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Pediatrics seek effective behavioral treatments for referral for 7% of US adolescents who have impaired fasting glucose. Data from 64 pediatrician-referred patients with diabetes risk factors (mean age, 14.1 years; BMI ≥ 95th percentile) demonstrated nutrition education alone may be insufficient for nutrition behavior change. Behavioral treatment lasting longer than 12 weeks and having a specific weightloss goal may be useful for BMI improvements, as a attention to participants’ self-concept and moved

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ON THE COVER
“River Bottom Fall” is an oil on canvas (6’ x 4’) by the Susan Guy, MD. Dr Guy is a Psychiatrist at the Oxnard Medical Center in CA. Dr Guy paints an plein air to relax and to promote environmental conservation.

Dr Guy painted “River Bottom Fall” while an Ojai Land Conservancy property.

More of Dr Guy’s work may be seen at: www.susankguy.com and www.rotpublishing.com.
51 Overview of Emerging Concepts in Metabolic Surgery. Michel Murr, MD, FACS; Arash Rafiei, MD; Habib Ajami, MD; Tannous K Falkhy, MD

Obesity is a worldwide health epidemic, and about two-thirds of US adults are overweight or obese. The link between diabetes and obesity is because of induction of insulin resistance by excess adipose tissue and generalized low chronic inflammation. Metabolic or bariatric surgery induces durable and sustainable weight loss, and its role is well established. This review includes the types of metabolic surgery, preoperative evaluation, postoperative care, follow-up, and the future of metabolic surgery.

57 Thiazolidinediones: A 2010 Perspective. Ashok Krishnaswami, MD, FACC; Shalini Ravi-Kumar, MD; John M Lewis, MD

As the incidence of cardiovascular complications related to diabetes mellitus increases, there is a sense of urgency to produce antidiabetic medications that achieve not only nontoxic glycemic control but also improved cardiovascular outcomes, including lowering mortality. The goal of this review is to shed light on the current understanding of, and the debate surrounding, thiazolidinedione use.

58 ECG Diagnosis: Hypothermia. Joel T Levis, MD, PhD, FACEP, FFAEM

An Osborn wave (J wave) is a characteristic electrocardiogram finding for hypothermia consisting of an extra deflection at the terminal junction of the QRS complex and the ST segment takeoff, and usually occurs when the core body temperature falls below 90°F (32°C). This is believed to result from an exaggerated outward potassium current leading to repolarization abnormality.

59 Image Diagnosis: Interesting Chest Radiographs from the Emergency Department. L Paige Sokolsky, MD; Gus M Garnel, MD, FACEP, FFAEM

Five chest x-rays represent left upper lobe pneumonia, right upper lobe pneumonia, right third and fourth lateral rib fractures, large pneumothorax, and pneumomediastinum with pneumopericardium and subcutaneous emphysema.

60 Innovation

Now that Kaiser Permanente (KP) HealthConnect, the KP electronic health record, is fully implemented, conducting research is supported by harnessing information systems to leverage internal improvements in outcomes, efficiency, and costs. Research challenges at KP are moving away from data access toward mechanisms through which raw data create meaningful clinical knowledge that is based on rigorous research. This report describes this research model.

64 Innovation

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73 From Tragedy, Opportunity—A New Beginning for Haiti and the Dominican Republic. John Freedman, MD

An important epiphenomenon created a new inflection point between Haiti and Dominican Republic, neighboring nations with a long history of violent relations. The Dominican authorities allowed thousands of Haitian refugees to cross the border to seek care in our emergency relief hospital.

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80 Haiti—Forgotten Already? Lee Jacobs, MD

The story yet to be written of the massive rebuilding and relocation that must be supported by people and finances from around the world is a challenge just too great to meet the basic living needs of displaced peoples. The Haitians wonder have you already forgotten them?

81 Mes Quatre Fils (My Four Sons). Mason Spain Turner, MD

In his late 30s, to restore the author’s balance and perspective realigning his life with his personal moral values, a watershed moment occurs within the unique family that was built with four young interpreters who had lost their parents, siblings and many friends.

82 Disaster Medical Relief—Haiti Earthquake January 12, 2010. Hernando Garzon, MD

Kaiser Permanente’s Global Health and volunteer programs support physician volunteerism, relationships with multiple medical relief organizations, created a KP National Volunteerism Web site, and developed and delivered CME courses.

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Factors Contributing to Door-to-Balloon Times of ≤90 Minutes in 97% of Patients with ST-Elevation Myocardial Infarction: Our One-Year Experience with a Heart Alert Protocol

**Abstract**

**Context:** Prompt percutaneous coronary intervention (PCI) for patients with ST-segment elevation myocardial infarction (STEMI) can significantly reduce mortality and morbidity, although its effectiveness may be limited by delays in delivery. In March 2008, our hospital implemented a Heart Alert protocol to rapidly identify and treat patients with STEMI presenting to our Emergency Department (ED) with PCI, using strategies previously described to reduce door-to-balloon times. Before the Heart Alert protocol start date, patients with STEMI presenting to our ED were treated with thrombolysis.

**Objective:** We evaluated data from patients with STEMI after one year of use of our Heart Alert protocol to determine protocol success on the basis of the percentage of patients for whom the recommended door-to-balloon times of ≤90 minutes were met. We examined factors involved in implementation of the protocol that contributed to these results.

**Design:** We conducted a retrospective data and chart review for patients in the ED with STEMI who underwent PCI after a Heart Alert protocol activation between March 17, 2008, and March 17, 2009.

**Results:** During the study period, our staff met the recommended door-to-balloon time of ≤90 minutes (mean door-to-balloon time, 57.3 ± 17.6 minutes) for 70 of 72 patients (97%) presenting to our ED with STEMI. Fifty of the 72 patients (90.3%) survived to hospital discharge.

**Conclusion:** Initiation of a Heart Alert protocol at our hospital resulted in achievement of door-to-balloon times of ≤90 minutes for 97% of patients with STEMI. This achievement was obtained through careful preparation, training, and interdepartmental collaboration and occurred despite immediate conversion from a previous thrombolytic protocol.

**Introduction**

Prompt percutaneous coronary intervention (PCI) for patients with ST-segment elevation myocardial infarction (STEMI) can significantly reduce mortality and morbidity; however, its effectiveness may be limited by delays in delivery.1–3 Door-to-balloon time refers to the interval from arrival of the patient with STEMI at the Emergency Department (ED) to balloon angioplasty of the occluded coronary artery in the cardiac catheterization laboratory (CCL). Guidelines from the American College of Cardiology/American Heart Association and the European Society of Cardiology recommend a goal of ≤90 minutes for door-to-balloon time; this measure is incorporated into national, publicly reported quality indicators for hospital performance.4–6 The Centers for Medicare and Medicaid Services and the Joint Commission consider the ≤90 minute door-to-balloon time a benchmark goal, and facilities must track this as a core measure.7,8

Strategies associated with shorter door-to-balloon times have been identified and include Emergency Medicine (EM) physician activation of the CCL through a single call to a central page operator while the patient is en route to the hospital, arrival of staff in the CCL within 20 minutes of activation, constant presence of an attending cardiologist on-site, real-time case feedback, and interdisciplinary collaboration throughout the process.9–11 The D2B Alliance was developed by the American College of Cardiology to improve door-to-balloon times for patients with STEMI undergoing PCI, and it has enrolled approximately 1000 hospitals.12 The D2B Alliance strategies include 1) EM physician activation of the CCL with a single call, 2) preparation...
of the CCL team within 20 to 30 minutes of the call, 3) real-time case feedback, 4) a team-based approach, and 5) administrative support. The use of prehospital electrocardiograms (ECG) by emergency medical services (EMS) personnel to activate the CCL is an optional strategy. Hospitals have implemented several of these strategies in attempts to improve door-to-balloon times, with varying levels of success.\textsuperscript{13–16}

In March 2008, our hospital initiated a Heart Alert protocol involving close collaboration between the Departments of EM, Cardiology, and Interventional Cardiology to efficiently identify and treat patients with STEMI presenting to our ED. Our protocol includes several of the key strategies to reduce door-to-balloon times and was preceded by careful training of both EM physicians, cardiology physicians, and staff before implementation. A unique feature of our protocol was the implementation of PCI for STEMI at the start of the Heart Alert protocol; before initiation of the Heart Alert protocol, all patients presenting with STEMI were treated using a thrombolytic protocol. Despite this, review of our first-year data indicates that we achieved door-to-balloon times of ≤ 90 minutes in 97% of patients with STEMI (70 of 72). This report describes the development, implementation, and key strategies of our system, as well as specific data resulting in the achievement of door-to-balloon times of ≤ 90 minutes. This report should benefit hospitals preparing to implement primary PCI for patients with STEMI, as well as those struggling to achieve target door-to-balloon times.

**Methods**

**Development and Implementation of the Heart Alert System**

The Santa Clara Medical Center is a suburban teaching hospital located in Santa Clara, CA, sponsoring a joint residency program in EM with Stanford University (Stanford/Kaiser EM Residency Program) and its own residencies in internal medicine, obstetrics-gynecology, and podiatry. Our hospital also hosts Stanford surgery and pediatrics residents, as well as Stanford University and visiting medical students. The hospital has 327 inpatient beds, a 46-bed ED with approximately 60,000 annual patient visits, and three cardiac catheterization laboratories and on-site cardiothoracic surgery. An average of 2200 diagnostic coronary angiograms and 1243 PCIs are performed each year. Our facility has six interventional cardiologists, each performing an average of 220 coronary catheterizations each year. Door-to-balloon times are reported to the American College of Cardiology National Cardiovascular Data Registry, to the Joint Commission, and to the Santa Clara County EMS Agency.

In developing the Heart Alert protocol, an interdisciplinary group of cardiologists, EM physicians, nurses, and administrators convened to outline the actions and procedures necessary for achieving door-to-balloon times of ≤ 90 minutes. Strategies previously demonstrated to reduce door-to-balloon time were incorporated into our protocol, including EM physicians activating the CCL through a single call, arrival of staff in the CCL within 20 minutes after activation, real-time case feedback, and substantial interdisciplinary collaboration throughout the process. Attending cardiologists were available on-site during daytime hours and were available by page to arrive in the ED within 20 minutes of a Heart Alert activation during all other hours. Heart Alert activation by the EM physician

![Figure 1. Steps involved in the Heart Alert protocol for achieving door-to-balloon times of ≤ 90 minutes in 97% of patients during the first year of protocol institution.]

ASA = aspirin; CCL = cardiac catheterization laboratory; CP = chest pain; ECG = electrocardiogram; ED = emergency department; EM = emergency medicine; EMS = emergency medical services; MD = physician; MSE = medical screening examination; NTG = nitroglycerin; PCI = percutaneous coronary intervention; pCXR = portable chest radiograph; STEMI = ST-segment elevation myocardial infarction.
Factors Contributing to Door-to-Balloon Times of ≤90 Minutes in 97% of Patients with ST-Elevation Myocardial Infarction: Our One-Year Experience with a Heart Alert Protocol

while a STEMI patient was en route to the hospital (on the basis of a prehospital ECG report) was encouraged but not mandated. Emergency medical services did not have the ability to transmit prehospital ECGs to our facility during this period.

The door-to-balloon time was broken down into the following clinically relevant intervals: door-to-ECG time (goal, ≤10 minutes), ECG-to-CCL activation time (goal, ≤5 minutes), CCL activation-to-CCL door time (goal, ≤45 minutes), CCL door-to-catheter access time (goal, ≤15 minutes), catheter access-to-guidewire time (goal, ≤15 minutes), for a door-to-balloon time goal of ≤90 minutes. Criteria for identification of STEMI on 12-lead ECGs included ST-segment elevation ≥1 mm (0.1 mV) in at least two anatomically oriented (contiguous) precordial or limb leads and new or presumably new left bundle branch block with a strong clinical suspicion of acute myocardial infarction. Order sets were created to streamline ordering of tests, procedures, and medication administration in the ED after CCL activation. For rapid procurement and administration of medications (eg, aspirin, nitroglycerin, heparin, epifibatide, metoprolol), a Heart Alert medication box was developed that would be immediately available in the event of a Heart Alert activation. Figure 1 outlines the steps involved at each time interval of the Heart Alert protocol.

Our hospital began a number of educational initiatives in advance of initiation of the Heart Alert protocol. The interventional cardiologists presented a STEMI lecture series to the EM physicians and staff. Interdisciplinary Critical Event Team Training sessions were conducted with mock activation of the Heart Alert protocol, allowing staff in both the ED and the CCL to familiarize themselves with the protocol procedures and identify any improvement opportunities. Finally, results of each Heart Alert case (including STEMI ECG image, interval times, catheterization results, and patient outcomes void of patient identifiers) were provided to all EM physicians, residents, and staff via e-mail within one week of each case.

Data Collection and Analysis

The Kaiser Permanente Northern California Institutional Review Board approved our retrospective chart review and data analysis. We performed a chart review of all Heart Alert cases presenting to our ED that received emergency PCI (angioplasty and stent placement) during the first 12 months of the Heart Alert protocol (March 17, 2008, to March 17, 2009). A total of 72 cases met these criteria during the study period. The following data were collected for each patient from electronic medical records: patient age, sex, race, presence and number of cardiac risk factors; history of coronary artery disease, previous PCI, or coronary artery bypass graft; mode of presentation (triage vs EMS); time from symptom onset to ED arrival; initial troponin I level; PCI results; and survival to hospital discharge. Data were then analyzed using the software program EpInfo (Centers for Disease Control and Prevention, Atlanta, GA, USA) for statistical analysis.

<table>
<thead>
<tr>
<th>Table 1. Patient characteristics for STEMI Heart Alert cases (total 72 cases)</th>
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<tbody>
<tr>
<td>Characteristic</td>
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<tr>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Sex (number and % male)</td>
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<tr>
<td>Age (mean ± SD)</td>
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<tr>
<td>Race</td>
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<td>African American</td>
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<td>Hispanic</td>
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<td>Other</td>
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<tr>
<td>Cardiac risk factors</td>
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<td>Hyperlipidemia</td>
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<td>Diabetes</td>
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<td>Tobacco</td>
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<td>Family history of CAD</td>
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<tr>
<td>No known risk factors</td>
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<tr>
<td>Personal history of CAD</td>
</tr>
<tr>
<td>Previous history of PCI</td>
</tr>
<tr>
<td>Previous history of CABG</td>
</tr>
</tbody>
</table>

CABG = coronary artery bypass graft; CAD = coronary artery disease; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction.

