanding. Potential to increase stigma. Potential to reinforce inequity across factors other than neighborhood (ie, easier to intervene on behalf of relatively healthier individuals in same neighborhood).</p>	<p><i>Limitations:</i> Can use only social determinants of health data that are available (practitioner has less control over how data are collected). May not have a direct impact on health system’s catchment population. Lack of timely data limits ability to monitor and adjust interventions.</p>

For example, the clinical organization leases and operates the Kalihi Valley Nature Preserve, which it maintains as a strategy for producing healthier food and encouraging physical activity for all residents (neighborhood-level intervention).

### DISCUSSION: VALIDITY THREATS

Each of these 4 approaches to collecting and using data depends on the interest and capacity of both the health care organization and the surrounding community. We highlight them to demonstrate a range of ways that health care organizations can incorporate information about patient- or neighborhood-level SDH into decisions about relevant patient- or neighborhood-level interventions. Table 1 summarizes strengths and limitations of the different data applications.

Two quadrants of Table 1 are worth special highlight—those that use patient-level data to guide neighborhood interventions and those that rely on neighborhood-level data to guide patient-level interventions. There may be compelling reasons to use aggregated patient-level data to inform neighborhood-level activities, especially when neighborhood surveillance data are difficult or impossible to obtain, lack sufficient granularity, or are collected/reported too infrequently to meaningfully guide interventions. A primary threat to validity when using patient-level data to guide neighborhood-level interventions, however, is when patients are not representative of the neighborhood's population. This can lead to the *exception fallacy*, which is when conclusions about a group are formed on the basis of nonrepresentative cases.<sup>76</sup> For instance, using data on the health impacts of local food pantries only from sick patients referred from a hospital overlooks the potential impacts of pantries on many other beneficiaries. This could lead to changes in hospital investments that could have substantial unintended consequences on other populations. To limit the effects of this bias, health care organizations can work with relevant local stakeholders to use additional data sources that are more representative of the neighborhood to inform neighborhood-level interventions.

Similarly, the use of neighborhood-level data to inform patient-level interventions may make sense when universal patient-level screening is infeasible. In this case, neighborhood-level data can help to initiate risk-stratification and to target screening resources toward populations most likely to benefit. However, using neighborhood-level data to guide patient-level interventions presents a threat known as the *ecological fallacy*, or the possibility of making incorrect assumptions about individuals on the basis of the profile of a group.<sup>77</sup> For instance, low-income patients who live in high-income areas may not be captured by clinical intervention programs triggered by neighborhood-level risk algorithms, yet those patients may experience higher stress or other negative health outcomes. Alternatively, patients may be subject to stigma from processes such as automated referrals to resources associated with lower socioeconomic status. Future work in this area should deepen our understanding of the overlap and differences in patients captured using individual level measures (eg, financial strain or reported income) vs neighborhood-level measures (eg, mean area-level poverty).<sup>78</sup> Meanwhile, to limit these unintended consequences, health care systems that stratify patients by neighborhood-level characteristics to target patient-level interventions

should validate and refine assessments with patient-level data whenever possible and collaboratively select interventions in the context of shared clinical decision making.

### CONCLUSION

The health care sector has experienced a steadily growing interest in identifying and incorporating information on patients' SDH in the context of care delivery. This stems from both increased awareness about the health effects of SDH and new value-based payment models that incentivize prevention. Despite this enthusiasm and experimentation, little guidance has existed to date for health care providers about how best to translate interest into action. Moreover, health care organizations of different sizes (and with different degrees of community connectedness) are likely to differ in their readiness and capacity to incorporate these new data.<sup>79,80</sup> Early adopters illustrate wide variation in both data collection approaches, instruments, and interventions. With this range of applications, weighing the strengths and limitations of different kinds of data is and will continue to be increasingly important, especially in light of the growth in big data-based predictive analytics that help to make both patient and population-level data more accessible.<sup>81</sup>

Beyond employing the right data in the right context, systems that aim to increase capacity to interpret and apply SDH data should also bring diverse perspectives to the explanation of trends and more creativity to the design of interventions. To do so, they might consider undertaking SDH analyses and investments in the context of partnerships with patients, families, and neighborhood organizations. Incorporating community perspectives into health care systems' interpretation and use of SDH data is part of the design of the alignment track in the new Centers for Medicare and Medicaid Innovation Accountable Health Communities demonstration project,<sup>82</sup> although these findings are still many years out.

Finally, we recognize that the health care sector's activities in this area are only a small part of reversing longstanding resource allocation decisions through power differentials on the basis of race, wealth, or other factors that have perpetuated health inequities.<sup>83-86</sup> At the same time, the sector is expanding previous efforts to recognize the influence of social and economic factors on health<sup>87</sup> and to act on that information. For now, health care systems investing in addressing SDH must avoid basic threats to validity in translating data into specific interventions, ensuring that data being applied are maximally relevant to the proposed level of intervention. ♦

<sup>a</sup> Some emerging research suggests that despite concerns about cost and time, clinic-level capacity to address patients' social needs may protect against practitioner burnout. Insofar as reduced burnout saves health systems money, it may be that the practitioner burnout benefits of social screening could be added to other potential savings.

#### Disclosure Statement

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

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# Toward Addressing Social Determinants of Health: A Health Care System Strategy

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## ABSTRACT

**Objectives:** In the US, there is growing recognition that social factors (eg, financial hardship, food insecurity, housing instability) influence individual and population health. This has led to increased efforts to address these social determinants of health (SDH) within the delivery system. Yet, limited information exists about the strategies health care systems employ to identify and address SDH. Kaiser Permanente Northwest (KPNW) is an integrated health care delivery system that has implemented a comprehensive approach toward addressing its patients' SDH. This article describes the tools and processes used at KPNW for identifying and addressing SDH.

**Methods:** Tools included use of electronic health record-based data elements, International Classification of Diseases, Tenth Revision social diagnostic codes (Z codes), and the development of novel workflows via nonclinical patient navigators to address patients' SDH through community resource referrals. Between March 31, 2016, and March 25, 2018, KPNW patient navigators screened patients with SDH.

**Results:** Patient navigators screened 11,273 patients with SDH, identifying and documenting 47,911 SDH in the electronic health record. During the same 2-year period, 18,284 community resource referrals were made for 7494 patients.

**Conclusion:** The novel electronic health record-based tools developed by KPNW have led to standardized, measurable, and actionable SDH data being used to tailor and target specific resources to meet the identified needs of our patients. By disseminating information about these efforts at KPNW, we aim to help build an evidence basis of different approaches for addressing SDH within the health care system as well as defining opportunities to improve care efficiency for patients with SDH.

## INTRODUCTION

In the US, there is growing recognition that social, economic, and behavioral factors (eg, financial hardship, food insecurity, housing instability, transportation) influence individual and population health, and may account for 40% to 90% of health outcomes.<sup>1-6</sup> These social, economic, and behavioral factors, commonly known as *social determinants of health* (SDH), are defined as circumstances in which people are born, live, learn, work, play, worship, and age, as well as the health systems they utilize.<sup>7</sup> Evidence indicates that unmet SDH influence individuals' ability to attain their full health potential, leading them to consume more health care services or require more intensive health care than those without SDH.<sup>8,9</sup> National policies such as the

Health Information Technology for Economic and Clinical Health (HITECH) Act<sup>10</sup> and the Patient Protection and Affordable Care Act (ACA),<sup>11</sup> in addition to new care delivery and payment models (eg, Accountable Care Organizations, the State Innovation Models Initiative), have placed increased emphasis on identifying patients' SDH and integrating these data into the electronic health record (EHR) as a critical first step toward addressing SDH within the health care system.<sup>12-14</sup> Consequently, US health care systems have increasingly implemented efforts to integrate SDH data into EHRs as part of addressing SDH to improve the quality of care and population health.<sup>11,15-17</sup>

Addressing SDH in a health system, however, is fundamentally different from treating medical problems.

Although health care systems are well equipped to treat disease,<sup>18</sup> they often lack the necessary tools and strategies to identify, document, and track SDH in EHRs systematically. This task will require standardized, measurable, and actionable SDH data. Furthermore, health systems must develop strategic workflows and partnerships with referral agencies that have the resources and expertise to address identified SDH.<sup>19</sup> Successful integration of SDH data into EHRs may enable more effective care management and treatment strategies for patients, facilitate more effective population health approaches, and inform new treatments and interventions as pathways linking SDH to disease processes are discovered.<sup>14,17</sup> Despite the promise of this work, however, there is limited information about the strategies employed by health care systems to identify and address SDH.<sup>15</sup>

To address the existing knowledge gap, this article describes an approach to identifying and addressing SDH among patients in a health care system. Specifically, we provide a "map" outlining the documentation of SDH in the EHR (Kaiser Permanente [KP] HealthConnect using Epic, Epic Systems Corp, Verona, WI), using the International Classification of Diseases, Tenth Revision (ICD-10) Z codes. As noted by Gottlieb and colleagues,<sup>17</sup> the use of ICD-10 codes aligns with the US Department of Health and Human Services' 2015 mandate for ICD-10 EHR documentation. It provides the potential for coding and billing on SDH in a clinical setting. We also describe the tools and processes used for making and tracking referrals to community resources. By providing this overview of a real-world health care system experience, we hope

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to inform the development of effective and actionable strategies to identify and address SDH in clinical settings that will improve the health of patients and communities.