Results

Patient characteristics for the 72 Heart Alert cases are shown in Table 1. Approximately 75% of the patients were men, with an average age of 61 years. The majority of patients (70%) were Caucasian, with a smaller percentage of Asian, Hispanic, and African-American patients. The most prevalent cardiac risk factor was hypertension (58%), followed by hyperlipidemia (44%), diabetes (21%), tobacco use (19%), and family history of CAD (18%). Twelve percent of patients had no known cardiac risk factors, 25% had undergone previous PCI, and 4% had a history of CABG. Sixty-five of the 72 patients (90.3%) in the cohort survived to hospital discharge. Six men and 1 woman comprised the 7 patients not surviving...
to discharge, with a mean age of 70.9 ± 17.5 years (range, 40–88 years). The causes of death in these 7 patients were cardiogenic shock (n = 5), anoxic brain injury after cardiac arrest (n = 1), and severe sepsis (n = 1).

Table 2 shows the mean, standard deviation, median, and range for each interval period comprising the door-to-balloon times for the 72 patients with STEMI. The mean door-to-ECG time was 3.3 ± 10.8 minutes (range, −50 to 28 minutes). The mean ECG-to-CCL activation time was 7.5 ± 8.8 minutes, whereas the mean CCL activation-to-CCL door time was 27.2 ± 11.4 minutes. The mean door-to-balloon time for the 72 patients was 57.3 ± 17.6 minutes. The times for 2 patients fell outside of the 90-minute door-to-balloon goal of ≤90 minutes: 94 and 106 minutes.

Table 3 lists ED arrival mode (EMS vs triage), time from symptom onset to ED arrival, and initial troponin I level. Nearly three-quarters of the patients arrived by personal transportation. Analysis of time from symptom onset to ED arrival indicated that 35% of patients arrived to the ED within one hour of symptom onset; 28% arrived between two and six hours, and 7% arrived >12 hours after symptom onset. The mean for the initial troponin I level was 1.02 ± 2.86 ng/mL, with a median of 0.05 ng/mL and a range of <0.02 to 14.92 ng/mL, with 58% of the measurements within the range of 0.00 to 0.09 ng/mL.

Table 4 demonstrates the distribution of coronary arteries (culprit lesions) involved in the 72 STEMs. The most common lesion involved the left anterior descending coronary artery (42%), followed by the right coronary artery (39%); one patient was found to have a left main coronary artery occlusion.

Discussion

Primary PCI has become the preferred treatment option for patients presenting with STEMI because it has helped achieve higher rates of TIMI (thrombolysis in myocardial infarction) grade 3 flow than thrombolysis has. Primary PCI has also been shown to be superior to thrombolysis in reducing rates of mortality, reinfarction, and stroke. This benefit appears to be related to a much higher early mechanical reperfusion rate compared with thrombolysis, to the ability of simultaneously treating the underlying stenosis, and to the lower risk of severe bleeding. In March 2008, our hospital converted from a thrombolysis protocol to a PCI protocol for treating patients presenting to our ED with STEMI.

After development of a Heart Alert protocol, we were able to achieve door-to-balloon times of ≤90 minutes in 97% of our patients with STEMI during the first year of implementation. The success of the Heart Alert protocol is predicated on its development on the basis of previous proven strategies, including published, continuous quality-improvement

**Table 2. Mean time intervals (minutes) for STEMI Heart Alert cases (total of 72 cases)**

<table>
<thead>
<tr>
<th>Interval</th>
<th>Mean ± SD</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Door-to-ECG time</td>
<td>3.3 ± 10.8</td>
<td>2.0</td>
<td>−50.0 to 28.0</td>
</tr>
<tr>
<td>ECG-to-CCL activation time</td>
<td>7.5 ± 8.8</td>
<td>5.0</td>
<td>−12.0 to 42.0</td>
</tr>
<tr>
<td>CCL activation-to-CCL door time</td>
<td>27.2 ± 11.4</td>
<td>23.5</td>
<td>6.0 to 61.0</td>
</tr>
<tr>
<td>CCL door-to-access time</td>
<td>9.0 ± 3.7</td>
<td>8.5</td>
<td>3.0 to 24.0</td>
</tr>
<tr>
<td>Access-to-guidewire time</td>
<td>10.6 ± 6.2</td>
<td>9.0</td>
<td>1.0 to 34.0</td>
</tr>
<tr>
<td>Door-to-balloon time</td>
<td>57.3 ± 17.6</td>
<td>56.5</td>
<td>30.0 to 106.0</td>
</tr>
</tbody>
</table>

CCL = cardiac catheterization laboratory; ECG = electrocardiogram; SD = standard deviation; STEMI = ST-segment elevation myocardial infarction.

**Table 3. Mode of ED arrival, time from symptom onset to ED arrival, and initial troponin I levels for STEMI Heart Alert cases (total of 72)**

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Value</th>
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<tr>
<td>Mode of ED arrival</td>
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<tr>
<td>Ambulance (EMS)</td>
<td>20 (27.8%)</td>
</tr>
<tr>
<td>Personal transportation</td>
<td>52 (72.2%)</td>
</tr>
<tr>
<td>Time from symptom onset to ED arrival</td>
<td></td>
</tr>
<tr>
<td>≤1 hour</td>
<td>25 (35.2%)</td>
</tr>
<tr>
<td>1–2 hours</td>
<td>14 (19.7%)</td>
</tr>
<tr>
<td>2–6 hours</td>
<td>20 (28.2%)</td>
</tr>
<tr>
<td>6–12 hours</td>
<td>7 (9.9%)</td>
</tr>
<tr>
<td>&gt;12 hours</td>
<td>5 (7.0%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Initial troponin I level</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>1.02 ± 2.86 ng/mL</td>
</tr>
<tr>
<td>Median</td>
<td>0.05 ng/mL</td>
</tr>
<tr>
<td>Range</td>
<td>&lt;0.02–14.92 ng/mL</td>
</tr>
</tbody>
</table>

ED = emergency department; EMS = emergency medical services; SD = standard deviation; STEMI = ST-segment elevation myocardial infarction.

**Table 4. Coronary artery (culprit lesion) involved in STEMI for Heart Alert cases (total of 72 cases)**

<table>
<thead>
<tr>
<th>Coronary artery involved</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left main</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>LAD</td>
<td>30 (41.7)</td>
</tr>
<tr>
<td>RCA</td>
<td>28 (38.9)</td>
</tr>
<tr>
<td>LCx</td>
<td>6 (8.3%)</td>
</tr>
<tr>
<td>Diagonal branch of LAD</td>
<td>2 (2.8%)</td>
</tr>
<tr>
<td>Obtuse marginal branch of LCx</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Posterior descending artery</td>
<td>4 (5.6%)</td>
</tr>
</tbody>
</table>

LAD = left anterior descending; LCx = left circumflex artery; RCA = right coronary artery; STEMI = ST-segment elevation myocardial infarction.
analyses resulting in expedited PCI for patients with STEMI.\textsuperscript{22-24} Several factors contributed to the success of our protocol, including

- Organization of an interdisciplinary working group of cardiologists, EM physicians, nurses, and administrators whose chief role was to develop and outline the training and protocol implementation.
- Educational and training activities for staff and physicians before protocol implementation, including STEMI lectures and critical-event team training involving mock Heart Alert simulations.
- Breakdown of the door-to-balloon time into clinically relevant intervals, with continued quality analysis of these intervals to look for areas of improvement.
- Continuous feedback on all Heart Alert cases to all EM physicians and residents, using a Heart Alert case series provided by e-mail within one week of each case. A survey of EM physicians 20 months after implementation of this series indicated that most EM physicians reviewed the Heart Alert cases and found them useful as an educational tool.

Several strategies implemented at each door-to-balloon interval in our protocol have contributed to the ability to obtain door-to-balloon times of ≤90 minutes in such a large proportion of patients with STEMI (Figure 1). When patients present to our ED triage with chest discomfort or angina-equivalent symptoms, a 12-lead ECG is obtained immediately before a detailed medical screening examination and patient registration, enabling rapid ECG acquisition. For similar patients presenting to the ED by EMS, an ECG is immediately requested by the charge nurse or unit assistant as the patient is being roomed (before physician assignment), again reducing any potential delays in ECG acquisition. Once obtained, the ECG must be presented to an EM physician as soon as possible for early detection and recognition of STEMI. When STEMI is diagnosed, the EM physician activates a Heart Alert through a single call to a central page operator, requiring the CCL team to be prepared for emergency PCI within 20 minutes of the page. Use of a Heart Alert medication box during the laboratory activation-to-CCL door interval contributes significantly to reducing this time interval, allowing nurses to quickly obtain a single medication box containing all of the necessary pre-PCI medications rather than needing to remove each medication piecemeal from the automated medication-dispensing system.

The number of STEMI cases in our first year of the protocol (72) is similar to those reported for other large hospitals with high-volume PCI capabilities.\textsuperscript{14,15} The majority of patients with STEMI in our study were men (78%; Table 1) with an average age of 61.3 years, similar to the sex and age distribution for patients with STEMI found in a large retrospective review of the National Registry of Myocardial Infarction (NRMI) for 2006.\textsuperscript{25} The racial and ethnic breakdown as well as the presence and distribution of documented cardiac risk factors for our patients with STEMI were similar to results found for patients with STEMI in the NRMI data review. The percentage of our patients who had previously undergone PCI was slightly higher than that noted in the 2006 NRMI registry (23.6% vs 15.5%), whereas the percentage of patients with previous CABG in both studies was low (4.2% vs 7.9%).

Evaluation of the interval times for our protocol indicated that the mean door-to-ECG time for all patients with STEMI was 3.3 ± 10.8 minutes, with a median of 2.0 minutes and a range of -50.0 to +28.0 minutes (Table 2). Door-to-ECG times for 85% of patients were ≤10 minutes. In one patient, STEMI was diagnosed by ECG in a clinic (door-to-ECG time, -50 minutes) before ED transport. After omitting this time from the data analysis, the mean door-to-ECG time for the remaining 71 patients was 4.1 ± 8.7 minutes. Phelan et al identified two main causes of door-to-ECG times >10 minutes in a study to assess and find ways to decrease door-to-ECG times in their ED: 1) priority delay (eg, completing triage and registration data entry before obtaining ECGs) and 2) failure to recognize patients with non-chest-pain STEMI.\textsuperscript{26} Before our protocol implementation, all ED staff were educated about the importance of obtaining ECGs for all patients presenting with chest pain or symptoms suggestive of ischemia without further delay, as well as about how to recognize potential non-chest-pain acute coronary syndrome symptoms. Once obtained, ECGs are immediately presented to an EM physician for rapid review.

Use of prehospital ECGs for STEMI activation before patient arrival can improve door-to-balloon times.\textsuperscript{27-30} This practice is noted as an optional strategy by the D2B Alliance. In the first year of our protocol, approximately 28% of patients with STEMI arrived to the ED by ambulance (Table 3), and half of those patients had Heart Alert activations that were based on prehospital ECG reports. All door-to-balloon times for the 10 STEMI cases in which an alert was activated before arrival fell below 50 minutes (36.5 ± 5.7 minutes; median, 35 minutes; range, 30–49 minutes). Transmission of prehospital ECGs for rapid triage of patients with STEMI has also been shown to reduce door-to-balloon times and can improve early survival of these patients.\textsuperscript{7,31}
Our county is currently developing a prehospital ECG transmission system to better improve the sensitivity and specificity of this application.

EM physician activation of the CCL team decreases door-to-balloon times. Mean ECG-to-CCL activation time during our study period (7.5 ± 8.8 minutes) exceeded the recommended goal of 5 minutes, with a total of 31 of 72 cases exceeding this goal. One case demonstrated an ECG-to-CCL activation time of 42 minutes. Review of that case indicated that the chief complaint was epigastric pain, and the door-to-ECG time for the same case was 0 minutes. It is likely that the symptoms were not recognized as potentially cardiac, possibly leading to delays in ECG presentation to and review by the EM physician. Evaluation of ambiguous ECGs may also result in delay of CCL activation (eg, ECGs obtained early in the evolution of a STEMI). Continued case feedback using the Heart Alert case series, as well as ability of EM physicians to fax ambiguous ECGs to the on-call cardiologist 24 hours/day should aid in further reduction of this time interval in our protocol.

The largest component of door-to-balloon time is typically the time spent within the ED before transfer to the CCL. Our mean CCL activation-to-CCL door time fell well within our recommended interval (27.2 ± 11.4 minutes; median, 23.5 minutes; recommended goal, ≤45 minutes; Table 2). Only 5 cases (7%) fell outside of the recommended interval. Careful preparation and training of the ED staff, well-designed and preprinted STEMI order sets, use of a Heart Alert medication box for pre-PCI medications, and careful coordination among EM physicians, interventional cardiologists, and ancillary staff contributed to the efficiency of patient preparation prior to CCL transfer. Use of an electronic STEMI order set implemented after the first year of the Heart Alert protocol should further improve the efficiency of this process.

Time from symptom onset to ED arrival is listed in Table 3. The percentage of patients presenting within the first hour of symptom onset in our study (35.2%) is nearly identical to that found in a similar study involving an identical number of patients (36%, Code STEMI study). In our study period, a smaller percentage of patients presented between 1 and 2 hours of symptom onset (19.7%), whereas more presented in the range of 2 to 6 hours (28.2%). The lowest proportion of patients with STEMI in our study period presented in the range of 6 to 12 hours (9.9%) and after >12 hours (7%) range, findings similar to the Code STEMI study. In the US, median delay time from symptom onset to hospital arrival ranges from 1.5 to 6.0 hours. Numerous factors, including old age, female sex, low education level, low socioeconomic status, race and ethnic differences, and presence of chronic health conditions and high-risk behaviors, have been associated with additional delays in patients seeking treatment for ACS.

Approximately 58% of the initial troponin I results for patients with STEMI fell within the normal range of 0.00 to 0.09 ng/mL. Because troponin I levels rise within 4 to 6 hours of myocardial injury, these results indicate that the majority of our patients with STEMI presented to the ED relatively early in the disease process. Although initial troponin I levels are less useful in diagnosing STEMI (compared with non-STEMI and unstable angina), baseline troponin levels have been shown to be independent predictors of 30-day cardiovascular death in patients with STEMI. The most common coronary artery involved in STEMI in our patients was the left anterior descending (41.7%), followed closely by the right coronary artery (38.9%) and the left circumflex coronary artery (8.3%) (Table 4). This distribution of coronary artery involvement is similar to that found in the Code STEMI study cited earlier, in which the right coronary artery (31%), left anterior descending (27%), and left circumflex (14%) were most commonly involved.

Sixty-five of the 72 patients (90.3%) in our study cohort survived to hospital discharge. The all-cause inhospital mortality rate for our cohort (9.7%) was higher than rates reported after implementation of two similar STEMI protocols (4.2% and 4.7%, respectively). This discrepancy may be due, in part, to the severity of illness in the nonsurvivors in our cohort. Five of 7 patients not surviving to discharge died from cardiogenic shock, 1 after out-of-hospital cardiac arrest and 1 after development of severe sepsis, all conditions associated with significantly higher in-hospital mortality rates. Further data acquisition and analysis over a longer time period will be required to determine a true survival benefit from our Heart Alert protocol.

Initiation of a Heart Alert protocol at our hospital has resulted in excellent door-to-balloon times during our first year of implementation, with the achievement of door-to-balloon times ≤90 minutes in 97% of patients with STEMI. This achievement was made possible by careful preparation, training, and interdepartmental collaboration and occurred despite immediate conversion from a previous thrombolytic protocol. A similar disciplined system can be readily implemented in hospitals.
that are considering developing PCI capability or by those in need of improvement of door-to-balloon times, using techniques described in this report. ♦

Disclosure Statement

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

Acknowledgments

Gus Carmel, MD, FACEP, FAAEM, assisted with study concept and design, and Avani Mehta and Lora Glasgow, RN, provided assistance with data acquisition.

Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

References


The Chief

Of all the ailments which may blow out life’s little candle, heart disease is the chief.

—William Boyd, 1885-1979, Scottish-Canadian pathologist and academic
Reasons for Not Meeting Coronary Artery Disease Targets of Care in Ambulatory Practice

Thomas Erling Kottke, MD, MSPH
Zacharia Ogwang, NP
James C. Smith, MD

Abstract

Introduction: Four targets of care: control of blood pressure, control of low-density lipoprotein cholesterol level, taking aspirin daily, and not using tobacco improve outcomes for patients with coronary artery disease (CAD). We sought to identify why, in a large multispecialty group, these targets were not being met in patients with CAD.

Methods: We thus conducted a retrospective review of patient records in the group practice’s CAD registry, which is updated quarterly.

Results: Of a random selection of 14,973 patients in the CAD registry, 353 charts were consecutively reviewed until theoretic saturation was achieved—that is, until no new information was found. We could not find any evidence of CAD in 14 patients, and we considered that all four targets had been met for 169 patients. The most frequent reasons for not meeting all targets of care among the 170 remaining patients were 1) the patient was in for a visit and the care team failed to address an unmet target of care (n = 98), 2) the patient was asked to come back for follow-up care but did not (n = 28), and 3) the patient declined an intervention that was offered (n = 14). Blood pressure and low-density lipoprotein cholesterol levels were the targets that were most frequently out of range.

Conclusion: Giving the health care team access to tools with which they can identify the concurrent care needs of their patients could significantly increase the proportion of patients with CAD for whom care targets are met. Lists generated by these tools would also be significantly more accurate than lists generated from quarterly reports.

Introduction

Causing half a million deaths each year, coronary artery disease (CAD) is the leading cause of mortality in the US.1 Close to 18 million Americans are thought to have the condition and, if hypertension is included, the prevalence is thought to be >81 million people in the US alone. Despite a decline in the rate of hospitalization for myocardial infarction that may be as great as 31%, these conditions continue to consume large quantities of health care resources.2 The Centers for Disease Control and Prevention projects that costs related to heart disease will be >$500 billion in 2010, largely because of an expected 72 million office visits and nearly 7 million hospitalizations.3 These statistics are driving policy makers and clinicians to search for more effective ways to manage heart disease.

In the past, heart-disease-management strategies have focused on developing new diagnostic tools and therapeutic interventions for the treatment of acutely ill patients. However, numerous recent outcome studies have shown that these strategies produce only short-term health benefits while increasing the cost of health care.4–7 Yet secondary prevention treatments for patients with heart disease have the potential to reduce subsequent mortality by as much as 75% to 90%.8–10 One of the authors (TEK) has published calculations showing that meeting all targets of care for patients with stable heart disease could prevent or postpone nearly 25% of all US deaths among those who are 30 to 84 years of age.11

With the current emphasis on value-driven care, coupled with a political environment that is emphasizing a change in the way that health care is delivered, primary and secondary disease-prevention strategies seem poised to dominate the future innovations of health care delivery. Several national and local institutions have set disease-reduction goals. For example, the American Heart Association has set a goal of improving the cardiovascular health of the entire American population by 20% as measured by the average change in four behaviors (never smoked or quit more than one year ago, body mass index less than 25 kg/m², physi-

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Reasons for Not Meeting Coronary Artery Disease Targets of Care in Ambulatory Practice

Reasons for using tobacco.

Taking aspirin daily

LDL cholesterol level <100 mg/dL

Blood pressure <140/90 mm Hg, low-density lipoprotein (LDL) level <100 mg/dL. The American Heart Association has also set a goal of reducing deaths by the same percentage by 2020. These goals are consistent with the Healthy People 2020 national heart disease and stroke management goals. To encourage better care at a regional level and to respond to the Healthcare Effectiveness Data and Information Set (HEDIS) and to Minnesota HealthScores, HealthPartners has begun to report performance on four targets of care for participating physicians who treat a significant number of patients who have CAD: blood pressure <140/90 mm Hg, low-density lipoprotein (LDL) level <100 mg/dL, taking aspirin daily, and not using tobacco. In 2006–2007, the average proportion of patients who met all four goals was only 37.5%, and no participating physicians met all four targets of care for more than 45% of HealthPartners members.

Data from another Medical Group suggests that significant improvements in performance on metrics of care require multicomponent interventions. As the first step in a local initiative to improve outcomes for patients with CAD by improving the process of care, the goal of this project was to identify why patients cared for by HealthPartners Medical Group fail to achieve the four targets of care.

Methods

The research protocol was approved by the HealthPartners Research Foundation Institutional Review Board and assigned protocol number 09–007. HealthPartners maintains a register of patients with CAD (“the CAD register”) who meet the following criteria:

- Insured by HealthPartners
- Being between the ages of 18 and 75 years
- Having had a hospitalization or clinic visit within the last two years
- Taking aspirin daily
- LDL cholesterol level <100 mg/dL
- Blood pressure <140/90 mm Hg
- Fasting blood glucose less than 100 mg/dl

Having been prescribed nitrates within the last two years.

The register is updated quarterly.

In the first quarter of 2009, one of two authors (JCS or TEK) reviewed the medical records of randomly selected patients who were in the CAD register at the time of the most recent available update—the end of the third quarter of 2008. To be selected for review, the patient also was required to have had at least one visit to a HealthPartners Medical Group primary care clinic during 2008 and to have not met one or more of the following criteria of optimal health as defined in the HealthPartners 2007 Clinical Indicators Report:

- Systolic blood pressure <140 mm Hg and diastolic blood pressure <90 mm Hg
- LDL cholesterol level measured in the preceding year
- LDL cholesterol level <100 mg/dL when measured
- Taking aspirin daily
- Not using tobacco.

To be considered met, a target of care had to be documented.

Each reviewing physician (TEK and JCS) was given a list of patients and one target of care for which the patient had out-of-range values at the end of the third quarter of 2008.

Only one target was identified for each patient. Consecutive records were reviewed until theoretical saturation was achieved. Theoretical saturation is the point at which no new information is gained from further collection of data. In this particular case, theoretical saturation was considered to be achieved when review of 30 consecutive records did not identify a new reason for a patient not meeting the targets of care. The number 30 was selected because it approaches the normal distribution and because if a reason is not found in 30 charts, it is unlikely to contribute to more than 3% to 5% of failures. A total of 353 records were reviewed.

Results

At the end of the third quarter of 2008, HealthPartners had 50,415 current members who had received a CAD code since January 1, 2000; 14,973 members were in the CAD register (Figure 1). The age of members in the register ranged from 19 to 77 years (mean, 61.4 years; standard deviation [SD], 9.4 years), and 67% were men. A total of 15,442 current members who had a CAD code were not in the register—93 because they were <18 years old, 9011 because they were >75 years old, and 6338 because they neither had a visit with a CAD code within two years nor were they prescribed nitrates in the same period.

The age of the patients who were randomly selected for review ranged from 31 to 77 years (mean, 62.9 years; SD, 8.9 years), and 65% were men. Although 170 patients were confirmed to have CAD but did not meet all four targets of care, the reviewing physicians could find no evidence of CAD in the records of 14 patients and considered that 169 patients met the targets of care at the time of review. More than...
half (n = 98) of the 170 patients who were confirmed to have CAD but did not meet all targets of care did not meet criteria because the out-of-range target had not been addressed at the time that they were seen by a primary care physician (Table 1). About 15% of the patients were asked to come back for follow-up care but did not, and <10% of the patients declined intervention. Other reasons for failure to meet the targets of care occurred less frequently.

Blood pressure (n = 43) and LDL cholesterol level (n = 55) were the targets of care that were most frequently out of control. Failure to take aspirin was the reason that the patient did not achieve all targets of care in only 17 cases, and 26 patients continued to use tobacco.

**Discussion**

The record-review data presented in this report document that the most common reasons HealthPartners Medical Group patients do not achieve CAD targets of care are simple: 1) most frequently, their needs are overlooked by the care team when the patient is in the office; 2) the patient has failed to return for a visit; and 3) the patient declined an intervention that was offered to them. These observations suggest that giving care teams access to timely data about the patients they treat could contribute to the elimination of 80% to 90% of the reasons for failure to meet the targets of care. The same reporting tools that could be used to prepare for patient visits could let the care teams benchmark their own performance to identify opportunities to improve care through process-improvement initiatives.

The data on which these conclusions are based have several limitations. Only one failure was examined for cause for each patient. Therefore, the proportion of patients with multiple failures cannot be calculated from these data. The data are from one multispecialty group practice; the causes of failure in other group practices may be different. About half of the patients who have CAD are not in the CAD register, so it is possible that patients in the CAD register are not representative of patients who are not in the CAD register. The hypotheses generated in this study will be verified only when redesigned care systems reduce failure rates by addressing the reasons for failure documented in this study.

The selection cascade provides information about why the reporting process must be tailored to the needs of the clinical care teams. Because the main purpose of the CAD register is to report performance to HEDIS and Minnesota HealthScores, performance is reported only for patients who are ≤ 75 years old and have had a CAD code assigned to one of their encounters within the preceding two years. Additionally, the register is updated only quarterly. Although the selection criteria and quarterly updates are appropriate for performance reporting, they miss older patients who are being actively treated by their clinical care teams, and the data generated from the register are frequently outdated at the time of a clinical encounter. Both of these problems, and the annoyance that data that are outdated or inaccurate, could be avoided by giving care teams access to real-time analysis.

**Figure 1.** The cascade from current HealthPartners members with at least one coronary artery disease (CAD) code since January 1, 2000, to the 170 randomly selected members with medical record evidence of CAD and not meeting at least one target of care.

and reporting tools. However, caution would have to be exercised if the data were to be used for other than self-evaluation because of the problem of small numbers leading to numeric instability and a multicomponent index having an achievable performance value that is significantly <100%.

Despite the fact that changing the way in which care is delivered to numeric instability and a multicomponent index having an achievable performance value that is significantly <100%.

Table 1. Reasons the targets of care were not achieved (n)

<table>
<thead>
<tr>
<th>Reason target not achieved</th>
<th>Number of times each target of care was not achieved, by reason</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BP controlled</td>
</tr>
<tr>
<td>The patient was in for a visit, but the care team failed to address a need</td>
<td>29</td>
</tr>
<tr>
<td>The patient was asked to come back but did not</td>
<td>5</td>
</tr>
<tr>
<td>The patient was offered an intervention but declined</td>
<td>6</td>
</tr>
<tr>
<td>The clinician changed a medication in response to an out-of-range value; the target was not due for reevaluation</td>
<td>1</td>
</tr>
<tr>
<td>The patient was not invited back for follow-up treatment</td>
<td>1</td>
</tr>
<tr>
<td>Aggressive goals were not appropriate for the patient because of a comorbid condition</td>
<td>—</td>
</tr>
<tr>
<td>The physician who ordered the test failed to follow-up</td>
<td>—</td>
</tr>
<tr>
<td>The patient was intolerant of statins</td>
<td>—</td>
</tr>
<tr>
<td>All other reasons</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>43</td>
</tr>
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</table>

BP = blood pressure; LDL = low-density lipoprotein.

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

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Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

References


Shenshen Dou is a former Molecular Biologist living in Portland, OR. This painting was inspired by one of her husband’s patients: a young dancer with an abnormal heart rhythm, which threatened her profession and her life. John Wu, MD, Ms Dou’s husband, corrected the rhythm with a pacemaker, which can be seen in the painting, and the young dancer, inspiration for this painting, is dancing again.
The Protective Effect of Family Strengths in Childhood against Adolescent Pregnancy and Its Long-Term Psychosocial Consequences

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Maurizio Macaluso, MD, DrPH
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Abstract

Background: Few reports have addressed associations between family strengths during childhood and adolescent pregnancy and its consequences. We examined relationships among a number of childhood family strengths and adolescent pregnancy, risk behavior, and psychosocial consequences after adolescent pregnancy.

Methods: Our retrospective cohort of 4648 women older than 18 years (mean age, 56 years) received primary care in San Diego, CA. Outcomes included adolescent pregnancy and psychosocial consequences compared with number of the following childhood family strengths: family closeness, support, loyalty, protection, love, importance, and responsiveness to health needs.

Results: Of the cohort, 3082 participants (66%) reported 6 or 7 categories of childhood family strengths. Teen pregnancy occurred in 39%, 33%, 30%, 25%, 24%, 21%, and 19% of those with 0 or 1, 2, 3, 4, 5, 6, and 7 childhood family strengths, respectively (p for trend < 0.00001). When childhood abuse and household dysfunction were present, adjusted odds ratios (ORs) for adolescent pregnancy demonstrated an increasingly protective effect as numbers of childhood family strengths increased from 0 or 1 to 2 or 3, 4 or 5, and 6 or 7 (1.0 to 0.80), (1.0 to 0.80, 0.60, and 0.34, respectively). These findings were partly explained by progressive delays in initiation of sexual activity as the number of childhood family strengths increased. Adjusted ORs for psychosocial problem occurring decades later decreased as the number of childhood family strengths increased from 0 or 1 to 2 or 3, 4 or 5, and 6 or 7 (job problems, 1.0, 0.8, 0.6, 0.4; family problems, 1.0, 1.1, 0.7, 0.6; financial problems, 1.0, 0.9, 0.9, 0.6; high stress, 1.0, 1.1, 0.9, 0.8; uncontrollable anger, 1.0, 0.7, 0.7, 0.4).