**METHODS**

**Setting and Process for Identifying Social Determinants of Health**

KP Northwest (KPNW) is an integrated health care delivery system,

operating in 34 medical offices and 2 hospitals, and providing health care to more than 600,000 members in Oregon and Southwest Washington. KPNW has implemented a comprehensive approach for addressing the SDH of its patients. Specifically, KPNW has trained staff across clinical and operational departments to assess and to identify SDH in the clinical setting. There are multiple points in the health care encounter

when health care staff initially identify patients' SDH: 1) a nonclinical staff member interacts with a patient during the health care visit but outside the clinical encounter (eg, a registration/check-in representative who learns that a patient has a transportation need); 2) a clinical staff member identifies a patient with SDH as part of the clinical encounter (eg, a nurse learns that a patient is currently homeless and unable to pay for

**Table 1. Social determinants of health (SDH) data collected in the EHR, corresponding ICD-10 Z codes, and examples of use<sup>a</sup>**

SDH domain (code)	Example of situation to use Z code
<b>Social</b>	
Caregiver stress (Z63.8)	Caregiver for child, adult, or senior with complex medical, social, physical, and behavioral needs
Family stress (Z63.8)	Social, economic, medical stressors affecting family and/or home environment
Insufficient social insurance or welfare support (Z59.7)	Lack of insurance, uninsured, or underinsured; needing SSI/SSDI or public assistance
Need assistance with community resources (Z74.8)	For general resources, when there is not a specific Z code for need
Unavailability or inaccessibility of other helping agencies (Z75.4)	Lack of community resources, ineligible for community resources, no capacity
Social isolation (Z62.4)	Lack of or limited availability of family, friends, community groups, or agencies to provide routine social support; member spends most of time alone (in home or facility)
Problems related to other legal circumstances (Z62.5)	Health-harming legal issues (guardianship or custody issues, renter's rights, employment rights, problems with income or public benefits, legal status, disability)
Problems related to release from prison (Z62.5)	Transition to work, access to health services, housing
<b>Economic</b>	
Financial problem (Z59.9)	Financial worries; difficulty paying for basic needs: Food, clothing, medical care, utility, rent, bills, at risk of debt, etc
Food insecurity (Z59.4)	Worry about finding affordable food; food stamps running out; lack of fresh fruits and vegetables available
Homelessness (Z59.0)	Camping, sleeping in shelter, couch surfing, etc
Housing or economic circumstance (Z59.9)	At risk of homelessness: Inability to pay rent, inability to find affordable or permanent housing, rent increases, etc
Inadequate material resources (Z59.9)	Lack of transportation, clothing, computer, phone, housing/hygiene goods, school supplies, working appliances, basic goods
Intentional underdosing of medication due to financial stressors (Z91.120)	Not taking medications, not filling prescriptions, intentionally underdosing medications, etc because of financial strain
Unemployment (Z56.0)	Unemployed, unable to find work, underemployed
Low income (Z59.6)	Not enough money to pay for necessities, has just enough to make ends meet, poverty line and under
<b>Environmental</b>	
Fall risk (Z91.81)	Does not want to use devices to help with walking, unsteady gait, poor housing conditions (hoarding, deteriorating floors, throw rugs)
Stressful work schedule (Z56.3)	Working multiple jobs, physically strenuous jobs, night shifts, long shifts, etc
Foster care status (Z62.21)	Child, adult, or senior living in foster care
Problem related to social environment (Z62.9)	Living alone, living in clutter (hoarding), dangerous or health-harming environment
<b>Health education</b>	
Dental well-care counseling (Z71.89)	Educating members on dental care benefit (Medicaid) and access to free or low-cost dental services
Referral to county mental health agency (Z68.81)	Educating members on community mental health organization, helping members schedule visit
Illiteracy and low-level literacy (Z55.0)	Educating members on how to navigate KP; helping member with follow-up instructions, education, etc
Nutrition and exercise counseling (Z71.3)	Educating members on low-cost gyms, KP Silver&Fit (exercise and healthy-aging program), community centers, community cooking classes, farmers markets

EHR = electronic health record; ICD-10 = International Classification of Diseases, Tenth Revision; KP = Kaiser Permanente; SSI/SSDI = Supplemental Security Income/Social Security Disability Income.

his/her prescribed medication); or 3) a patient is assessed for SDH proactively, as part of an initial assessment for care management or as part of a targeted outreach for patients who may be at risk of having social barriers to care. For example, the latter scenario might include patients who have “bounced back” to the Emergency Department (ED) twice within 5 days who will receive a proactive outreach call from a patient navigator to assess issues such as lack of transportation or inability to pay for medications.

At KPNW, nonclinical patient navigators play an integral role on the health care team, engaging with patients to identify and address patients' SDH. Patient navigators are part of interdisciplinary care teams, where they work alongside nurses, social workers, behavioral health specialists, clinicians, and other health care staff to help patients connect with needed resources. Patient navigators are nonclinically licensed health care staff members who are frontline public health workers. Most patient navigators at KPNW have a bachelor's or graduate degree in public health, social work, community health, and/or other social science/humanities (eg, anthropology). Patient navigators are trained in motivational interviewing, trauma-informed care, and mental health first aid, among other specialties. All KPNW patient navigators obtain state (ie, Oregon Health Authority) and federal training and certification as Certified Application Counselors to help patients look for health insurance coverage options (eg, Medicaid, Children's Health Insurance Program, or the Health Insurance Marketplace) and complete eligibility and enrollment forms.<sup>20</sup> Additionally, many patient navigators are certified community health workers. KPNW patient navigators represent diverse cultural backgrounds, with more than 7 languages spoken across the team, including English, Mandarin Chinese, Spanish, Russian, and multiple African languages.

Referrals to patient navigators for SDH follow-up most often occur through either direct contact (by phone or in person) or an EHR-based notification from the referring nonclinical

DIAGNOSIS

▼ Social

- COMMUNITY RESOURCES COUNSELING [Details](#)
- CAREGIVER STRESS [Details](#)
- FAMILY STRESS [Details](#)
- INSUFFICIENT SOCIAL INSURANCE OR WELFARE SUPPORT [Details](#)
- NEEDS ASSISTANCE WITH COMMUNITY RESOURCES [Details](#)
- UNAVAILABILITY OR INACCESSIBILITY OF OTHER HELPING AGENCIES [Details](#)
- SOCIAL ISOLATION [Details](#)
- PROBLEMS RELATED TO OTHER LEGAL CIRCUMSTANCES [Details](#)
- PROBLEMS RELATED TO RELEASE FROM PRISON [Details](#)
- LANGUAGE PROBLEM [Details](#)

▼ Economic

- FINANCIAL PROBLEM [Details](#)
- FOOD INSECURITY [Details](#)
- HOMELESSNESS [Details](#)
- HOUSING OR ECONOMIC CIRCUMSTANCE [Details](#)
- INADEQUATE MATERIAL RESOURCES [Details](#)
- INTENTIONAL UNDERDOSING OF MEDICATION BY PATIENT DUE TO FINANCIAL HARDSHIP [Details](#)
- UNEMPLOYMENT [Details](#)
- LOW INCOME [Details](#)

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Figure 1. Social determinants of health (SDH) SmartSet in Kaiser Permanente HealthConnect electronic health record.<sup>a</sup>

<sup>a</sup> Screenshot shows 2 of 4 SDH domains included in the Kaiser Permanente Northwest SmartSet as provided in Table 1.

or clinical staff member. These referrals come from staff members in various roles (eg, membership services, social work, preregistration) and departments in the health care system (eg, primary care, emergency, other specialty care). On receiving the SDH referral, the patient navigator engages the patient by phone, by email, or in person when possible. In many instances, the patient navigator can meet with the patient on the same day, during a clinical encounter. When same-day contact is not possible, the patient navigator contacts the patient by phone or email within 48 hours of the SDH referral. Once in contact with the patient, the patient navigator uses a standardized and vetted social needs assessment called Your Current Life Situation (available online at: [www.thepermanentejournal.org/2018/18-095-App.pdf](http://www.thepermanentejournal.org/2018/18-095-App.pdf)) to fully understand, identify, and prioritize SDH. Additionally, patient navigators educate and inform patients about KPNW-specific resources (eg, KPNW Medical Financial Assistance Program) and community resources available to meet the identified SDH, and coordinate with patients to help facilitate connections to resources.

### International Classification of Diseases, Tenth Revision Z Codes

Identified SDH are documented in the EHR using a taxonomy of approximately 24 ICD-10 Z codes (Table 1). Table 1 presents the ICD-10 Z codes grouped into 4 overarching SDH domains—social, economic, environmental, and health education—and example scenarios of when each Z code may be used to identify a patient's SDH. The ICD-10 Z codes (Z00-Z99) are referred to as “factors influencing health status and contact with health services” and may be used to identify reasons for a health care encounter, to identify first-listed or principal diagnosis (only certain Z codes), and to provide useful information on the circumstances that could affect a patient's health care and treatment.<sup>20</sup> The SDH SmartSet (described in the next section) used by KPNW helps facilitate quick data entry to support clinical flow. The Z code, on the other hand, enables extraction of SDH data from the EHR for use in clinical (eg, quality assurance), operational, (eg, reporting), and research (eg, empirical studies) purposes.

Often, more than 1 Z code is entered into the EHR because patients can have

multiple unmet SDH that are inter-related. A patient who is homeless, for example, may also have financial problems, lack material resources, and be food insecure. In such a scenario, the use of multiple Z codes allows us to identify co-occurring social risk factors. Patient navigators strive to prioritize and address SDH on the basis of patient preferences, as well as perceived level of need, opportunity for acute intervention, and availability of resources.