Conclusions: Childhood family strengths are strongly protective against adolescent pregnancy, early initiation of sexual activity, and long-term psychosocial consequences.

National data describing adolescent childbearing have been available for the US since 1940.1 Teen birth rates after the ensuing 60 years reached an all-time record low of 48.7 births per 1000 women age 15 to 19 years in the year 2000.2 In spite of noteworthy reductions in rates of adolescent pregnancy and births during the 1990s, teen pregnancy rates in the US exceeded those of other industrialized countries by 2 to 15-fold.3–4 Of the approximately 900,000 pregnancies in a typical year,5 about half end in live births and the other half are associated with abortion, miscarriage, or stillbirth.5

Research in prevention since 1990 has identified a variety of factors, including individual, family, peer,
and community influences, that protect against early sexual debut and adolescent pregnancy. Several reports have examined the role of adolescents’ family context in building resilience and in providing protection against unfavorable reproductive outcomes. Adolescents reporting higher family assets have been significantly less likely to report early sexual debut or adolescent pregnancy. A limitation of these reports, however, is the absence of an analysis on whether the protective effect of family assets persists when the fuller constellation of negative family cofactors is considered.

Recent reports have used the Adverse Childhood Experiences (ACE) Study to address the association between major causes of death and disability in the US and childhood abuse and family dysfunction. These and related reports demonstrate strong and graded associations between cumulative exposure to categories of ACE and many unfavorable reproductive health outcomes, including early onset of sexual activity, adolescent pregnancy, sexually transmitted diseases, increased risk of HIV infection, violence perpetration, unintended pregnancy in adulthood, and fetal death. Data collected in the second wave of the study also included measures of family strengths, which should protect against these unfavorable outcomes. Seven questions used to assess family strengths during childhood covered family closeness, support, loyalty, and protection; feelings of being loved and important; and responsiveness to needs for health care.

We recently reported that ACE had a dose-response effect on adolescent pregnancy and on long-term psychosocial outcomes commonly attributed to adolescent pregnancy. Here, we examine whether childhood family strengths protect against adolescent pregnancy, against sexual risk behavior leading to adolescent pregnancy, and against long-term psychosocial outcomes commonly attributed to adolescent pregnancy. Furthermore, we examine whether the protective effect of family strengths remains among women who were exposed to ACE (various types of abuse and household dysfunction, as detailed in the “Methods” section).

Methods

The methods used for the ACE Study have been described in detail. The study was a retrospective cohort study conducted among adults enrolled in a large health maintenance organization (Kaiser Permanente [KP] Medical Care Program) in San Diego, CA. Approval was granted by the institutional review boards of Emory University and KP and by the office of Human Research Protection, Department of Health and Human Services.

Each year, more than 50,000 adult KP members underwent a standardized biopsychosocial health evaluation, and more than 80% of continuously enrolled members obtained this service at least once over a typical four-year period. The evaluation included a health history, psychosocial evaluation, laboratory studies, and physical examination. The primary purpose of the evaluation is to perform a complete health assessment rather than to provide care that is based on symptoms or illness. The ACE Study sample was drawn from the Health Appraisal Center and consisted of two survey waves (wave I and wave II). Wave I was conducted among 13,494 consecutive KP members attending the Health Appraisal Center between August 1995 and March 1996, and the response rate was 70% (N = 9508). Wave II was conducted between June and October 1997 among 13,330 KP members, and the response rate was 65% (N = 8667). The overall response rate for both waves was 68%. Within two weeks after their clinic visit, participants received a mailed ACE questionnaire that assessed exposure to childhood abuse or household dysfunction and childhood family strengths. The wave II survey included questions on family strengths, which were not included in wave I. Therefore, this study report includes only wave II data. After the exclusion of women who had missing data on race or education (n = 21) or on all categories of childhood family strengths (n = 26), our sample included 4648 women.

Definitions of Childhood Family Strengths, Adverse Childhood Experiences, Adolescent Pregnancy, and Psychosocial Consequences

All questions about childhood family strengths and ACE pertained to the respondent's first 18 years of life (Table 1). For the childhood family strengths questions, participants were asked about how applicable to their lives each of seven statements was regarding closeness, support, loyalty, protection, importance, love, and responsiveness to health needs. Response categories included “never true,” “rarely true,” “sometimes true,” “often true,” and “very often true.” The questions about ACE dealt with verbal and physical abuse, contact sexual abuse, violence against one's mother, household substance abuse and mental illness, having an incarcerated household member,
<table>
<thead>
<tr>
<th>Questions</th>
<th>Defining responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family closeness: While you were growing up, during your first 18 years of life, how true were each of the following statements? People in your family felt close to each other.</td>
<td>Often true or very often true</td>
</tr>
<tr>
<td>Family support: While you were growing up, during your first 18 years of life, how true were each of the following statements? Your family was a source of support.</td>
<td>Often true or very often true</td>
</tr>
<tr>
<td>Family loyalty: While you were growing up, during your first 18 years of life, how true were each of the following statements? People in your family looked out for each other.</td>
<td>Often true or very often true</td>
</tr>
<tr>
<td>Family protection: While you were growing up, during your first 18 years of life, how true were each of the following statements? You knew there was someone to take care of you and to protect you.</td>
<td>Often true or very often true</td>
</tr>
<tr>
<td>Family importance: While you were growing up, during your first 18 years of life, how true were each of the following statements? There was someone in your family who helped you feel important or special.</td>
<td>Often true or very often true</td>
</tr>
<tr>
<td>Family love: While you were growing up, during your first 18 years of life, how true were each of the following statements? You felt loved.</td>
<td>Often true or very often true</td>
</tr>
<tr>
<td>Responsiveness to health care needs: While you were growing up, during your first 18 years of life, how true were each of the following statements? There was someone to take you to the doctor if you needed it.</td>
<td>Often true or very often true</td>
</tr>
</tbody>
</table>

**Adverse childhood experiences questions**

<table>
<thead>
<tr>
<th>Questions</th>
<th>Defining responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verbal abuse: Sometimes parents or other adults hurt children. While you were growing up—that is, in your first 18 years of life, how often did a parent, stepparent, or adult living in your home 1) swear at you, insult you, or put you down? 2) threaten to hit you or throw something at you but didn’t do it?</td>
<td>Often or very often to either question</td>
</tr>
<tr>
<td>Physical abuse: Sometimes parents or other adults hurt children. While you were growing up—that is, in your first 18 years of life, how often did a parent, stepparent, or adult living in your home 1) push, grab, slap, or throw something at you? 2) hit you so hard that you had marks or were injured?</td>
<td>Often or very often to the question 1 or sometimes, often, or very often to question 2</td>
</tr>
<tr>
<td>Sexual abuse: Some people, while they were growing up in their first 18 years of life, had a sexual experience with an adult or someone at least 5 years older than themselves. These experiences might have involved a relative, family friend, or stranger. During your first 18 years of life, did an adult, relative, family friend, or stranger ever 1) touch or fondle your body in a sexual way, 2) have you touch their body in a sexual way, 3) attempt to have any type of sexual intercourse with you (oral, anal, or vaginal), or 4) actually have any type of sexual intercourse with you (oral, anal, or vaginal)?</td>
<td>Yes to any of the 4 questions</td>
</tr>
<tr>
<td>Intimate-partner violence: Sometimes physical blows occur between parents. While you were growing up in your first 18 years of life, how often did your father (or stepfather) or mother’s boyfriend do any of these things to your mother (or stepmother): 1) push, grab, slap, or throw something at her? 2) kick, bite, hit her with a fist, or hit her with something hard? 3) repeatedly hit her over at least a few minutes? 4) threaten her with a knife or gun, or use a knife or gun to hurt her?</td>
<td>Sometimes, often, or very often to at least 1 of the first 2 questions or any response other than never to at least one of the third and fourth questions</td>
</tr>
<tr>
<td>Household substance abuse: During your first 18 years of life, did you live with anyone who was a problem drinker or alcoholic? During your first 18 years of life, did you live with anyone who used street drugs?</td>
<td>Yes to either question</td>
</tr>
<tr>
<td>Mental illness in household: During your first 18 years of life, was anyone in your household depressed or mentally ill? During your first 18 years of life, did anyone in your household attempt to commit suicide?</td>
<td>Yes to either question</td>
</tr>
<tr>
<td>Incarcerated household member: During your first 18 years of life, did anyone in your household go to prison?</td>
<td>Yes</td>
</tr>
<tr>
<td>Parental separation or divorce: Were your parents ever separated or divorced?</td>
<td>Yes</td>
</tr>
</tbody>
</table>
and parental separation or divorce. Each of these areas has been described in detail.13–22 Our questions regarding emotional and physical abuse, violence against one’s mother,23 contact sexual abuse during childhood,24 and household substance abuse25 were adapted from previously used scales. The childhood family strengths questions were taken from the Childhood Trauma Questionnaire developed by Bernstein et al,27 which has been showed to have high reliability and validity.

Information about adolescent pregnancy, defined as a pregnancy that occurs in a female between the ages of 11 and 19 years, was obtained through self-report. The question was “How old were you the first time you became pregnant?” Age of initiation of sexual activity was obtained through the question “How old were you the first time you had sexual intercourse?”

Statistical Analyses

The unadjusted associations between each of the seven categories of childhood family strengths and adolescent pregnancy were estimated using relative risks (RRs) and 95% confidence intervals (CIs). Subsequently, logistic regression modeling was employed to evaluate the protective association between numbers of categories of childhood family strengths and adolescent pregnancy, as well as long-term psychosocial consequences associated with that event.26 The Mantel-Haenszel $\chi^2$ test for linear trend in proportions was used to evaluate whether increasing numbers of family strengths (classified as 0, 1, 2, 3, 4, 5, or 7) were associated with reductions in adolescent pregnancy and with reductions in early initiation of sexual activity.27 Covariates in all models included age, education, and race (“other” vs “white”). Additionally, both ACE and adolescent pregnancy were included in models that examined whether there was a long-lasting protective effect of childhood family strengths on the psychosocial consequences described earlier.

Maximum likelihood ratio $\chi^2$ were used to evaluate whether the effect of childhood family strengths was significantly modified by the presence of ACE.

Finally, we examined the protective association between childhood family strengths and both adolescent pregnancy and unfavorable psychosocial consequences persisted in analyses stratified by birth cohort, to assess whether our findings might have been influenced by changes in these outcomes over time.

Results

Our study population was racially mixed (76% white), most had attended or completed college, and more than half were age 50 years or older at the time of interview (Table 2). Those reporting 6 or 7 family strengths were significantly more likely than those reporting fewer family strengths to be age 65 years or older at interview and to be unem-

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number of family strengths</th>
<th>Total participants</th>
<th>6 or 7 (N = 3082) percentage</th>
<th>0–5 (N = 1566) percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race or ethnicity*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>3549</td>
<td>76.4</td>
<td>76.2</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>201</td>
<td>4.8</td>
<td>3.4</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>191</td>
<td>3.4</td>
<td>5.6</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>416</td>
<td>9.4</td>
<td>8.0</td>
<td></td>
</tr>
<tr>
<td>American Indian</td>
<td>18</td>
<td>0.4</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>273</td>
<td>5.6</td>
<td>6.5</td>
<td></td>
</tr>
<tr>
<td>Education*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some high school</td>
<td>381</td>
<td>7.3</td>
<td>9.9</td>
<td></td>
</tr>
<tr>
<td>High school graduates</td>
<td>800</td>
<td>17.4</td>
<td>16.9</td>
<td></td>
</tr>
<tr>
<td>Some college</td>
<td>1505</td>
<td>40.9</td>
<td>44.9</td>
<td></td>
</tr>
<tr>
<td>College graduates</td>
<td>1962</td>
<td>34.4</td>
<td>28.4</td>
<td></td>
</tr>
<tr>
<td>Age at interview (years)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19–34</td>
<td>547</td>
<td>11.8</td>
<td>11.8</td>
<td></td>
</tr>
<tr>
<td>35–49</td>
<td>1252</td>
<td>24.5</td>
<td>31.7</td>
<td></td>
</tr>
<tr>
<td>50–64</td>
<td>1460</td>
<td>31.1</td>
<td>32.1</td>
<td></td>
</tr>
<tr>
<td>≥65</td>
<td>1389</td>
<td>32.7</td>
<td>24.4</td>
<td></td>
</tr>
<tr>
<td>Employment*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full time</td>
<td>1969</td>
<td>41.9</td>
<td>47.1</td>
<td></td>
</tr>
<tr>
<td>Part time</td>
<td>684</td>
<td>14.4</td>
<td>16.6</td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>1851</td>
<td>43.6</td>
<td>36.0</td>
<td></td>
</tr>
<tr>
<td>Adverse childhood experiences*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3097</td>
<td>57.3</td>
<td>85.1</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1551</td>
<td>42.7</td>
<td>14.9</td>
<td></td>
</tr>
</tbody>
</table>

*p < 0.0005.
The Protective Effect of Family Strengths in Childhood against Adolescent Pregnancy and Its Long-Term Psychosocial Consequences

ployed or retired. Although more than half of those with a high number of childhood family strengths (6 or 7) reported having 1 or more ACE, they were significantly less likely than the group with fewer family strengths (0–5) to report a history of ACE (57% vs 85%; p < 0.0005).

Exposure to each of the seven categories of childhood family strengths was associated with a significant 30% to 40% decreased risk of adolescent pregnancy (data not shown). Compared with women who experienced family strengths never, rarely, or sometimes (“no” in Table 2), those reporting such experiences often or very often (“yes” in Table 2) had reductions in teen pregnancy for each family strength: 37% reduction for protection (35.3% vs 22.0%; RR, 0.63; 95% CI, 0.56–0.71); 42%, support (33.5% vs 19.6%; RR, 0.58; 95% CI, 0.53–0.65); 34%, closeness (30.7% vs 21.0%; RR, 0.66; 95% CI, 0.59–0.73); 37%, loyalty (33.6% vs 21.0%; RR, 0.63; 95% CI, 0.56–0.70); 29%, feeling important (29.0% vs 20.8%; RR, 0.71; 95% CI, 0.63–0.77); 34%, feeling loved (31.9% vs 21.0%; RR, 0.66; 95% CI, 0.59–0.74); and 33%, responsiveness to health care needs (31.9% vs 22.2%; RR, 0.67; 95% CI, 0.57–0.78). Furthermore, a significant trend effect on adolescent pregnancy was observed as the frequency of each childhood family strength increased, from “never/rarely” to “sometimes” to “often” to “very often” (Figure 1).

As the number of childhood family strengths increased, the risk of adolescent pregnancy decreased significantly (Table 3). Adjusted odds ratios (OR) for adolescent pregnancy were 1.0, 0.86, 0.74, 0.59, 0.55, 0.48, and 0.46, respectively, among those with 0 to 1, 2, 3, 4, 5, 6, and 7 categories of family strengths. The absolute percentage of adolescent pregnancies for women with 7 family strengths (19%) was about half that for women with 0 or 1 family strengths (39%). We found that the magnitude of protective effect of childhood family strengths on adolescent pregnancy was significantly altered by the cofactor of ACE, which functioned as an effect modifier. Among those reporting one or more ACE, there was a highly significant protective (p < 0.000001) trend effect of childhood family strengths against adolescent pregnancy. Adolescent pregnancy rates among those women with ACE decreased from 42% to 33%, 26%.

<table>
<thead>
<tr>
<th>Numbers of family strengths</th>
<th>Adolescent pregnancy, percentage</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 or 1 (340)</td>
<td>38.8</td>
<td>1.0 (referent)</td>
<td>1.0 (referent)</td>
</tr>
<tr>
<td>2 (340)</td>
<td>33.2</td>
<td>0.82 (0.60–1.1)</td>
<td>0.86 (0.62–1.2)</td>
</tr>
<tr>
<td>3 (285)</td>
<td>29.5</td>
<td>0.69 (0.50–0.96)</td>
<td>0.74 (0.52–1.0)</td>
</tr>
<tr>
<td>4 (273)</td>
<td>25.3</td>
<td>0.56 (0.40–0.79)</td>
<td>0.59 (0.41–0.85)</td>
</tr>
<tr>
<td>5 (323)</td>
<td>23.5</td>
<td>0.51 (0.36–0.71)</td>
<td>0.55 (0.39–0.77)</td>
</tr>
<tr>
<td>6 (664)</td>
<td>21.4</td>
<td>0.45 (0.34–0.60)</td>
<td>0.48 (0.36–0.65)</td>
</tr>
<tr>
<td>7 (2407)</td>
<td>19.4</td>
<td>0.40 (0.32–0.50)</td>
<td>0.46 (0.36–0.59)</td>
</tr>
</tbody>
</table>

*Sample decreased slightly because of missing data.
*Percentage of those with the listed number of categories of childhood family strengths who experienced an adolescent pregnancy.
*All ORs are adjusted for race, education, and age at interview.
CI = confidence interval. OR = odds ratio.

p for trend < 0.0001.

Figure 1. Risk of adolescent pregnancy according to characterization of childhood family strengths.

*p < 0.05.
and 24%, respectively, for those reporting 1 to 2, 2 to 3, 4 to 5, and 6 to 7 categories of childhood family strengths (Table 4). After adjustment, we observed a 46% reduction in adolescent pregnancy rates (adjusted OR = 0.54) among with both high family strengths (6 or 7 categories) and coexisting ACE, compared with women with low childhood family strengths (0 or 1 category) and coexisting ACE.

Women without ACE, regardless of their family strengths, were at lower risk of adolescent pregnancy than the reference group (ACE, 0 or 1 family strengths; Table 4). No significant difference was seen in the risk of adolescent pregnancy among those with 6 or 7 family strengths (14%) and those with 0 to 5 (combined rate of 17.3%).

We also examined whether childhood family strengths were associated with delays in initiation of sexual activity in analyses that simultaneously considered ACE (Table 5). Among women with ACE, significant protective trends (p < 0.005) against initiation of sexual activity either before age 15 years or at ages 15 to 19 years (compared with initiation of sexual activity at ages 20 years and older) were seen with greater numbers of childhood family strengths; however, the lowest risk of early initiation of sexual activity was consistently observed among women without ACE and was consistent across the 0 to 7 range of childhood family strengths. Of those with ACE and 0 or 1 family strength, 67.6% initiated sex at age 15 to 19 years; among those with ACE and 6 or 7 family strengths, 57.5% initiated in this age range; among those without ACE and 0 to 7 family strengths, 40.4% of women initiated sexual activity at age 15 to 19 years.

Finally, we analyzed long-term psychosocial consequences, which were measured at the time of interview, when the interviewees were at a mean age of 56 years. We found significant positive trends

### Table 4. Numbers of childhood family strengths and adolescent pregnancy until age 18 among women with adverse childhood experiences and those without adverse childhood experiences

<table>
<thead>
<tr>
<th>Numbers of childhood family strengths</th>
<th>Adolescent pregnancy, percentage (n)</th>
<th>OR unadjusted (95% CI)</th>
<th>OR adjusted* (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>With ACE (n = 3097)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 or 1</td>
<td>42.0 (126)</td>
<td>1.0 (referent)</td>
<td>1.0 (referent)</td>
</tr>
<tr>
<td>2 or 3</td>
<td>33.2</td>
<td>0.72 (0.55–0.97)</td>
<td>0.80 (0.59–1.10)</td>
</tr>
<tr>
<td>4 or 5</td>
<td>26.1</td>
<td>0.52 (0.38–0.70)</td>
<td>0.60 (0.44–0.81)</td>
</tr>
<tr>
<td>6 or 7</td>
<td>24.2</td>
<td>0.47 (0.37–0.60)</td>
<td>0.54 (0.42–0.70)</td>
</tr>
<tr>
<td>No history of ACE (n = 1555)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 or 1</td>
<td>15.0 (6)</td>
<td>0.26 (0.11–0.64)</td>
<td>0.20 (0.08–0.51)</td>
</tr>
<tr>
<td>2 or 3</td>
<td>17.9 (12)</td>
<td>0.32 (0.17–0.62)</td>
<td>0.34 (0.17–0.68)</td>
</tr>
<tr>
<td>4 or 5</td>
<td>17.4 (22)</td>
<td>0.32 (0.19–0.53)</td>
<td>0.29 (0.17–0.50)</td>
</tr>
<tr>
<td>6 or 7</td>
<td>14.0 (183)</td>
<td>0.24 (0.18–0.32)</td>
<td>0.29 (0.22–0.38)</td>
</tr>
</tbody>
</table>

*All ORs are adjusted for race, education, and age at interview.
ACE = adverse childhood experiences; CI = confidence interval; OR = odds ratio.

### Table 5. Childhood family strengths and adverse childhood experience status as predictor of age of initiation of sexual activity

<table>
<thead>
<tr>
<th>Numbers of family strengths and ACE</th>
<th>Age of initiation of sexual activity (N = 4389)*</th>
<th>15 years</th>
<th>15–19 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Percentage (n/N)</td>
<td>p for trend</td>
<td>Percentage (n/N)</td>
</tr>
<tr>
<td>0 or 1 with ACE (N = 287)</td>
<td>8.7 (25/287)</td>
<td>&lt; 0.005</td>
<td>67.6 (194/287)</td>
</tr>
<tr>
<td>2 or 3 with ACE (N = 532)</td>
<td>6.6 (35/532)</td>
<td>&lt; 0.005</td>
<td>63.4 (337/532)</td>
</tr>
<tr>
<td>4 or 5 with ACE (N = 450)</td>
<td>6.9 (31/450)</td>
<td>&lt; 0.005</td>
<td>58.4 (263/450)</td>
</tr>
<tr>
<td>6 or 7 with ACE (N = 1678)</td>
<td>3.0 (50/1678)</td>
<td>&lt; 0.005</td>
<td>57.5 (965/1678)</td>
</tr>
<tr>
<td>0–7 without ACE (N = 1442)</td>
<td>1.0 (15/1442)</td>
<td>&lt; 0.005</td>
<td>40.4 (582/1442)</td>
</tr>
</tbody>
</table>

*Sample decreased because of missing data.
* Compares age of initiation of sexual activity with that of women age ≥20 years, among whom the following distributions were observed: 23.7% (66/287), 30.1% (160/532), 34.7% (136/450), 29.5% (663/1678), and 38.6% (843/1442) among women with these numbers of family strengths: 0 or 1 with ACE, 2 or 3 with ACE, 4 or 5 with ACE, 6 or 7 with ACE, 0–7 without ACE.
ACE = adverse childhood experiences.
for childhood family strengths and each of the psychosocial outcomes considered, including serious or disabling problems with jobs, family, or finances, high stress, or uncontrollable anger (Table 6). After adjusting for age, race, education, adolescent pregnancy, and history of coexisting childhood abuse or family dysfunction, we found that a high number of family strengths (6 or 7) led to a significant protective effect against job, family, and financial problems, as well as uncontrollable anger. These findings did not vary by whether ACE were reported.

In analyses stratified by age cohort (19–34, 35–49, 50–64, and ≥65 years), we found a significant trend for each age cohort when we compared the number of childhood family strengths with the rate of adolescent pregnancy (data not shown). For 0 or 1, to 2 or 3, 4 or 5, and 6 or 7 family strengths, we found that the risk of adolescent pregnancy was decreased as numbers of family strengths increased (p for trend for each group < 0.0001): 19–34 years: 42.9%, 25.6%, 28.1%, and 16.1%; 35–49 years: 38.2%, 36.6%, 26.4%, and 21.0%; 50–64 years: 39.7%, 35.2%, 26.3%, and 24.0%; and ≥65 years: 36.6%, 22.7%, 18.0%, and 16.4%. Also, for each age cohort, the odds of psychosocial consequences decreased as numbers of family strengths increased (data not shown).

### Table 6. Numbers of childhood family strengths and long-term psychosocial problems*

<table>
<thead>
<tr>
<th>Long-term psychosocial consequences</th>
<th>Numbers of categories of family strengths</th>
<th>0 or 1</th>
<th>2 or 3</th>
<th>4 or 5</th>
<th>6 or 7</th>
<th>p for trend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job problems</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage (n)</td>
<td></td>
<td>0.26</td>
<td>0.43</td>
<td>0.27</td>
<td>0.77</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>OR adj (95% CI)</td>
<td></td>
<td>0.80</td>
<td>0.41</td>
<td>0.96</td>
<td>0.61</td>
<td></td>
</tr>
<tr>
<td>Family problems</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage (n)</td>
<td></td>
<td>0.24</td>
<td>0.42</td>
<td>0.29</td>
<td>0.56</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>OR adj (95% CI)</td>
<td></td>
<td>0.80</td>
<td>0.41</td>
<td>0.96</td>
<td>0.61</td>
<td></td>
</tr>
<tr>
<td>Financial problems</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage (n)</td>
<td></td>
<td>0.24</td>
<td>0.42</td>
<td>0.29</td>
<td>0.56</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>OR adj (95% CI)</td>
<td></td>
<td>0.80</td>
<td>0.41</td>
<td>0.96</td>
<td>0.61</td>
<td></td>
</tr>
<tr>
<td>High stress</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage (n)</td>
<td></td>
<td>0.26</td>
<td>0.43</td>
<td>0.27</td>
<td>0.77</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>OR adj (95% CI)</td>
<td></td>
<td>0.80</td>
<td>0.41</td>
<td>0.96</td>
<td>0.61</td>
<td></td>
</tr>
<tr>
<td>Uncontrollable anger</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage (n)</td>
<td></td>
<td>0.24</td>
<td>0.42</td>
<td>0.29</td>
<td>0.56</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>OR adj (95% CI)</td>
<td></td>
<td>0.80</td>
<td>0.41</td>
<td>0.96</td>
<td>0.61</td>
<td></td>
</tr>
</tbody>
</table>

*p ORs are adjusted for age, race, education, adolescent pregnancy and ACE. ACE = adverse childhood experiences; CI = confidence interval; OR adj = adjusted odds ratio.

Discussion

Our study findings indicate that a positive childhood protects against adolescent pregnancy in a graded fashion when the character of that childhood is measured in identifiable family strengths. The progressively protective effects of childhood family strengths were especially noteworthy among those who reported ACE, where those with the highest level of family strengths had roughly half the risk of adolescent pregnancy of those with only one or no family strengths. We also found that childhood family strengths were especially protective of early initiation of sexual intercourse among those women who had experienced child abuse or household dysfunction, as measured by ACE. More than half of the women with high levels of childhood family strength reported one or more ACE, indicating that ACE are by no means incompatible with living in a family with numerous strengths. Moreover, we observed that increases in the number of childhood family strengths were associated with progressive reductions in long-term psychosocial problems that have been attributed to adolescent pregnancy, including serious problems with jobs, family, finances, and uncontrollable anger.

Our findings are consistent with those of previous reports, indicating that the quality of family relationships influences the adoption of sexual risk behaviors associated with adolescent pregnancy. Specifically, adolescents who perceive their family communication as good or their parents as supportive tend to engage in safer sexual behaviors, including having a later sexual debut, having fewer
sex partners, and increasing condom use.\textsuperscript{7,9,30,31} Similarly, adolescent females who have positive perceptions of their parental relationships appear less likely to experience adolescent pregnancy.\textsuperscript{7,32}

The fundamental role of family strengths in promoting adolescent health was persuasively demonstrated through the National Longitudinal Study on Adolescent Health,\textsuperscript{5,35,34} which showed that family assets protected adolescents from young age at sexual debut, emotional distress, suicidal thoughts and behaviors, violence, cigarette use, alcohol use, and marijuana use.\textsuperscript{9}

This report extends our previous work, which demonstrated that ACE have a cumulative detrimental effect on both adolescent pregnancy and long-term psychosocial problems that are often attributed to adolescent pregnancy.\textsuperscript{22,35} Here, we found that family strengths during childhood appear to be factors that protect women against both the harmful short-term (e.g., adolescent pregnancy) and long-term effects (e.g., psychosocial consequences) of ACE. Furthermore, our findings suggest that the behavioral mechanisms through which childhood family strengths act may delay initiation of sexual activity. Some of the same qualities believed to account for the success of youth-development programs in preventing adolescent pregnancy may explain the effectiveness of family strengths: Both may build competence and confidence by promoting supportive relationships with parents, peers, and/or mentors.\textsuperscript{3,36–38} It is also conceivable that strong familial interpersonal connectedness during childhood may reduce the tendency to seek that relational closeness by engaging in early sexual activity.