**Community Resource Referrals**

To address the identified SDH of patients, KPNW has developed SDH SmartSets in the EHR for community resource referral and for tracking. Epic defines the *SmartSet* as “a group of orders and other elements, such as notes, chief complaints, SmartGroup Panels, and levels of service, that are commonly used together to document a specific type of visit.”<sup>21</sup> The KPNW SDH SmartSets were developed by KP Information Technology, clinical and operational stakeholders, and others (eg, Epic Systems Corp). More information about the KPNW SDH SmartSets is available on request. The KPNW patient navigators use the SDH SmartSets to identify SDH (Figure 1) and to make a referral for a patient to a targeted community resource or resources (Figure 2) in an effort to help meet the patient’s SDH. The KPNW Community Resource Referral SmartSet is generated with a list of more than 200 resources, both internal (ie, resources offered at KPNW, such as the Medical Financial Assistance Program) and external (ie, a community-based organization). Examples of the Community Resource Referral SmartSet are shown for food insecurity (Code Z59.4; Figure 2, top panel) and homelessness (Z59.0) or housing or economic circumstance (Z59.9; Figure 2 bottom panel). As shown in Figure 2, the Community Resource Referral SmartSet associates the identified SDH with 1 or more specific resources and provides the opportunity to prioritize the patient need as routine or immediate. New resources can be added or removed from the resource list as appropriate.

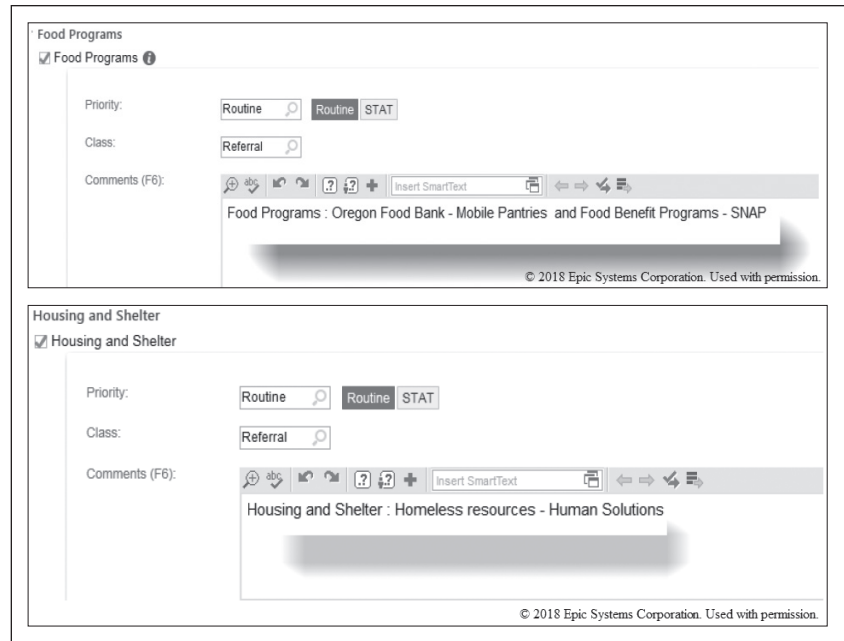


Figure 2. Social determinants of health Community Resource Referral SmartSet in Kaiser Permanente HealthConnect electronic health record.<sup>a</sup>

<sup>a</sup> Screenshot in top panel shows an example of a community resource referral for food insecurity (International Statistical Classification of Diseases, Tenth Revision [ICD-10] Code Z59.4). Bottom panel shows an example of community resource referral for homelessness (ICD-10 Code Z59.0) or housing or economic circumstance (ICD-10 Code Z59.9).

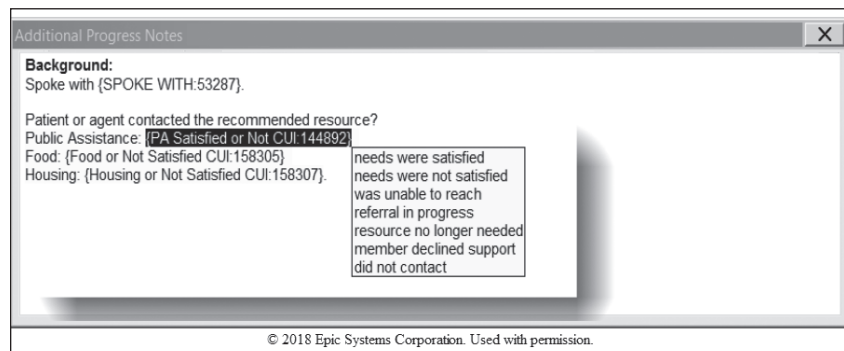


Figure 3. Social determinants of health (SDH) Community Resource Summary Progress Notes SmartSet in Kaiser Permanente HealthConnect electronic health record.<sup>a</sup>

<sup>a</sup> Information documented in this SmartSet includes the health care staff member with whom the patient spoke, the list of SDH, and the status of each referral.

The third component is the SDH Community Resource Summary Progress Notes SmartSet (Figure 3), which provides a comprehensive overview of recommendations for resources and health care services for the patient, the health care staff member that collected initial information about the patient’s SDH, referrals to other health care staff members, the timeline for next patient

contact, the focus areas for next contact, and background for the baseline referral. This information is essential for comprehensive documentation of a patient’s SDH and creates actionable data that can be retrieved and reviewed by any KPNW patient navigator, at any point throughout the patient experience.

A key feature of this SmartSet is the ability to track the status of each

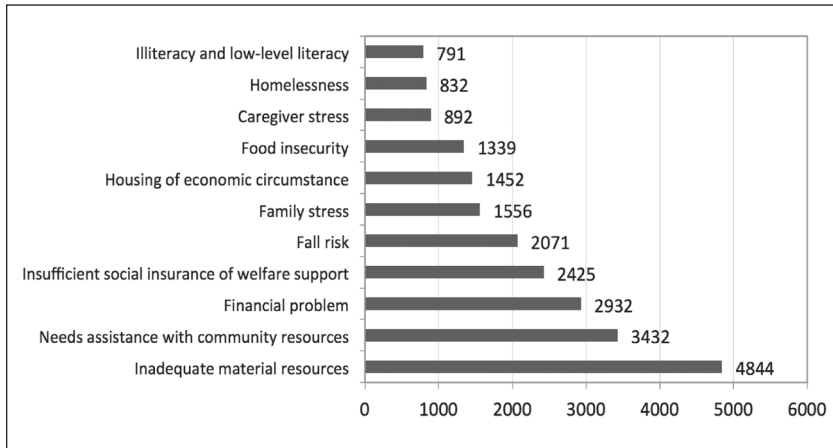


Figure 4. Most commonly identified social determinants of health (SDH) among Kaiser Permanente Northwest (KPNW) patients.<sup>a</sup>

<sup>a</sup> Top International Classification of Diseases, Tenth Revision Z codes identified among 11,273 KPNW patients between March 31, 2016, and March 25, 2018. Numbers shown represent the number of times that each Z code was documented in the electronic health record. This is not an exhaustive list of SDH identified in KPNW patients.

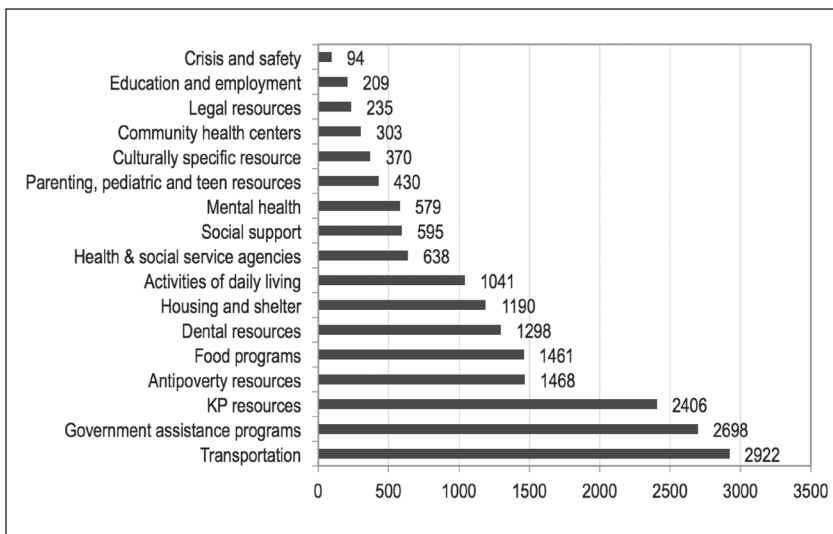


Figure 5. Most common categories of community resource referrals made for Kaiser Permanente (KP) Northwest (KPNW) patients.<sup>a</sup>

<sup>a</sup> Top community resource referrals, by category, made by KPNW patient navigators between March 31, 2016, and March 25, 2018. This is not an exhaustive list because patient navigators made nearly 18,300 referrals during this time frame. Numbers shown represent the number of times that each category of community resource referral was made in the electronic health record.

community resource referral (Figure 3). The tracking tool allows patient navigators and other staff members to track the status of SDH referrals over time by documenting the results of follow-up contact between the patient and the patient navigator (typically by phone or in person during a subsequent health care visit), which are then pulled into an automated weekly report for review. Furthermore, the tracking SmartSet

provides an opportunity to document patient preferences about declining support for their SDH. Without this integration, health systems are at risk of putting patients through unintended harm by screening for social needs without knowledge about whether the patient wants resource support, as well as the extent to which the patient has received (or not received) the referred resource or resources over time.

## RESULTS

### Identified Social Determinants of Health and Community Resource Referrals

Between March 31, 2016, and March 25, 2018, KPNW patient navigators screened 11,273 patients with SDH. They identified and documented 47,911 SDH in the EHR. Among the 11,273 patients, 28% had Medicare, 24% had a commercial health plan, 22% had Medicaid, and 26% were non-KP members. As shown in Figure 4, the most commonly identified SDH included inadequate material resources, needing assistance with community resources, financial problems, and inadequate social insurance or welfare support, among several others. Of note, these SDH data include information documented in the EHR problem list, diagnoses that are associated with referrals, and encounter-level data.

During the same period, patient navigators made 18,284 unique community resource referrals for 7494 patients (approximately 66% of the 11,273 patients identified with SDH). Accordingly, some patients received multiple referrals for different SDH (ie, transportation, food, utility assistance) or received multiple referrals for different agencies for the same SDH. Figure 5 shows the most common community resource referral categories (not individual agencies).