We considered limitations that might have biased our findings. The need to recall exposure to childhood family strengths and ACE might have led to either their under- or over-reporting, but we would not expect mistakes in reporting to differ between those who did and who did not experience an adolescent pregnancy. Thus, any errors in reporting would likely have led to underestimation of the strength of association between family childhood strengths and adolescent pregnancy. A second concern is that our interest in whether childhood family strengths protected against long-term psychosocial sequelae commonly associated with adolescent pregnancy required us to enroll a cohort whose exposure to these protective family strengths occurred three or more decades earlier. Given the many changes that have taken place in the decades since the older women in our cohort were children, the question of whether our findings can be generalized to adolescents or young women of today must be raised. However, even a prospective study addressing long-term sequelae would face this same limitation. The fact that our results regarding both adolescent pregnancy and long-term sequelae for each of the birth cohorts followed the same pattern seen in the general analysis suggests that our findings of a protective effect of family strengths against both adolescent pregnancy and long-term outcomes are robust and enduring.

At a national level, the Healthy People 2010 initiative proposed lowering pregnancy rates for 15- to 17-year-olds by approximately 35% by 2010,\textsuperscript{39} with programs strategically focused on youth development and/or changing sexual practices.\textsuperscript{3,38} Our findings suggest that reductions in teen pregnancy may be facilitated by including programs that build family strengths and that such programs appear to have particular potential for prevention among those who have experienced adversity as children. Interventions directed at strengthening the family have a unique potential to provide continuous, progressive, and timely guidance that should improve decision making about sexual and reproductive health matters among adolescents, including promotion of abstinence and prevention of pregnancy among adolescents. Olds et al\textsuperscript{40,41} have shown that interventions by public-health nurses directed at strengthening at-risk families by home visits can be effective. Public health, media, and Web-based programs that build family strengths in childhood have a strong potential to prevent adolescent pregnancy. Our findings suggest that such strengths have favorable consequences for women’s health that likely persist for many years. \textbullet

Disclosure Statement

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

Acknowledgments

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The Protective Effect of Family Strengths in Childhood against Adolescent Pregnancy and Its Long-Term Psychosocial Consequences


Prevention and Cure

“Just say no” prevents teenage pregnancy the way
“Have a nice day” cures depression.

— Anonymous
“Slot Canyon Lower Antelope Valley, Page, Arizona”
photograph

Gerald Levy, MD, MBA

Gerald Levy, MD, MBA, is a Rheumatologist at the Downey Medical Center in CA. Dr Levy has been taking pictures for more than 40 years, beginning with black and white and processing the film with his father in their makeshift darkroom. This photograph was taken with a Nikon D700 using a tripod.
Effects of 12- and 24-Week Multimodal Interventions on Physical Activity, Nutritional Behaviors, and Body Mass Index and Its Psychological Predictors in Severely Obese Adolescents at Risk for Diabetes

Abstract

Background: Although 7% of US adolescents have impaired fasting glucose, a precursor of type 2 diabetes, research has suggested that few interventions for obese adolescents at risk for diabetes have been effective. Therefore, pediatricians seek effective behavioral treatments for referral for this age group.

Objective: We wanted to determine the effects of two different durations of nutritional and exercise treatments on changes in nutrition, physical activity, body mass index (BMI), and psychological predictors of BMI change in overweight and obese adolescents at risk for type 2 diabetes.

Methods: We obtained data from 64 pediatrician-referred patients with diabetes risk factors (mean age, 14.1 years; BMI ≥ 99th percentile). Study participants were assigned to nutrition and exercise treatments for 12 weeks (n = 35) or 24 weeks (n = 29). A specific weight-loss goal was given only for the 24-week group.

Results: Both treatments demonstrated significant within-group changes over 12 weeks in days per week of physical activity of at least 60 minutes, physical self-concept, general self, and overall mood. However, they failed to demonstrate significant 12-week increases in fruit and vegetable intake, decreases in sweetened-beverage consumption, or decreases in BMI. Between-group differences were found only in mood changes in favor of the 12-week treatment. In the 24-week treatment, BMI change from week 12 to week 24 was significantly better than corresponding normative data (d = 0.37). Physical self-concept, general self, and mood scores at week 12 explained a significant portion of the variance in BMI change (R² = 0.13, p = 0.04).

Conclusion: Nutrition education alone may be insufficient for nutrition behavior change. Behavioral treatment lasting longer than 12 weeks and having a specific weight-loss goal may be useful for BMI improvements, and attention to participants’ self-concept and mood may be important treatment considerations.

Introduction

In 2000, 7% of adolescents in the US had impaired fasting glucose, a precursor of type 2 diabetes. An inappropriately high body weight is a major risk factor for the development of diabetes in youth. Although it is also a problem for younger children, recent data indicate that more than one-third of US adolescents between ages 12 and 19 years are overweight (body mass index [BMI] in the 85th to 94.9th percentile) or obese (BMI ≥ 95th percentile), with the highest prevalence of obesity being in African-American teenagers at 24%. It is suspected that an inadequate, high-calorie diet and a physically inactive lifestyle are largely to blame. Objective analyses of physical activity of 12- to 15-year-olds suggest that only 8% obtain the minimum exercise level of 60 minutes on each of 5 days per week (a total of 300 minutes/week). Analyses of adolescents’ eating patterns suggest that consumption of an overabundance of sweetened beverages and low consumption of fruits and vegetables predicts overweight and obesity. Because it is a time of increasing independence from parents, adolescence presents an im-

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Ann M Walsh, MS, RD
Alice E Smith, MS, MBA, RD
Important opportunity for establishing physical activity and eating patterns that will minimize health risks such as obesity throughout the life span.4

Because pediatricians are rarely able to dedicate sufficient time to each patient, they seek to refer adolescent patients with obesity and risks for diabetes to external treatment providers.4 Overall, however, results of such treatments have been disappointing. Recent research suggests that only about 1 in 5 youth interventions studied since the mid-1980s were successful at significantly reducing gain in BMI, with effect sizes being smallest in those who were beginning adolescence.5 Although increased physical activity and an improved diet are consistent strategies of overweight and obese adolescents successful at weight loss10 and are included in virtually all interventions, a true picture of what is specifically required to reliably induce weight management in this age group remains unclear. For example, treatment approaches range from an emphasis on social support and acceptance of one’s body, with nominal accountability for actual behavioral changes and results,11,12 to a high focus on measurable short- and long-term goals, use of behavioral strategies (eg, positive self-talk, cognitive restructuring, stimulus control), and regular tracking of goal progress.13

Regarding the nutritional component of interventions, some research points to the benefits of an educational approach,14 whereas other studies suggest that a strong behavior-modification focus is critical.15 Treatments may also be educational but have a high focus on specific nutrition behaviors such as consumption of fruits, vegetables, and sweetened beverages (eg, Type 2 Diabetes Intervention and Prevention Programs [TIPPs]).16 Although some studies suggest that parental involvement is essential,17 others indicate no additional effect on BMI.9 The intervention component of promoting increased physical activity has also appeared in divergent forms. Information approaches intended to be palatable specifically to adolescents have been attempted,18 whereas more invasive, behaviorally based methods that focus on building feelings of competence and improved feeling states through measurable progress have also been administered.19 The Coach Approach protocol, for example, is an extensively tested exercise support protocol. It was originally intended for adults and seeks to increase physical activity through building self-regulatory skills to counter lapses, even in the face of barriers such as physical discomfort, self-consciousness, and slow progress.20 Process goals such as increase in minutes spent doing physical activity each week are initially emphasized, with outcome goals such as a specific reduction in weight soon added. Research suggests that the induction of self-competence, self-esteem, and improved mood through usage of behavioral skills needed to maintain an exercise program also positively affects weight loss through carryover effects on eating behaviors.21,22 Physical activity has also been shown to improve low mood,23 which is associated with obesity in adolescents.24

The length of treatment required for meaningful improvements in weight is also unclear. Such data are needed for the development of comprehensive interventions that will also address maintenance of weight loss (which may require processes distinctly different from losing weight).13,23 Although a meta-analysis demonstrated a surprising overall inverse relationship between treatment length (in weeks) and reduction in BMI gain,9 effective interventions ranged widely from 5 to 84 weeks.23–28 Effects were also significantly greater for girls than for boys in this research.2 A meta-analysis of school-based interventions for youth suggested that treatments lasting longer than one year increased positive effects on obesity when contrasted with treatments of shorter durations.29 The Coach Approach treatment demonstrated additional effects on physical activity at weeks 12 through 24 in individuals 18 years and older30; however, an intervention for 5- to 12-year-olds that was based on the same behavior-change principles demonstrated significant BMI improvements at only 12 weeks, with no difference in effects by sex.31

Thus, we decided that a preliminary study was warranted to investigate several of the treatment variables that are presently unclear regarding their effects on adolescents of an inappropriately high weight and at risk for diabetes. The study would incorporate into the protocol for each of the two tested groups a 12-week educationally based nutrition treatment component with parental involvement, emphasizing increased fruit and vegetable intake and reduced consumption of sweetened beverages (TIPPs).16 Additionally, the Coach Approach protocol would serve as the physical activity support component and be abbreviated to 12 weeks in one group and would be incorporated for its full 24 weeks in the other. Only the group with 24 weeks of treatment would have a specific amount of weight loss designated as a goal. This is consistent with Coach Approach processes that emphasize such outcome goals in weeks 12 through 24. A YMCA setting would be used for treatment administration to increase generalizability of...
findings, which we deemed to be an important consideration. We would assess changes in a 12-week period in physical activity, fruit and vegetable intake, consumption of sweetened beverages, physical self-concept, general self, overall mood, and BMI, as well as longer-term effects on physical activity and BMI for the 24-week group. Additionally, we would evaluate physical self-concept, general self, and mood for their ability to predict short-term change in BMI. We hoped that the results of this preliminary investigation would help to inform future, more comprehensive, research where findings might ultimately be applied to treatment design, duration, and administration methods, and that our results would also contribute to theory related to psychological factors' effects on weight management.

Methods
Participants
Pediatricians referred patients fulfilling the inclusion criteria to health-promotion administrators from Children’s Healthcare of Atlanta, who then contacted parents or guardians to determine interest in participation. Inclusion criteria were 1) age of 12 to 17 years, 2) age- and sex-adjusted BMI ≥ 85th percentile, 3) an additional risk factor for diabetes (a list of possible risk factors that included race/ethnicity, family history, and conditions associated with insulin resistance [eg, acanthosis nigricans, hypertension, and dyslipidemia was provided to the physicians), and 4) willingness of parents or guardians to attend scheduled classes concerning their child’s nutrition and physical-activity needs. A written statement of sufficient health to participate was also required from the referring physician.

Group assignment was based on date of referral. Approximately 80% of referred patients and their parents or guardians accepted the offer to participate at no cost to them. Group 1 (n = 35) and group 2 (n = 29) did not significantly differ on sex (overall composition, 69% female), age (overall mean, 14.1 years; standard deviation [SD], 1.8), BMI (overall mean, 37.5 kg/m²; SD, 7.0, which corresponded to above the 99th age- and sex-adjusted percentile for BMI), or ethnic or racial group make-up (overall composition: 8% white, 90% African American, and 2% of other ethnic or racial groups). Written informed consent was obtained from parents or guardians, and written assent was obtained from participants. Appropriate approval was received from the institutional review board of Children’s Healthcare of Atlanta.

Measures
All surveys were intended by their developers for the study’s age group and/or previously used in related research with that same age group.

Nutrition—Two items from the Food Frequency Questionnaire for Youth were used to recall the combined number of fruits and vegetables typically consumed per day at the time of survey administration. One item was used to recall the number of sweetened beverages consumed per day. Examples of possible fruits, vegetables, and sweetened beverages were given in corresponding items. Items were similar to those in the Behavioral Risk Factor Surveillance System. Responses ranged from “3 or more times a day” to “never.” Test-retest reliabilities over 48 hours ranged from 0.67 to 0.77.

Physical Activity—An item adapted from the Youth Risk Behavior Survey was used to measure the number of days “over a typical or usual week” that the respondent was “active for a total of at least 60 minutes per day” (excluding physical education classes). A minimum of 60 minutes is the recommended daily duration of moderate-to-vigorous physical activity for children and adolescents. Instructions were to include any kind of physical activity that increased heart rate and caused hard breathing “at least some of the time.” The directions required physical activity during physical education to be excluded because as with recent research, physical activity carried out of one’s own volition (rather than because it was mandated) was of primary interest.

Physical Self—The Physical Self-Concept Scale, a subscale of the Tennessee Self-Concept Scale: 2 Child Form, measures feelings of adequacy regarding the physical self. Responses for the 12-item scale (eg, “My body is healthy”) range from 1 (always false) to 5 (always true). Internal consistency for adolescents averaged 0.70, and test-retest reliability during a one-week period was 0.71. Validity was supported through significant correlations between Physical Self-Concept Scale scores and scores on the Piers-Harris Children’s Self-Concept Scale and other generally accepted inventories of physical characteristics and activities.

Overall Self—The General Self Scale is a subscale of the Self-Description Questionnaire. It measures an adolescent’s perceptions of his or her overall self. The eight-item scale (eg, “Overall I have a lot to be proud of”) requires responses that range from 1 (false) to 5 (true). Internal consistency of the scale was 0.81. Although usual test-retest
Methods were considered inappropriate because of expected changes in the measured construct over time, findings suggested systematic change during a six-month period. Validity was supported through significant correlations between General Self Scale scores and scores on the Perceived Competence Scale and other well-accepted inventories of the overall self.

Mood—Total Mood Disturbance is an aggregate measure of mood derived from the six subscales of the Profile of Mood States—Short Form. Respondents rate feelings that occurred “over the past week” on 30 items ranging from 0 (not at all) to 4 (extremely). Internal consistency for the Tension, Depression, Fatigue, Confusion, Anger, and Vigor subscales ranged from 0.81 to 0.95, and test-retest reliability at three weeks averaged 0.69. Concurrent validity was suggested through contrasts with generally accepted measures such as the Beck Depression Inventory, Manifest Anxiety Scale, and Minnesota Multiphasic Personality Inventory.

Body Composition—A digital scale and stadiometer were used to calculate BMI, an estimate of health risks associated with body fat, which is derived from a ratio of weight to height (kg/m²). Correlations with the most precise measure of body fat, dual energy x-ray absorptiometry, have been reported as ranging from 0.80 to 0.90 in other studies. Recent research suggests that for children, direct measurement of BMI change is advantageous, rather than adjustment of BMI by percentile or z-score. However, we also used age- and sex-adjusted BMI percentile data, which were based on data from the National Center for Health Statistics, for descriptive purposes. A BMI change score for each participant was derived by subtracting the score at baseline from the score at week 12.

Procedure

For both groups, participants and at least one parent or guardian reported to the YMCA that served as the experimental facility for a brief orientation with a study administrator. Components of either the 12-week (group 1) or 24-week (group 2) treatment process were described to them on the basis of their date of referral. For both groups, the 12-week TIPPs protocol was the basis of the nutritional portion of the treatment. It included six 30-minute group classes for parents and six 45-minute group classes for participants and their parents or guardians (on alternate weeks) that were lead by specially trained registered dietitians. Structured education and interaction on topics such as “Building a Healthy Plate,” “Beverages for Teens,” “Healthy Snack Sharing,” “Parents as Role Models,” “Meal Planning/Grocery Shopping,” and “Recipe Sharing” was provided and supported by interactive workbooks. The dietitians were also available for brief individual consultations if requested by participants or their parents or guardians. Throughout the treatment, appropriate eating, with a specific focus on reducing consumption of sweetened beverages and increasing fruit and vegetable consumption, was emphasized.

The Coach Approach protocol was the basis of the physical activity support portion of the treatment. It was administered by a trained YMCA wellness specialist via a series of monthly one-on-one meetings, guided by a computer program. The Coach Approach has previously been associated with increased physical activity in adults with and without obesity. Duration of the Coach Approach treatment was reduced to 12 weeks (four meetings) for group 1. It was for the usual 24 weeks (six meetings) for group 2. Within the meetings, a focus was kept on specific goals. Although short-term goals were kept process-orientated (eg, increase cumulative cardiovascular exercise from 150 to 250 minutes per week within one month) for the initial 12 weeks, outcome-orientated goals (eg, lose 5 lb [2.3 kg] per month) were added in the final 12 weeks for group 2. At least 5% weight loss by treatment termination (week 24) was incorporated as a long-term outcome goal for all participants in group 2. Physical activity data were entered electronically so that goal progress could be highlighted.

A behavioral contract to complete an agreed-on volume of regular exercise, along with training in an array of self-management and self-regulatory skills such as cognitive restructuring, stimulus control, and relapse prevention, was included within meetings. Physical activity modalities and volumes were selected in cooperation with an exercise specialist and revised on the basis of individual progress. Participants were free to use all YMCA exercise facilities anytime or, alternatively, exercise outside of the facility. Typical exercise regimens included use of treadmills, stationary bicycles, and resistance bands; however, physical activities such as group exercise classes, walking on a track, or swimming could also be selected.

Treatment fidelity was monitored by a study administrator. Physiological tests and surveys were administered at baseline and at week 12 in a private area, and participants’ identifying data were
removed. Only BMI and physical activity level were also recorded at week 24 (for group 2).

**Data Analyses**

Statistical significance was set at α = 0.05 (two-tailed). Consistent with recent related research, \(^4^4\) imputation due to missing data (for the 8% of missing cases overall) was by the last-observation-carried-forward method. Missing BMI scores were additionally adjusted for expected increases associated with maturation.\(^4^3\) Analyses of skewness and kurtosis suggested that the data were distributed approximately normally, and thus use of parametric statistical testing was appropriate. Because of the exploratory nature of this small-sample field investigation, and recent suggestions,\(^4^4\) there were no statistical adjustments for multiple tests.

A series of mixed-model repeated-measures analyses of variance (ANOVAs) were first conducted to determine whether changes during the 12-week period in physical activity level, consumption of fruits and vegetables, number of sweetened beverages consumed, and Physical Self-Concept Scale, Total Mood Disturbance, General Self Scale and BMI scores at baseline. There were no significant improvements during the 12 weeks in consumption of fruits and vegetables scores \((F[1, 62] = 0.36; p = 0.55)\) or number of sweetened beverages consumed \((F[1, 62] = 3.54; p = 0.07)\). There were significant improvements in physical activity level \((F[1, 62] = 68.27; p < 0.001; \eta^2 = 0.524)\), and Physical Self-Concept Scale \((F[1, 62] = 9.73; p = 0.003; \eta^2 = 0.135)\) and General Self Scale \((F[1, 62] = 25.19; p < 0.001; \eta^2 = 0.289)\) with no significant between-group differences. Improvements in Total Mood Disturbance scores were significant \((F[1, 62] = 36.68; p < 0.001; \eta^2 = 0.38)\), with group 1 demonstrating significantly greater improvements \((F[1, 62] = 4.62; p = 0.04; \eta^2 = 0.045)\; see Table 1 for descriptive statistics). A planned within-group contrast indicated that physical activity level at week 24 was not significantly different from that at week 12 (for group 2).

**Results**

**Changes in Behavioral and Psychological Variables**

There were no significant between-group differences in physical activity level, consumption of fruits and vegetables, number of sweetened beverages consumed, and Physical Self-Concept Scale, Total Mood Disturbance, General Self Scale and BMI scores at baseline. There were no significant improvements during the 12 weeks in consumption of fruits and vegetables scores \((F[1, 62] = 0.36; p = 0.55)\) or number of sweetened beverages consumed \((F[1, 62] = 3.54; p = 0.07)\). There were significant improvements in physical activity level \((F[1, 62] = 68.27; p < 0.001; \eta^2 = 0.524)\), and Physical Self-Concept Scale \((F[1, 62] = 9.73; p = 0.003; \eta^2 = 0.135)\) and General Self Scale \((F[1, 62] = 25.19; p < 0.001; \eta^2 = 0.289)\) with no significant between-group differences. Improvements in Total Mood Disturbance scores were significant \((F[1, 62] = 36.68; p < 0.001; \eta^2 = 0.38)\), with group 1 demonstrating significantly greater improvements \((F[1, 62] = 4.62; p = 0.04; \eta^2 = 0.045)\; see Table 1 for descriptive statistics). A planned within-group contrast indicated that physical activity level at week 24 was not significantly different from that at week 12 (for group 2).

**Table 1. Descriptive statistics for behavioral and psychological variables, plus body mass index (BMI)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>Week 12</th>
<th>Week 24</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Physical activity level(^a)</td>
<td>1.74</td>
<td>1.60</td>
<td>3.31</td>
</tr>
<tr>
<td>Group 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>1.97</td>
<td>1.09</td>
<td>3.55</td>
</tr>
<tr>
<td>Combined number of fruits and vegetables</td>
<td>2.71</td>
<td>0.86</td>
<td>2.77</td>
</tr>
<tr>
<td>Group 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>3.03</td>
<td>0.94</td>
<td>2.83</td>
</tr>
<tr>
<td>Number of sweetened beverages consumed per day</td>
<td>2.03</td>
<td>1.25</td>
<td>1.97</td>
</tr>
<tr>
<td>Group 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>2.52</td>
<td>1.38</td>
<td>1.93</td>
</tr>
<tr>
<td>Physical Self-Concept Scale</td>
<td>38.71</td>
<td>6.29</td>
<td>41.14</td>
</tr>
<tr>
<td>Group 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>39.52</td>
<td>4.39</td>
<td>41.45</td>
</tr>
<tr>
<td>Total Mood Disturbance</td>
<td>11.51</td>
<td>14.19</td>
<td>-1.89</td>
</tr>
<tr>
<td>Group 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>7.44</td>
<td>8.74</td>
<td>1.07</td>
</tr>
<tr>
<td>General Self Scale</td>
<td>30.57</td>
<td>4.83</td>
<td>33.06</td>
</tr>
<tr>
<td>Group 1</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Group 2</td>
<td>32.14</td>
<td>4.68</td>
<td>35.00</td>
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<tr>
<td>BMI</td>
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</tr>
<tr>
<td>Group 2</td>
<td>38.80</td>
<td>6.14</td>
<td>38.88</td>
</tr>
</tbody>
</table>

\(^a\) Active for a total of at least 60 minutes per day.

Group 1, n = 35; group 2, n = 29.

SD = standard deviation.
**Changes in Body Mass Index**

When contrasted with normative changes in BMI during the 12-week period (mean, 0.23), changes in both group 1 (mean, 0.12; SD, 1.39) and group 2 (mean, 0.08; SD, 0.81) were not significantly different ($t_{154} = 0.20; p = 0.84$; $d = 0.07$; 95% confidence interval [CI] = –0.33 to 0.47). During the 24-week period (mean, 0.27; SD, 1.70), group 1 (mean, 0.12; SD, 1.39) and group 2 (mean, 0.08; SD, 0.81) were also more favorable from week 12 to week 24 (mean, –0.35; SD, 0.96; $r_{28} = 3.25; p = 0.003$; $d = 0.37$; 95% CI = –0.59 to –0.11) (Figure 1).

**Prediction of Body Mass Index Change**

A significant 13% of the variance in BMI change was accounted for by simultaneous entry of Physical Self-Concept Scale, Total Mood Disturbance, and General Self Scale scores at week 12 into a multiple-regression equation (Table 2, model 1). There were no differences in the variance in BMI change explained, adjusted for number of predictors ($R^2_{adj}$), by adding group membership into the equation (Table 2, model 2).

**Post Hoc Analyses**

**Effects of Sex**—To test whether sex affected the various relationships, we conducted additional analyses. Linear bivariate correlations indicated that participants’ sex was not significantly associated with physical activity level, consumption of fruits and vegetables, number of sweetened beverages consumed, Physical Self-Concept Scale, Total Mood Disturbance, General Self Scale, or BMI scores at week 12 ($r$ values, –0.10 to 0.14) or with changes from baseline to week 12 ($r$ values = –0.22 to 0.23). Additionally, accounting for the longer time frame for group 2, physical activity level and BMI were similarly not significantly related to participants’ sex at week 24 ($r = –0.20$ and 0.20, respectively) or change during the 24-week period ($r = –0.17$ and 0.09, respectively).

**Frequency of Recommended Volumes of Physical Activity**—In contrast to the expected 8% frequency of the recommended 5 days per week of ≥60 minutes of moderate-to-vigorous physical activity for population-based data for the participants’ age range,7 participants’ corresponding data at the aforementioned criteria were 2% at baseline, 16% at week 12, and 17% at week 24.

**Discussion**

In our samples of severely obese adolescents, referred to interventions because of their risk for diabetes, we found useful preliminary findings. Both of the treatments consisting of nutrition education and support of increased exercise through cognitive-behavioral means were associated with equivalent, significant increases in reported days per week of 60 minutes of voluntary exercise and significant

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![Figure 1. Contrast of expected changes in body mass index (BMI) with observed changes in group 1 and group 2.](image)

**Table 2. Results of simultaneous multiple-regression analyses for the prediction of changes in body mass index (BMI) in all participants (n = 64)**

<table>
<thead>
<tr>
<th>Model</th>
<th>$\beta$</th>
<th>$R$</th>
<th>$R^2$</th>
<th>$R^2_{adj}$</th>
<th>$F$</th>
<th>df</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model 1</td>
<td>0.36</td>
<td>0.13</td>
<td>0.09</td>
<td>0.04</td>
<td>3.04</td>
<td>3, 60</td>
<td>0.04</td>
</tr>
<tr>
<td></td>
<td>Physical Self-Concept Scale</td>
<td>–0.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total Mood Disturbance</td>
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Scores of psychological variables are at week 12.

Adjusted $R^2 (R^2_{adj}) = 1 – (1 – R^2) (N – 1)/(N – k – 1)$, where $k$ denotes number of predictors in the regression model.
improvements in perceptions of the physical and overall self and overall mood. BMI did not significantly decrease within 12 weeks; however, in the 24-week treatment that included a specific goal of 5% weight loss, significant BMI decreases emerged during weeks 12 through 24. It is unclear whether the extended treatment or the mandated outcome goal was not sufficient for significant BMI change to occur overall. The Physical Self-Concept Scale, General Self Scale, and Total Mood Disturbance scores at week 12 significantly predicted change in BMI. Although this suggests that these psychological factors should be an important focus of interventions, it was not clear what, specifically, in the treatments induced these changes. They were, however, consistent with findings of the Coach Approach treatment with adults.20

Because there is a dearth of related research with samples like ours, considerable study is still needed of the association of treatment-induced changes in psychological variables such as self-efficacy, self-concept, body image, anxiety, and depression, and weight loss; what treatment components maximize these effects; and their impact on physical activity, eating, and weight loss.

Because the treatments that we used failed to significantly increase intake of fruits and vegetables and to reduce consumption of sweetened beverages, researchers should seek methods to reliably accomplish these and other important nutritional outcomes for subgroups similar to that of this study. Because our intervention focused on nutrition education without establishing limits in caloric consumption, extensions of this research may seek to evaluate nutritional approaches with a more cognitive-behavioral focus, where specific parameters are provided and self-regulatory skills are a central part of the intervention. The role of parents and guardians also remains unclear and warrants additional research attention. Although treatment components effectively addressing both nutrition and physical activity appear necessary to increase the minimal improvement in BMI observed here, further research into the effects of exercise-induced psychological changes’ association with reductions in caloric intake has recently been suggested and will be important in future studies with youth at risk for diabetes.

Because of the field nature of this research and because of logistic limitations, provisions were not made for follow-up data for group 1 or for data collection beyond 12 weeks in nutrition and psychological variables for group 2. Future research should extend data collection to establish longer-term treatment effects. Also, this study’s participants were primarily African American and had quite severe obesity. Thus, replication with larger and more diverse samples is required to increase confidence in findings and test their generalizability. The applied setting also did not allow control of factors such as social support and expectation effects emanating from instructors or other participants. Practical settings such as used here, however, have been specifically advocated because of the ease in generalizing findings to treatments.21

In summary, findings suggested that areas for extending treatment research with obese adolescents with diabetes risk factors include intervention content and length and predictors of effects on BMI and eating behaviors. After further focused research and intervention trials, pediatricians may have increased confidence in referring their obese adolescent patients with additional diabetes risk factors to efficient and reliable external treatments. Until then, it appears that nutrition and exercise treatments lasting longer than three months, with a behavior-change focus that is sensitive to participants’ self-concept and mood, are prudent for referral. We suggest that professionals with a medical focus, behavior change focus, and program implementation focus coordinate their efforts to reliably improve health behaviors in youths with modifiable health risk factors. 