### Patient Example

A KPNW patient navigator received an SDH referral from a KPNW staff member about a patient who was undergoing cancer treatment and was uninsured (Z59.7) and had transportation needs (Z59.9). The patient navigator contacted the patient by phone to understand the specific SDH needs. During the initial discussion, the patient navigator discussed and prioritized the patient's needs, deciding that the first steps would be to attempt to get the patient re-enrolled in Medicaid (ie, Oregon Health Plan). The patient navigator helped by calling the state Medicaid program and advocating for the patient, as part of the patient's health care team, and was successful in getting health insurance reinstated through Medicaid as well as setting up the transportation benefit for the patient.

This alleviated the patient's stress associated with not having health insurance coverage and transportation to cancer treatment. This work enabled the patient to focus on getting to appointments and completing treatment.

## DISCUSSION

This article highlights the KPNW approach for identifying and addressing patients' SDH. The novel EHR-based tools developed by KPNW have led to use of standardized, measurable, and actionable SDH data to tailor and target specific resources to meet the identified needs of our patients. Between 2016 and 2018, KPNW patient navigators screened 11,273 patients for SDH, identifying and documenting 47,911 SDH, and making nearly 18,300 SDH referrals. By disseminating information about these efforts at KPNW, we are building an evidence basis of different approaches for addressing SDH within the health care system, as well as defining opportunities to improve care efficiency for patients with SDH.

### Impact on Medical Care

Importantly, collecting and documenting SDH data in the EHR, where it is clear and visible for clinicians, enables KP to adapt care on the basis of this information. If a clinician is aware that a patient is homeless and needs a medication that requires refrigeration, for example, the clinician may change or augment the clinical prescription to a medication that does not require refrigeration.

Briar Ertz-Berger, MD, MPH, an emergency medicine physician in KPNW, gives another example of how SDH data enables her to provide more holistic care (Briar Ertz-Berger, MD, MPH, personal communication, 2018 April): *"When I see a frail and elderly person in my emergency room who has had a fall, I look on the problem list to see if they are food insecure. I not only ask them about their pain, I ask them if they have difficulty buying enough food to eat or cook for themselves. I, now, not only can make a referral to physical therapy or a fracture clinic, I can make a referral to [patient] navigators to ensure the patient has food, transportation, caregiver support, etc."*

### Considerations of the Approach to Social Determinants of Health

Although there are many strengths to KPNW's approach to addressing SDH, there are certain considerations and challenges that must be acknowledged. A key challenge in these efforts has been developing effective workflows for referring members with identified SDH to appropriate community resources and tracking the progress of such referrals to ensure needs are addressed. The KPNW approach relies on patient navigators to recontact patients (primarily through follow-up phone calls) to determine whether they were able to access the community resources to which they were referred, which requires a great deal of resources. Every week KPNW patient navigators screen hundreds of patients and make hundreds of new community resource referrals. Accordingly, tracking the outcome of all community resource referrals becomes challenging for a team of approximately 30 patient navigators. Approximately 23% of the 18,284 community resource referrals resulted in the patients' identified SDH being satisfied, partially satisfied, or in progress (ie, SDH need was resolved). Most follow-up data on community resource referrals is unknown because of the overwhelming burden on patient navigators to track the progress of the referrals as well as barriers such as patients not returning calls or not having a working phone or the means to follow-up after the referral has been made. Anecdotally, KPNW patient navigators have observed increased SDH resolution among patients who are enrolled in care management, case management, or similar programs that provide more "touch points" or opportunities for interaction between the patient and patient navigator within the health care setting to check on the status of the patient's referrals and needs. However, this also underscores an opportunity to collect data, both quantitative and qualitative, to learn about the information needs, barriers, and facilitators of the SDH community resource referral process from the perspectives of the community organizations that serve as the resources, patients who receive the referrals, and

health care team members who make the referrals. Such work may inform the development of workflows to assess the impact of both community referrals and community connections, emphasize the value vs volume of community referrals, and foster partnerships that could lead to the development of bidirectional communication channels between stakeholders to track the resolution of identified SDH.

KPNW developed a risk stratification system to prioritize community resource referral follow-up. Patient navigators consider several factors, including the patient's number of unmet needs, the patient's health care use patterns (ie, heavy ED use in the past 3 months), prior success of connecting the patient to community resources, patient's self-reported confidence following-up with community resource referrals, and the patient's social support. Nevertheless, even with such a system in place, some patients who need more aggressive follow-up and support are still missed. To address this issue, KP is currently working to create a Social Services Resource Locator (SSRL). The SSRL will be a shared enterprise tool deployed at the hyperlocal level to connect patients to community resources that effectively address their SDH needs. Initially, the SSRL will 1) provide a consistent approach to connect patients to community resources, 2) confirm that patients' SDH needs have been addressed, 3) incorporate information on the progress of community resource referral into ongoing care plans, and 4) collect data to track community resource referral trends across community partners and KP Regions. The SSRL will provide automated bidirectional communication between KP and the community agencies, help prioritize follow-up on the basis of real-time data of which patients have and have not connected with their resources, and facilitate closed-loop referrals.

Recognizing patients' most pressing SDH and making appropriate community resource referrals to help address those needs is a critical element of many of KP's strategies for addressing SDH. KPNW has been a leader in this effort and is the voice for why we need a scalable and interoperable solution across



KP Regions. We have an opportunity with the SSRL to make more efficient and effective community resource referrals, such as making a referral to a single community-based organization that can address multiple needs rather than a “shotgun” approach of multiple referrals to various community organizations. The SSRL is a novel tool that will enable our health care system and care teams to address the SDH of our patients and the communities we serve.

Other strategies may also be employed by health care systems in their efforts to assess and intervene on SDH. Identifying priority populations or subgroups for SDH assessment may help with issues related to staff capacity (ie, patient navigator-to-patient ratio) and ensure that the patient workload is manageable. For instance, patient navigators may focus on assessing SDH on high-cost/high-utilizer populations or patients seen in the ED who are uninsured. At KPNW, individuals who receive medical care and are found to be uninsured are screened for eligibility for Medicaid or medical financial assistance programs and enrolled immediately, when possible, by patient navigators. Moreover, establishing strategic, cross-sectoral partnerships with community organizations that offer different types of services is an approach that may facilitate the provision of a broad range of resources to help patients and limit the burden on the health care system or on any single organization.<sup>19,22</sup> KP has a history of developing partnerships with community organizations to help address SDH.<sup>23</sup> Last, establishing clear communication lines and workflows across health care staff roles (eg, patient navigators, social workers, financial counselors) to address specific SDH may help facilitate quicker connections to resources for patients.<sup>19</sup>

## CONCLUSION

Reducing the burden of patients’ SDH at the individual and population levels requires a culture of health within communities to develop and to maintain strong connections between health care systems and community-based organizations that address such needs.<sup>15,24–26</sup> Developing

successful, efficient approaches to making and maintaining these connections could bolster the community’s capacity to fulfill patients’ SDH and could foster future work that generates evidence that resolution of SDH affects downstream health care use, costs, and health disparities. As clinicians at an integrated health system committed to total health, we at KP cannot expect our patients to manage their health or to engage in behavior change if they do not have enough basic resources to eat healthfully, pay bills, or manage their daily responsibilities.

The KPNW approach to SDH is designed to help KP better understand the nonmedical social factors that have an impact on health outcomes and to address them with a standardized, reliable connection to nonmedical resources in the community. We hope this effort will help align care delivery, community health, research and evaluation, information technology, marketing and business strategy, and other assets of our organization to invest social, economic, and health capital in the organizations and agencies that best meet the needs of the patients and communities we serve. ❖

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Keywords: ICD-10 Z code, integrated delivery system, patient navigator, social determinants of health, social needs

## Ten Yards Behind

What's important to recognize is that in the US today, tens of millions of kids start life on an uneven playing field. Imagine having to try to run a race if you started ten yards behind everyone else, hadn't eaten breakfast that morning, or maybe even dinner the night before, had slept in your third homeless shelter that month and didn't have shoes that fit right. Catching up would be really, really hard. With almost 32 million American kids living in low-income families, that means four out of ten runners are starting far back.

— Chelsea Clinton, b 1980, Board member of the Clinton Foundation and the Clinton Global Initiative

# Lessons Learned from Implementation of the Food Insecurity Screening and Referral Program at Kaiser Permanente Colorado

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## ABSTRACT

Traditionally, health care systems have addressed gaps in patients' diet quality with programs that provide dietary counseling and education, without addressing food security. However, health care systems increasingly recognize the need to address food security to effectively support population health and the prevention and management of diet-sensitive chronic illnesses. Numerous health care systems have implemented screening programs to identify food insecurity in their patients and to refer them to community food resources to support food security. This article describes barriers encountered and lessons learned from implementation and expansion of the Kaiser Permanente Colorado's clinical food insecurity screening and referral program, which operates in collaboration with a statewide organization (Hunger Free Colorado) to manage clinic-to-community referrals. The immediate goals of clinical screening interventions described in this article are to identify households experiencing food insecurity, to connect them to sustainable (federal) and emergency (community-based) food resources, to alleviate food insecurity, and to improve dietary quality. Additional goals are to improve health outcomes, to decrease health care utilization, to improve patient satisfaction, and to better engage patients in their care.

management of chronic illnesses. In this article, we describe lessons learned from the Kaiser Permanente (KP) Colorado (KPCO) food insecurity pilot screening and referral program, designed with the intended goals of promoting food security and improving diet quality and health outcomes in KPCO and the community (Figure 1).

When the pediatric food insecurity pilot began in 2011, the food insecurity rate in Colorado was 13.9% and in the US was 14.6%.<sup>15</sup> Colorado ranked in the bottom 10 states nationally for participation in every federal nutrition program, including SNAP, the nation's largest nutrition program.<sup>16</sup> In response, KPCO, a health care organization with a patient population that includes 14% Medicare and 10% Medicaid beneficiaries, launched a food insecurity screening and referral program in 2 pediatric clinics. KPCO collaborated with a nonprofit advocacy and hunger relief organization, Hunger Free Colorado (HFC, [www.hungerfreecolorado.org/](http://www.hungerfreecolorado.org/)), which was established in 2009 with funding from The Denver Foundation and KPCO. Hunger Free Colorado administers a statewide bilingual toll-free hotline, which provides a one-stop resource for Colorado residents to access federal and community-based food resources. Navigators at the hotline assess clients for eligibility to all federal nutrition assistance programs, submit applications to the county for those eligible for SNAP, and direct clients to other federal programs. In addition, they provide referrals to community organizations

## INTRODUCTION

Food insecurity, defined as unreliable access to adequate food caused by lack of money or other resources, is associated with poorer health, poorer diet quality (including reduced consumption of fruits and vegetables), a higher prevalence of chronic diseases, and higher health care costs.<sup>1-3</sup> In the US, 12% of households experienced food insecurity in 2016, with particularly high rates in households with children, single parents, and low household income.<sup>4</sup> Enrollment in federal food assistance programs, such as the Supplemental Nutrition Assistance Program (SNAP) and the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), is associated with improved outcomes across multiple dimensions, including food security, nutrition, health, development, and health care costs.<sup>5-11</sup> However,

most health professionals have not been trained to assess food insecurity, and clinical algorithms to support nutrition education generally do not address food insecurity. Additionally, most health care systems lack standardized protocols or systems for referring food-insecure patients to federal or community-based programs that provide food resources.

Despite these barriers, the American Academy of Pediatrics, the American Diabetes Association, and the Centers for Medicaid and Medicare Services, among other professional organizations, have highlighted the clinical relevance of food insecurity through recommendations for food insecurity screening and referral to food resources.<sup>12-14</sup> These guidelines exemplify broader efforts in the medical community to address social determinants of health because of their implications for prevention and

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such as food pantries for emergency food resources. The data collected from the hotline informs HFC's public policy agenda, which advocates for changes in food policy and systems, to reduce food insecurity in Colorado.

### PROGRAM DESCRIPTION AND LESSONS LEARNED Screening Program to Identify Food Insecurity

Two pediatric clinics, 1 with 33% Medicaid beneficiaries and the other with 23% Medicaid beneficiaries, piloted the screening intervention. Because this operational program did not include human study subjects, the program was not reviewed by the KP institutional review board. At both pediatric clinic sites, parents were initially given a paper form at check-in with the Hunger Vital Sign screening tool. This 2-item assessment of food insecurity has high sensitivity and specificity and has been validated in households with children as well as in high-risk adult populations.<sup>17,18</sup> The 2 items are as follows:

1. Within the past 12 months, we worried whether our food would run out before we got money to buy more.
2. Within the past 12 months, the food we bought just didn't last, and we didn't have money to get more.

Parents were instructed to circle "often true," "sometimes true," or "never true" to each statement, with responses of "often true" or "sometimes true" to either question indicating food insecurity.

During the 3-month pilot, we learned that clinical teams were often unaware that food insecurity was prevalent in KPCO and that it contributed to reduced diet quality, poorer health outcomes, and increased health care utilization and expenses. Additionally, clinical teams lacked awareness of the availability of the SNAP and WIC nutrition programs, the types of support they provided, and their health benefits. Clinicians and staff were often uncomfortable discussing food insecurity with patients for fear it would feel stigmatizing to parents or raise parental concerns about being reported to social services.

Interventions to address these knowledge barriers included the development

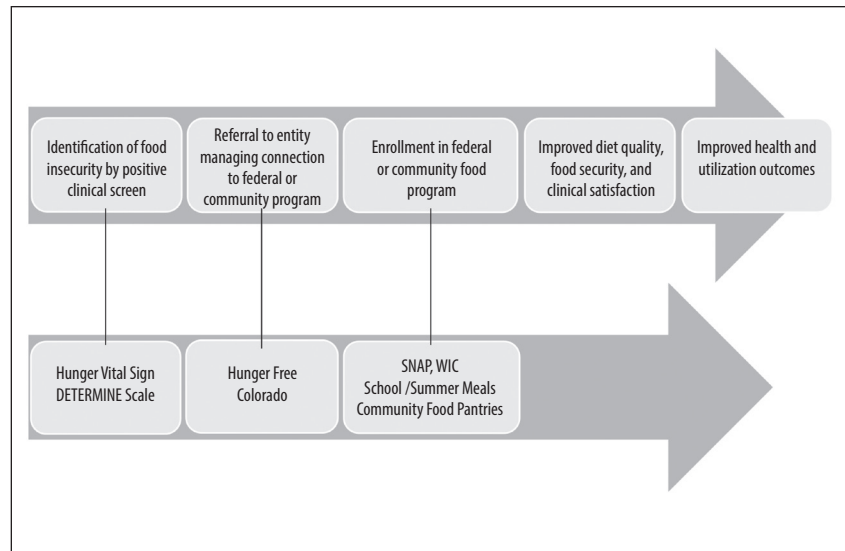


Figure 1. Processes and desired outcomes for the food insecurity screening program in Kaiser Permanente Colorado.<sup>a</sup>

<sup>a</sup> Upper arrow describes the general process of food insecurity screening programs and their intended outcomes.

Bottom arrow describes the specifics of how these general processes were implemented at KPCO clinics.

KPCO = Kaiser Permanente Colorado; SNAP = Supplemental Nutrition Assistance Program; WIC = Special Supplemental Nutrition Program for Women, Infants, and Children.

of educational handouts for clinicians and staff that described the following: Prevalence of food insecurity in households with children in Colorado, clinical manifestations of food insecurity, support provided by WIC and SNAP, validated food insecurity screening questions, and the referral process to HFC (Table 1). These handouts were distributed and discussed at departmental meetings. In addition, we presented case studies at departmental continuing medical education programs highlighting both food insecurity prevalence and its association with other health conditions.

We also used multiple strategies to increase the comfort of clinicians and staff in talking with patients about food insecurity, attempting to reduce stigma associated with screening. We facilitated communication skill-building exercises to aid clinicians in conveying empathy to parents and supporting them in accepting referrals to food resources. We also provided written scripts, including one adapted from the WECARE survey<sup>19</sup> that described motivation for screening: "Our goal is to provide the best possible care for your child and family. We would

like to make sure that you know all the resources that are available to you for your problems. Many of these resources are free of charge."

Data tracking in the pilot phase revealed that 18% of parents in the KPCO clinic with higher Medicaid enrollment and 12% of parents in the clinic with lower Medicaid enrollment lived in food-insecure households; these findings were much higher than anticipated by clinicians and staff at both clinics but were consistent with national data. The screening increased clinicians' awareness of food insecurity among their patient population and reinforced the extent to which food insecurity was jeopardizing the prevention and treatment of many of their patients' health conditions, including iron deficiency, obesity, failure to thrive, and school behavioral and attention concerns. As a result, these clinicians advocated for permanent integration of the Hunger Vital Sign into the standard well-child visit questionnaires. Other clinical systems have experienced a similar increase in support for food insecurity screening after pilot testing revealed the high clinical prevalence of food insecurity

and of caregiver acceptability of screening.<sup>20-22</sup> These observations demonstrate the extent to which clinical staff reluctance to screen for food insecurity out of concern that patients will feel stigmatized is unfounded.

### Referral Processes

In the program's initial implementation, a medical assistant handed parents reporting food insecurity a card with the phone number of the HFC Food Resource Hotline and instructed parents to call for support in accessing food resources. HFC tracks each referral and whether it results in a household member contacting the organization. Comparison of these data with data on the number of cards distributed from the clinic revealed that only 5% of households receiving the card called HFC for support in obtaining food services. This very low connection

rate spurred the implementation team to develop a more active referral process. Instead of placing the burden on the parent to call the HFC hotline, parents were asked for permission to have an HFC representative call them to discuss food resources. For the clinic to share the necessary demographic information with HFC, parents needed to complete a brief consent, as required by the Health Insurance Portability and Accountability Act (HIPAA). We developed a semiautomated process to provide demographic information of parents reporting food insecurity to HFC by embedding an HFC referral form in the "letter" section of the electronic medical record. Demographic information was autopopulated into the letter, which was then printed and faxed to HFC.

After this change to an active referral that offered parents more support in

accessing HFC, the percentage of referred parents who spoke with an HFC hotline navigator increased from 5% to 75%.<sup>23</sup> Thus, as the food insecurity screening program was disseminated to other clinics and KPCO departments (described later), they adopted the same active referral model.

Despite its success, we encountered a few barriers in creating and sustaining the more active referral processes. First, we had to address both compliance and legal concerns to ensure we maintained patient confidentiality and adhered to all regulations and legal requirements.

Second, clinical teams spent valuable time printing and hand-faxing referrals to HFC. The subsequent formation of the KPCO community specialist team, with funding from KP primary care and community benefits, addressed this barrier. In this iteration of referral processes, when a food-insecure household is identified, the KPCO clinical staff send an electronic referral through the electronic medical record to the community specialist team, who then connects members with needed social resources. The community specialist team assesses household needs for a broad range of social support in addition to food, and faxes a referral to HFC. This new implementation model has advantages and disadvantages. Although it reduces the burden on the clinical team, it also adds an additional outreach step for patients. Survey results indicated that patients are confused by the multiple handoffs and outreaches, which potentially reduces the number of patients who ultimately connect with HFC. Continuous data tracking and quality improvement efforts are essential to understand practices that result in access to food resources and patient satisfaction.

### Enrollment in Food Programs

When HFC connects with referred patients, it assesses eligibility for various federal and community resources available for food and then provides information about how to enroll in eligible programs. In the case of SNAP, HFC is also able to complete the SNAP application for the patient and to submit it to the administrative office of the county of residence. The ability to track

**Table 1. Action steps and resources for food insecurity screening and referral programs**

Steps	Resources
Engage clinicians and staff	<ul style="list-style-type: none"> <li>▪ CME: <a href="http://seniorhealthandhunger.org/">http://seniorhealthandhunger.org/</a></li> <li>▪ Clinical algorithms: <a href="https://nopren.org/">https://nopren.org/</a></li> <li>▪ Resources: <a href="https://sirenetwork.ucsf.edu/">https://sirenetwork.ucsf.edu/</a>; <a href="http://www.rootcausecoalition.org/">www.rootcausecoalition.org/</a>; <a href="http://www.childrenshealthwatch.org/">www.childrenshealthwatch.org/</a></li> </ul>
Screen for food insecurity	<ul style="list-style-type: none"> <li>▪ The Hunger Vital Sign: <a href="https://goo.gl/neMVit">https://goo.gl/neMVit</a></li> <li>▪ Motivational interviewing, trauma-informed care</li> <li>▪ EHR processes for screening</li> </ul>
Refer to federal or community-based food support programs	<ul style="list-style-type: none"> <li>▪ Outreach referral with HIPAA protection: <a href="http://www.rootcausecoalition.org/hipaa-webinar/">www.rootcausecoalition.org/hipaa-webinar/</a></li> <li>▪ Community specialist teams to facilitate referral and follow-up</li> <li>▪ Secure referral platforms in EHR to government enrollment sites or community organizations</li> </ul>
Connect to food resources	<ul style="list-style-type: none"> <li>▪ Support community organization capacity to enroll in SNAP, WIC, and community-based food resources</li> <li>▪ Patient education about health benefits of SNAP/WIC</li> </ul>
Document in chart and analyze screening and referral data	<ul style="list-style-type: none"> <li>▪ Capture screening and referral data in chart fields, which are extractable</li> <li>▪ Consistent charting and coding of food insecurity: <a href="http://childrenshealthwatch.org/foodinsecuritycoding/">http://childrenshealthwatch.org/foodinsecuritycoding/</a></li> <li>▪ Data-sharing agreements with government and community partners</li> <li>▪ Clinical outreach to referred patients to assess outcomes</li> </ul>
Perform collaborative quality improvement	<ul style="list-style-type: none"> <li>▪ Business associate agreements for clinical and community partners to formalize responsibilities</li> <li>▪ Establish incentives for successful connection to food resources</li> <li>▪ Build quality-improvement structure and expertise</li> </ul>
Improve outcomes	<ul style="list-style-type: none"> <li>▪ Standardized metrics to measure changes in satisfaction, diet quality, food security, health outcomes, and utilization of food resources</li> </ul>

CME = continuing medical education; EHR = electronic health record; HIPAA = Health Insurance Portability and Accountability Act; SNAP = Supplemental Nutrition Assistance Program; WIC = Special Supplemental Nutrition Program for Women, Infants, and Children.

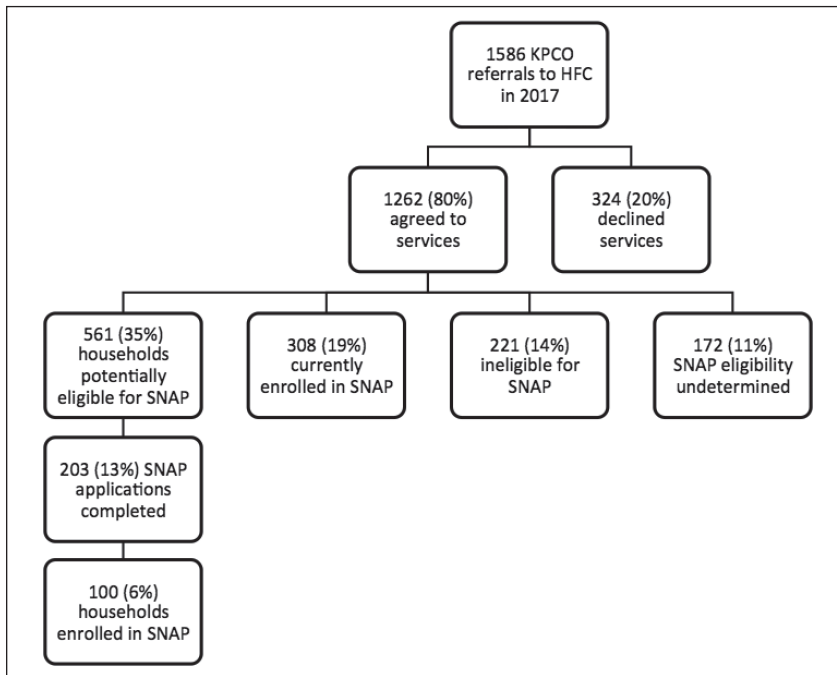


Figure 2. Kaiser Permanente Colorado (KPCO) referrals to Hunger Free Colorado (HFC) resulting in household enrollment in SNAP, 2017.

SNAP = Supplemental Nutrition Assistance Program.

the success of these referrals is critical to understanding the impact of the KPCO screening and referral program. Monthly, HFC provides reports to KPCO by secure information transfer. HFC provides data on whether referred households are interested in and eligible for SNAP, whether HFC submits a SNAP application to the county, and whether the application is approved.

In 2017, approximately 6% of the 1586 referrals made from KPCO to HFC resulted in SNAP enrollment, presenting a clear opportunity for further quality improvement efforts for both KPCO and HFC. Increasing the 6% enrollment rate could be accomplished by KPCO referring patients most likely to be eligible for SNAP, including Medicaid beneficiaries not currently enrolled in SNAP, and by improving HFC follow-up of SNAP-eligible households that do not successfully enroll. Figure 2 illustrates the challenges of connecting patients to sustainable food resources. The 6% SNAP enrollment rate also emphasizes the importance of having referral processes in

place to multiple food resources, not just SNAP. Additionally, HFC tracks referrals to other federal nutrition programs (eg, WIC) and community-based nutrition programs (eg, food pantries, summer meal programs, and home-delivered meals program). However, HFC is unable to track whether referrals to any of these programs are successful because of a lack of capacity to call clients back and a lack of data-sharing agreements (particularly with WIC).

### Outcomes

Evaluators and researchers are in the process of assessing patients' and clinicians' satisfaction with screening; the time required for the screening and referral; and the impact of food security on diet quality, food security, health, and health care system utilization. KPCO is collaborating with HFC to administer a patient survey that assesses food resources received, changes in diet quality and food security, and satisfaction with the screening and referral processes. Analysis of these data is ongoing.

## PROGRAM DISSEMINATION

### Internal Dissemination

Awareness of food insecurity screening rose across the Pediatric Department with the distribution of handouts at departmental meetings highlighting population-specific impacts of food insecurity, validated screening questions, and referral processes to HFC; case studies of food-insecure patients at departmental continuing medical education programs; and communication skill-building activities during departmental meetings with a member of the community resource team and HFC hotline navigator. This experience in child health informed expansion of the food insecurity screening program to other KPCO departments. Expansion locations were determined by departmental capacity and enthusiasm for project implementation.

Clinical teams in the expansion locations had to determine how best to embed food insecurity screening into existing screening workflows, such as with health maintenance questionnaires, prenatal questionnaires, or intake assessments (for chronic disease managers and registered dietitians). In one case, the measurement tool was adapted to align with existing screening processes. The Centers for Medicare and Medicaid Services requires health care systems that participate in the Medicare Advantage program to administer a Medicare Total Health Assessment to beneficiaries during an Annual Wellness Visit. The KPCO Medicare Total Health Assessment already included a single-item assessment of food insecurity as part of the DETERMINE nutritional risk assessment for older adults.<sup>24</sup>

Team composition also influenced the likelihood of adopting food insecurity screening and implementation processes. Teams with staff experienced in linking patients with social services, such as social workers, were more likely to embrace food insecurity screening. When a social worker was easily accessible, clinic staff were more accepting of screening and more confident that a referral to the social worker would result in patients receiving food. In contrast to the system set up by the pilot clinics, social workers

referred food-insecure patients directly to HFC and personally followed up at subsequent appointments to ensure connection to food resources. Departments with embedded social workers had the highest number of HFC referrals.

This dissemination to other departments has highlighted the effort required to screen such a large number of KPCO patients, prompting a discussion about the possibility of using predictive modeling to target screening to certain high-risk population groups. For example, analysis of Medicare Total Health Assessment data from 50,097 older adults screened revealed an overall food insecurity rate that was relatively low at 5.7%, but with much higher risk among certain population subgroups (> 25% among dual Medicare-Medicaid enrollees and  $\geq 10.0\%$  among patients who are African American or Latino, or who have extreme obesity). Unfortunately, targeting only those high-risk groups for screening would have missed 50% of food-insecure older adults (those not in a high-risk group), suggesting that a universal screening approach may be necessary.<sup>25</sup>

Other efforts to decrease the burden of screening for food insecurity have focused on whether patients who are likely to qualify for SNAP benefits should be screened for food insecurity or screened for SNAP and WIC enrollment instead. Most Medicaid beneficiaries in Colorado are eligible for SNAP and WIC as well because of overlapping eligibility criteria (income eligibility for Medicaid is < 138% of the Federal Poverty Level; SNAP, < 200% of the poverty level; and WIC, < 185% of the poverty level). Rather than screen for food insecurity, Medicaid beneficiaries at KPCO will now be asked if they are enrolled in programs demonstrated to improve their health, including SNAP and WIC. Those who are not enrolled will be referred to HFC for SNAP enrollment or directly to WIC if the household includes a pregnant woman or child younger than age 5 years.

The adoption of different systems in different clinics for food insecurity screening and referral has also created

challenges. As part of ongoing quality improvement, KPCO formed a community and clinic integration committee in 2018 to standardize and expand screening, referral, and charting processes across clinical departments; build communication skills across clinical departments; and maximize use of technology to facilitate information exchange between clinic and community organizations and to collect extractable data for evaluation. This committee includes clinicians, staff supervisors, community health representatives, and experts in information technology and evaluation, and it is coordinated by a program manager. This interdepartmental group crosses traditional reporting lines and functional responsibilities in KPCO. The group is exploring opportunities with community organizations to refine charting and data exchange processes and to leverage new funding models. The group is also expanding evaluation efforts to increase awareness of who is being screened for food insecurity and how many KPCO patients report being food insecure, particularly among vulnerable subgroups. The group recognizes that extractable social needs data could better inform decisions about the composition of clinical and complex care teams that can optimally address both medical and social needs.

### External Dissemination

As part of its mission to improve the health of the broader community it serves and with its experience implementing and disseminating food insecurity screening and referral programs internally, KPCO in 2016 began providing grants and technical assistance to other health care systems caring for large numbers of Medicaid patients and interested in food insecurity screening. The screening protocol adopted by these systems included universal screening using the Hunger Vital Sign, recording of screening results into the electronic medical record, and automatic referral of patients screening positive to a community specialist, who then created the referral to HFC. Several of these systems improved on the KPCO approach by

creating an automatically generated fax referral to HFC within the electronic medical record, which removed the barrier of hand-generating a referral or generating a semiautomated referral to be manually faxed. Because clinical staff recorded all screening results in the electronic medical record, screening rates and food insecurity rates could be easily tracked. The high rates of food insecurity that were identified motivated many health care systems to hire additional community specialist support.

Lessons learned in KPCO and in other health care systems involved in food insecurity screening throughout the state are shared during quarterly calls hosted by the Colorado Prevention Alliance and KPCO. Both HFC and the state WIC director participate in these calls, providing the leadership engagement necessary to leverage these calls to support continuous quality improvement. Current quality improvement efforts focus on improving referral processes, standardizing tracking measures across sites, and developing data sharing agreements to allow tracking of successful WIC referrals.

### DISCUSSION

Deep engagement of KPCO in establishing systems for screening patients for food insecurity and referring food-insecure patients to federal and community food resources has fueled 3 initiatives. These initiatives are 1) targeted outreach to vulnerable subpopulations such as Medicaid enrollees, 2) an organizational standardization of screening and referral practices and processes to address food insecurity and other social determinants of health, and 3) a policy engagement strategy.

Evaluation of our processes and intermediate outcomes has created numerous process improvements, informed broad dissemination, and helped to build a business case for health care system funding of community organizations that successfully connect patients to food resources.

Advancing organizational, state, and federal policy to support food security, in partnership with other sectors, including

business and government agencies, continues to be a priority. KPCO, other medical systems, and HFC are continuing engagement with partners across the state to implement the newly released Colorado Blueprint to End Hunger. In addition to food insecurity screening and referral programs, some medical systems in Colorado are using other strategies to improve food security and diet quality, including promoting fruit and vegetable incentives, developing hospital policies on local food procurement and food reuse, and connecting patients to medically tailored home-delivered meals. Ultimately, a better understanding of the impact of nutrition programs on health outcomes and health care utilization can inform changes in federal and state nutrition assistance policies, and may encourage Medicare and Medicaid to reimburse for screening and referral services.

Work to better identify food-insecure patients in clinical settings is occurring in the context of increased awareness of the need to identify patients with a range of social needs. Food insecurity often occurs with multiple other social needs, and understanding the patient's prioritization of needs, and ideal composition of care teams needed to address social needs, will be essential to optimizing the clinical encounter for both the patient and the care team. Evaluation of models which are most effective at enrolling Medicaid beneficiaries in SNAP and WIC as well as models that successfully connect identified patients with SNAP, WIC, other federal nutrition programs, and other food resources is needed. KP's Social Needs Network for Evaluation and Translation (SONNET, <http://sonnet.kaiserpermanente.org/about-us.html>) provides infrastructure for designing, implementing, evaluating, and disseminating heterogeneous social needs interventions within KP. Social needs evaluation has the potential to inform clinical process improvements and effective Medicaid, Medicare, and state and federal policies.

## CONCLUSION

Health care systems can play an important role in supporting food security

and improving diet quality by screening patients for food insecurity and connecting patients to a variety of food resources, including SNAP and WIC. However, processes for operationalizing these efforts are often poorly tested and inadequately supported by technology. Successful technologic solutions can promote bidirectional communication between clinics and state and community organizations; allow for data collection and tracking to inform process improvements and evaluate effectiveness; and streamline workflows. Health care systems can play a critical policy role in advocating for systems that use and integrate existing datasets, encourage enrollment in multiple benefits, and support access to community and federal food resources. ❖

## Disclosure Statement

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

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**Keywords:** community engagement, food insecurity, quality improvement, social determinants of health, social services

## Diminished Capacity

Recent research shows that many children who do not have enough to eat wind up with diminished capacity to understand and learn. Children don't have to be starving for this to happen. Even mild undernutrition—the kind most common among poor people in America—can do it.

— Carl Sagan, 1934-1996, American astronomer, cosmologist, astrophysicist, astrobiologist, and author

# The Best Year of Angela's Life

Kumara Raja Sundar, MD

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## ABSTRACT

Using a patient story, this narrative demonstrates why health care organizations, specifically primary care clinics, should strive to identify and to address social needs. This story demonstrates how Kaiser Permanente Washington, by using community resource specialists, has empowered primary care clinics to address social needs in a health care setting to improve patient care and experience.

## ANGELA

Angela (name has been changed), in her late 50s, had achieved some stability in her life after a painful childhood and a tumultuous adulthood. She had secured subsidized senior housing because of a severe mental health disability requiring weekly electroconvulsive therapy. As a family medicine physician at Kaiser Permanente Washington (KPWA), I witnessed the value of a community resource specialist in my clinical practice, but I longed for patients to share their stories. Angela volunteered. Her eagerness to share her story with me was tempered only by her occasional memory lapses. Pushing aside the 1000-piece puzzle on her table, she asked me to sit while she explained how Larnette, the community resource specialist at her primary care clinic, had provided her with the support, motivation, and hope to improve her health by addressing her social needs.

During Angela's first visit with her new primary care physician, Dr Bryce, she mentioned that she wanted to find more ways to exercise in the community but didn't know where to start. After addressing her chronic conditions and ensuring her preventive care needs were met, Dr Bryce referred Angela to Larnette. Dr Bryce did not have knowledge about all the resources available in the community to help Angela start exercising; nor did she feel like she had adequate time in her 20-minute clinic visit to identify and prescribe her the right community resources.

## COMMUNITY RESOURCE SPECIALIST

The community resource specialist at KPWA has many roles in the primary care clinic, but for the patient, the goal is two-fold: To connect patients with resources—inside and outside KPWA—and to provide a level of supportive health coaching that primary care practitioners lack time for during quick office visits. Larnette, as the community resource specialist in Dr Bryce's clinic, typically connects to patients through a warm handoff. A warm handoff in clinic is when one member of the care delivery team introduces Larnette, as a fellow team

member, to the patient in real-time and explains the role of the community resource specialist in addressing the patient's needs.

After connecting to Angela, Larnette was able to identify challenges facing Angela through 10 encounters during the following 3 months. During this time, she connected Angela with several resources and coached her on how to receive the care she deserves.

Because Dr Bryce had specifically referred Angela for group exercise opportunities, Larnette, in her first conversation with Angela, shared with her the "Walk and Talk" program—a free weekly event where health care teams walk for 30 to 45 minutes with community members in accessible community settings. During her assessment, however, she also learned that Angela had limited access to adequate food and received food from a local food bank. Larnette realized that she would qualify for a program called Fresh Bucks because of her food insecurity—a term that signifies Angela had inadequate food for healthy living owing to a lack of money.<sup>1</sup>

Fresh Bucks is a program that provides vouchers matching the value of recipients' weekly food stamp allotments for use at farmers markets in King County, WA. In King County, about 12% of households are food insecure, matching the national statistic.<sup>2,3</sup> Angela fell within that percentage. Fresh Bucks is one solution to address the problem of food insecurity and poor access to healthful foods in King County. The program is a success by many measures. As of 2016, it had 4556 participating residents and 14,743 shopper visits and contributed \$591,786 to the local economy.<sup>4</sup> Although she qualified for this program, Angela did not even know it existed.

Larnette explained to Angela how the program works and how to apply for it. After her conversation with Larnette, Angela was curious to see if anybody else she knew had knowledge about the program. She asked her neighbors and friends at the senior housing complex about Fresh Bucks, but she was met with blank stares. She even asked the housing resident services manager, but that person had not heard about the program either. No one she knew had heard about Fresh Bucks.

## ACCESSING COMMUNITY RESOURCES

In the US—because of a myriad of cultural, economic, and political factors—the ratio of spending on social services to health care is 1:1 compared with 2:1 in many peer countries in the Organization for Economic Co-operation and Development.<sup>5</sup> This has hamstrung the social services sector from adequately addressing social needs. King County is better off than many other counties in the nation. There was a program

already available and accessible to help address food insecurity. Angela was just unaware the program existed.

Creation of more robust communication outlets by the social services sector would ensure people like Angela were aware of community resources and had the necessary support to access those resources. Unfortunately, the current system was not meeting Angela's needs. The community resource specialist was one way for our organization and our clinic to bridge this gap by understanding the resources available in our community and ensuring our patients were connected with these resources, especially if we were their sole means to improve their health.

Now, Angela receives \$40 every 2 weeks through Fresh Bucks and goes to the farmers market every Saturday. "I get fresh fruits and vegetables. My favorite dish now is spaghetti squash with mushroom, onions, zucchini, and tomatoes." She added, "Before, I didn't get any vegetables or fruits. It was just too expensive. The best part is that I get to go to the farmers market and get out on the weekends." She repeated, "Seeing other people. That's the best part." By building better connections with her community, Angela felt she had decreased her social isolation, a known predictor of increased mortality.<sup>6</sup> Through Larnette, we had improved Angela's health by not only addressing her food insecurity but also helping her form stronger connections with her community.

### ADDRESSING SOCIAL NEEDS IN THE PRIMARY CARE CLINIC

Health care organizations have created various models to identify and address social needs. Some have created call centers to conduct telephonic outreach to patients.<sup>7,8</sup> Others have staffed Emergency Departments with community health workers.<sup>9</sup> Our approach has been to place the community resource specialist in the primary care clinic. Over time, the community resource specialist has become a vital and irreplaceable member of the primary care team.

When I asked Dr Bryce about what she would have done in Angela's case if there was no community resource specialist, she paused. "I'm not sure. I don't know. I would have probably said, 'I'll look into it' because I couldn't have done anything at that visit. I would've tried to find something at the end of the day." However, Dr Bryce had an infant waiting for her at home. Adding more work to the end of the day did not seem to be the best answer. She reflected on several patients who presented to her in acute crisis with social needs. She emphasized that she could not have provided appropriate medical care to them if Larnette had not helped address the patients' social needs first. She continued, "We just need the support. I think addressing social needs is a core aspect of being an effective healer." She had no doubt that a primary care clinic should address patients' unmet social needs, particularly if their existing support network had failed to meet those needs.

Angela didn't hesitate to answer the question about where social needs should be addressed. "The clinic. It's convenient, it's where I would go first, and it's where I already go for my appointments. And the doctor knows me and what I'm going through," she replied.

For Angela, it was also about trust. Angela recounted a clinic visit decades ago when her son was a year old. She tried to tell the doctor about not having enough food, following a particularly painful night where she had only one can of green beans for both her and her infant. She recalled tearfully, "It just felt like they didn't care. I could tell when I looked at the doctor. It was like they didn't have time for what I was going through. They just wanted to talk about my medical problems." That day, she stated, she lost trust in her physician and her clinic. Soon after, she stopped going to the clinic regularly.

It was clear that Angela and Dr Bryce treasured having Larnette at their primary care clinic. Although social needs can be, and should be, addressed in a variety of settings to ensure that every person accesses the resources needed to thrive, Angela's case demonstrates that primary care clinics must identify and address social needs. A primary care clinic's ability to address acute, chronic, and preventive care is affected by social needs, often negatively if unidentified and unaddressed. Addressing social needs does not divert resources from a clinic's core responsibilities or diminish its quality of care; it bolsters them.

### ADVOCACY AND NEGOTIATION

After helping address her food insecurity, Larnette continued to help Angela in several other ways. She helped Angela navigate a complex health care system to get the right care from the right person at the right time. Dr Bryce had advised her that she needed a walker because of her gait instability and referred her to a gastroenterologist for an ongoing medical problem, but Angela was already seeing 4 other specialists and had trouble coordinating her care. She was lost and didn't know who could help. Even in an integrated health system, care can be difficult to obtain. Larnette made a 3-way phone call with Angela and the durable medical equipment company to get her the walker. Then, she made a 3-way phone call with the gastroenterology team to elaborate on Angela's history and schedule the appropriate procedure for her.

Angela didn't see it as merely navigating the system. "Larnette advocates for me when I feel like I can't. It's hard. I have trouble negotiating to get what I want." For Angela, it was Larnette's advocacy and ability to negotiate that she valued the most. Negotiating is an important skill for a patient in a complex, multilayered health care system. Patients must be able to state what they want and need and compare it with what each staff member has to offer. By always making 3-way calls, Larnette advocated for Angela, helped her navigate KPWA, and taught her how to seek and receive the care she needs and deserves.

Angela ended the conversation with me by saying, "Sixty is going to be the best year of my life." I was amazed at the bold statement and wanted clarification. I asked with curiosity, "Why is that?" She replied confidently, "I just know it. I'm finally getting the right treatment for my mood. I'm eating better. Larnette also connected me to a Walk and Talk program. I haven't had a chance to go yet. But I'm going to try to. Sixty is going to be the best year of my life."

As a team, we are providing more than health care. We are giving Angela—and other patients like her—hope by addressing all their needs, including social needs. We are realizing our mission of helping our patients achieve better health. ❖

#### Disclosure Statement

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

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Keywords: community health workers, food supply, patient experience, primary health care, social determinants of health

## Test of Progress

The test of our progress is not whether we add more to the abundance of those who have much; it is whether we provide enough for those who have too little.

— Franklin D Roosevelt, 1882-1945, American statesman and political leader, 32nd President of the United States

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**Section A.**

**Article 1. (page 4) Effect of an Electronic Alert on Targeted HIV Testing Among High-Risk Populations**

Which of the following statements regarding HIV screening is false?

- a. persons aware of their HIV status tend to be less likely to engage in risky sexual behaviors than those unaware of their HIV status
- b. in the US, populations at high risk for HIV infection are commonly screened for HIV infection in medical care settings
- c. the Centers for Disease Control and Prevention recommends routine opt-out HIV screening of persons aged 13 years to 64 years in all health care settings except in communities where the prevalence of undiagnosed HIV infection is documented at less than 0.1%
- d. persons with indication of unsafe sexual activities who seek medical care and tests for sexually transmitted infections are at particularly high risk of HIV infection through unprotected sexual activities

All of the following regarding implementation of a best practice alert at Kaiser Permanente were observed except:

- a. implementation of the best practice alert was associated with a moderate and statistically significant increase in the same-day HIV testing rate
- b. factors associated with a greater probability of receiving a same-day HIV test included male sex and minority status
- c. patients who received a sexually transmitted infection test in a primary care clinic were more likely to receive an HIV test than those seeking care in an infectious disease clinic
- d. patients with a history of HIV tests were more likely to receive a same-day HIV test at the index encounter

**Article 2. (page 21) Contraception after Abortion and Risk of Repeated Unintended Pregnancy among Health Plan Members**

In this study, women initiating short-acting contraception after their abortion were:

- a. significantly more likely to have an unintended pregnancy within 12 months than women initiating long-acting reversible contraception (LARC)
- b. as likely to have an unintended pregnancy within 12 months as women initiating LARC
- c. significantly less likely to have an unintended pregnancy within 12 months than women initiating no contraception
- d. just as likely to have an unintended pregnancy within 12 months as women initiating no contraception
- e. a and d

Which of the following statements is false? Initiation of long-acting reversible contraception (LARC) immediately after completion of an abortion:

- a. is not safe; it is better to wait until the next menstrual period to initiate LARC
- b. is the ideal time because the woman just had an unintended pregnancy
- c. may help prevent another unintended pregnancy
- d. is the ideal time because the woman is not currently pregnant

**Article 3. (page 28) Urate-Lowering Therapy in Moderate to Severe Chronic Kidney Disease**

The goal of urate-lowering therapy is to reduce the total body urate load. Which of the following statements correctly reflects the American College of Rheumatology recommendation?

- a. achieve a serum uric acid < 7 mg/dL
- b. achieve a serum uric acid < 6.8 mg/dL
- c. achieve a serum uric acid < 6 mg/dL

When patients who have chronic kidney disease (CKD) and hyperuricemia, lowering the serum uric acid < 6 mg/dL can help improve renal function:

- a. at all levels of CKD
- b. at CKD levels 2 and 3
- c. at CKD levels 4 and 5
- d. it does not help regardless of CKD level

**Article 4. (online) Survival Outcomes in BRCA1 or BRCA2 Mutation Carriers and the Influence of Triple-Negative Breast Cancer Subtype**

Online at: <https://tpj.page.link/Tn65>

Which of the following statements is false? Compared with women with breast cancer who are BRCA2 mutation carriers, women who are BRCA1 mutation carriers are more likely to:

- a. be diagnosed with early-stage breast cancer
- b. be younger on the date of breast cancer diagnosis
- c. have triple-negative breast cancer
- d. have a lower rate of subsequent breast cancer

Which of the following statements is false? Women with triple-negative breast cancer:

- a. have breast tumors lacking expression of estrogen, progesterone, and human epidermal growth factor-2 (HER2) receptors
- b. have a lower risk of subsequent breast cancer or death compared with those with Luminal A, Luminal B, or HER2-enriched tumors
- c. do not respond well to adjuvant hormonal therapy
- d. should be considered for referral for genetic counseling and testing, especially if they have a family history of breast cancer

**Section B.**

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

**Key**  
 5 = highly likely  
 4 = likely  
 3 = unsure  
 2 = unlikely  
 1 = highly unlikely  
 0 = I already did this

	Objective 1 Integrate learned knowledge and increase competence/confidence to support improvement and change in specific practices, behaviors, and performance.	Objective 2 Lead in further developing "Patient-Centered Care" activities by acquiring new skills and methods to overcome barriers, improve physician/patient relationships, better identify diagnosis and treatment of clinical conditions, as well as, efficiently stratify health needs of varying patient populations.	Objective 3 Implement changes and apply updates in services and practice/policy guidelines, incorporate systems and quality improvements, and effectively utilize evidence-based medicine to produce better patient outcomes.
Article 1	[5] [4] [3] [2] [1] [0]	[5] [4] [3] [2] [1] [0]	[5] [4] [3] [2] [1] [0]
Article 2	[5] [4] [3] [2] [1] [0]	[5] [4] [3] [2] [1] [0]	[5] [4] [3] [2] [1] [0]
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?

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Section D.** (Please print)

Name \_\_\_\_\_

Physician       Non-Physician

Title \_\_\_\_\_

Email \_\_\_\_\_

Address \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_