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

Acknowledgment
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References
5. Troiano RP, Berrigan D, Dodd KW,
Effects of 12- and 24-Week Multimodal Interventions on Physical Activity, Nutritional Behaviors, and Body Mass Index and Its Psychological Predictors in Severely Obese Adolescents at Risk for Diabetes


A Life Sentence

“Tell me about the benefits of obesity.” I asked them.
“What are the advantages of being fat?”

He had been quiet up to now, sitting in the back row of the bariatric surgery group, arms folded across his belly.
“It don’t last as long,” he said.

Confused, I asked, “What doesn’t last as long?”

“Your life,” he answered.

—Vincent J Felitti, MD, FACP, retired Internist from the Department of Preventive Medicine at the Clairemont Mesa Medical Office in San Diego, CA.
Proactive Office Encounter: A Systematic Approach to Preventive and Chronic Care at Every Patient Encounter

Abstract
In 2007, Kaiser Permanente’s (KP) Southern California Region designed and implemented a systematic in-reach program, the Proactive Office Encounter (POE), to address the growing needs of its three million patients for preventive care and management of chronic disease. The program sought staff from both primary and specialty care departments to proactively identify gaps in care and to assist physicians in closing those gaps. The POE engaged the entire health team in a proactive patient-care experience, creating standard work flows and using information technology to identify gaps in patient care. The goals were to improve consistency of preventive care and improve quality of care for chronic conditions and to improve reliability of staff support for physicians. The POE has been implemented in all outpatient settings in KP’s Southern California Region’s 13 medical centers and 148 medical office buildings. The program has contributed to significant improvements in key clinical quality metrics, including cancer screenings, blood pressure control, and tobacco cessation. It is now being extended into the inpatient setting and is being shared with other KP Regions.

Introduction
“The necessity of living with a limited supply of physicians in the face of increasing demand forces us to focus on the need for a medical care delivery system that utilizes scarce and costly medical manpower properly.” Sidney Garfield, MD, the co-founder of Kaiser Permanente (KP), wrote those words in 1970 for an article that appeared in Scientific American (reprinted in the Summer 2006 issue of The Permanente Journal), but they could well have been written today to describe the growing demands on primary care, particularly for preventive care and management of chronic disease.

The medical literature reports that for a primary care physician to ensure that all patients on a hypothetical panel of 2000 receive the preventive screenings and treatment of chronic diseases that they need, the primary care physician would need to devote an estimated 18 hours per day. That being the case, it is hardly surprising that only 54.9% of adult patients receive the preventive care recommended by medical evidence.

Southern California Permanente Medical Group (SCPMG) now serves more than three million KP patients, generating 12 million visits to outpatient offices with 60% of these visits occurring outside of primary care. The concept of the Proactive Office Encounter (POE) began as a question: How can we turn each of these encounters, in either primary or specialty care, into preventive screenings and care for chronic conditions?

This is a simple idea to describe, but implementing it meant a cultural shift. The POE, a regionwide in-reach program, gave ancillary staff and specialty departments more responsibility for preventive screenings and management of chronic care. To succeed, the team had to convince administrators, physicians, and staff of its potential value. Other key elements included:

- Electronic tools to identify gaps in any patient’s care, regardless of which department they visited
- New work flows and training modules to proactively identify gaps in care to draw them to a physician’s attention
- Reports to monitor improvement in closing gaps and to identify areas needing more support

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Team members are noted in Table 1. Staff now play a more active role in patient care and the culture has changed so that specialty departments are also responsible for identifying and addressing preventive screenings and chronic care needs. Since its inception, POE has contributed to sharp improvement in the Southern California Region’s clinical quality performance, including double-digit improvements in colorectal cancer screening, advice to quit smoking, and blood pressure control.

Additionally, the POE team created shortcuts known as SmartTools within KP HealthConnect to improve efficiency in the medical office. By scrolling through a list of common preventive care needs, a nurse or medical assistant can set up pending orders for screening examinations or supplies, immunizations, or laboratory tests and can select and print appropriate patient information on topics ranging from body mass index to tobacco cessation. Using “SmartPhrases,” staff can document preventive or chronic care actions taken.

**Early Technical Challenges**

Initially, patient information in POINT and KP HealthConnect was not integrated, creating confusion and mistrust early in the implementation of the POE tool, because alerts were sometimes inaccurate or redundant. The project team worked with Pharmacy Analytics Services and the KP HealthConnect team to integrate the POINT database and the EMR.

The team added functionality to document or to set up pending orders, streamlining these processes to make the POE tool more efficient and user-friendly.

**Electronic Tools: Step 1 in the Proactive Office Encounter**

Early attempts made to systematically identify and address preventive care needs were less comprehensive than the POE, for example, a few years ago, identifying needs required a manual search through a patient’s chart and use of a paper checklist (the Care Management Summary Sheet) to identify preventive screenings and gaps in chronic care. The Pharmacy Analytic Services group converted the paper to an electronic checklist on its Permanente Online Interactive Network Services group converted the paper to an electronic checklist, which is now available to improve efficiency in the medical office. By scrolling through a list of common preventive care needs, a nurse or medical assistant can set up pending orders for screening examinations or supplies, immunizations, or laboratory tests and can select and print appropriate patient information on topics ranging from body mass index to tobacco cessation. Using “SmartPhrases,” staff can document preventive or chronic care actions taken.

![Figure 1. Computer-screen view of a Proactive Office Encounter checklist for adult primary care.](image)

**Table 1. Proactive Office Encounter team members**

<table>
<thead>
<tr>
<th>Proactive Office Encounter team members</th>
<th>Job title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kristen Andrews</td>
<td>Proactive care group lead</td>
</tr>
<tr>
<td>Christopher Baek, MBA, PharmD</td>
<td>Project manager</td>
</tr>
<tr>
<td>Robert Blair, MPH</td>
<td>Medical Group administrator</td>
</tr>
<tr>
<td>Terry Bream, RN</td>
<td>Manager, ambulatory clinical practice</td>
</tr>
<tr>
<td>Mark Eastman, MD</td>
<td>Proactive care physician lead</td>
</tr>
<tr>
<td>Sylvia Everroad</td>
<td>Regional Medical Group administrator</td>
</tr>
<tr>
<td>Amanda Hauser DeHaven, MPH</td>
<td>Project Manager, SPCMGA regional operations</td>
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<tr>
<td>Joyce Johnson, RN-BC, PhD</td>
<td>Regional Director, education and research</td>
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<tr>
<td>Chris Jones, RN</td>
<td>Senior management consultant</td>
</tr>
<tr>
<td>Gail Lindsay, RN</td>
<td>Managing Director, clinical program development</td>
</tr>
<tr>
<td>Michael Kanter, MD</td>
<td>Regional Medical Director of quality and clinical analysis</td>
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<td>Osvaldo Martinez, MPH</td>
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<tr>
<td>Paul Minardi, MD</td>
<td>Regional Medical Director of operations</td>
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<td>Diana Moulder</td>
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<td>Monica Padilla</td>
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<tr>
<td>Christine Ruigrok, RN</td>
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</tr>
<tr>
<td>SPCMGA Medical Directors</td>
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<td>SPCMGA POE area leads</td>
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<td>Kurt VanRiper, PharmD</td>
<td>Director, Pharmacy Analytical Services</td>
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<tr>
<td>Ralph Vogel, PhD</td>
<td>Practice Leader</td>
</tr>
</tbody>
</table>

POE = Proactive Office Encounter; SPCMGA = Southern California Permanente Medical Group.
Table 2. Standard work flows for all office visits

<table>
<thead>
<tr>
<th>Setting or task category</th>
<th>Actions to take</th>
</tr>
</thead>
</table>
| **Daily preparations**  | • If not acquainted, introduce yourself to the physician and ask if there are any special work flow requests.  
• Huddle with physician during early part of the shift to plan the day.  
• Anticipate the needs of the physician for every office visit.  
• Stock examination rooms daily. Confirm that examination-room equipment is working properly.  
• Room patients in a timely manner so that physicians can start on time.  
• Obtain and review the physician preference list for additional physician-preferred work flows. |
| **Rooming a patient**    | • Enter chief complaint(s), with comments.  
• Enter vital information: blood pressure, pulse, respiratory rate, temperature, weight and height, exercise vitals, last known menstrual period for females ages 11–65 years.  
• Verify/edit tobacco history and provide local information for tobacco cessation.  
• Recheck elevated blood pressures and enter the second reading as “New Set of Vitals.”  
• Complete Interpretation Services Questionnaire as needed.  
• Review allergies and enter any newly reported allergies or adverse reactions in the “Allergy” tab.  
• **New patients:** Enter past medical and surgical history, social history, and family history in KP HealthConnect.  
• Select the preferred pharmacy, including outside pharmacy if relevant.  
• Review medications with patient and place a red check mark next to active medications—do not click “Reviewed.”  
• Set up pending refill requests using the reorder edit tool.  
• If an active medication is not in KP HealthConnect, gather the exact name, dose, and directions and set up a pending order in the “Orders” area.  
• Click the “Proactive Care” tab and advise the patient of any care gaps and the process for resolving the gaps.  
• Use the POE SmartSet to set up pending orders for POE Care Gaps, exclusion codes, and patient instructions.  
• Address any Best Practice Alerts that pop up.  
• Set up pending orders for Point-of-Care Tests, immunizations, and nursing procedures.  
• Perform any specialty-specific work flows.  
• Document POE tasks in the “Nursing Notes” section using the proactive or pedproactive Smart Phrase. |
| **Patient forms**        | • Do not give blank patient forms to physicians for completion.  
• Have patients complete their portion of forms, including medical/surgical/social history, medications, allergies, and the context or reason for the form.  
• Complete the physician’s name, office address, phone number, Drug Enforcement Administration and medical license numbers, and vitals or other patient information, if relevant.  
• Forward patient forms to the insurance department after visit, as appropriate. |
| **Preparing a patient**  | • Ensure that the patient is appropriately undressed, gowned, and prepared for the examination on the basis of the chief complaint.  
• Prepare needed supplies and instruments in advance, on the basis of the chief complaint.  
• Review and carry out any specialty-specific guidelines for patient preparation. |
| **Performing ordered procedures** | • Administer immunizations, injections, medications, and nursing procedures per physician orders.  
• Medical assistant to obtain medication verification by a licensed nurse or clinician for all medications and immunizations.  
• Input immunization information into the Kaiser Immunization Tracking System and KP HealthConnect.  
• Record results of Point-of-Care Tests using “Enter/Edit Results” tool. |
| **Discharging a patient** | • Schedule appointments as directed by the physician, using the Direct Booking Process if applicable.  
• Complete durable medical equipment orders as instructed by the physician.  
• Set up a pending e-Referral at physician’s request.  
• Complete and print Activity Rx forms per physician’s instructions.  
• Print After-Visit Summary and review patient instructions and follow-up appointments with patient.  
• Complete additional forms and documents as directed. |

KP = Kaiser Permanente; POE = Proactive Office Encounter.
Methods
Developing and Implementing New Work Flows: Step 2 in the Proactive Office Encounter

Information technology alone is not sufficient to transform the approach to preventive and chronic care. A standardized structure of work flows and processes was built to address individual care gaps in every outpatient setting (Table 2), to increase efficiency and to improve the reliability and consistency of staff support for physicians.

The POE includes three main components, detailed in the next section (Figure 2).

Before an Encounter (Pre Encounter)
Before a patient comes in, a medical assistant or nurse reviews the patient’s record to identify needed laboratory tests and health screenings, and to determine whether the patient is registered with KP.org, which gives the patient online access to most laboratory results, prescription and immunization status, and the opportunity to e-mail the physician’s office.

During an Encounter (Office Encounter)
In the office, the nurse or medical assistant follows a standard workflow (Figure 3) that includes reviewing and updating documentation of the patient’s chief complaint, vital signs, physical activity levels, medications, allergies, and preferred pharmacy. The nurse or medical assistant then:

• identifies gaps in care using decision-support tools
• sets up any necessary pending orders and/or exclusion codes for the clinician
• flags needed screenings and/or uncontrolled conditions for the clinician to discuss during the visit
• prepares the patient and examination room for procedures (eg, Papanicolaou test, diabetic foot examination, etc.), and
• assists the clinician through the process.

After an Encounter (Post Encounter)
Immediately after the visit, the medical assistant or nurse ensures that the patient receives information to obtain preventive screenings or to address health issues, including providing an after-visit summary, after-care instructions, health education materials, information on accessing KP.org, and follow-up appointments or referrals. In addition, the patient may be contacted after the visit at the clinician’s direction.

Managing the Change
Because the POE represented a cultural shift, it therefore required a comprehensive change in management approach. In 2007, the POE team widely presented the concept to internal audiences, including Medical Directors, Chiefs, nonphysician administrative leaders, and department managers.

One challenge was ensuring that tasks remained within the scope of practice for medical assistants and nurses. They identified physicians and administrators who could serve as POE team leads at the local level.

The team also developed extensive training materials for both preventive screenings and management of chronic conditions. Participants learned to use the tools and perform new tasks, for example, communication tips about sensitive patient issues, such as weight. It also provided instructions on how to prepare the patient and the examination room for specific procedures, such as a diabetic foot examination.

Persuading people to work in a new way meant...
engaging them emotionally. To demonstrate the difference that nonphysician staff can make identifying care gaps, the POE team worked with California’s Multimedia Department to produce videos of patients telling how an early screening made a difference in their lives. The videos, which have since been shown in internal meetings and are available on KP’s Intranet, included patients’ physicians and key staff (including receptionists, medical assistants, and nurses).

By the end of 2007, all primary care offices trained for the POE. The following year, specialty care staff trained on a streamlined version of the program. In 2009, staff in Urgent Care and Emergency Departments (ED) used work flows for the POE. Those concepts now extend to inpatient settings, with four pilot studies underway.

**Results**

**Measuring Improvement: Step 3 in the Proactive Office Encounter**

SCPMG measured the program’s success by tracking Healthcare Effectiveness Data and Information Set results on a bimonthly basis. In addition, SCPMG developed a new set of reports (dubbed “Successful Opportunities”) to measure improvements specific to the POE (Table 3). These reports monitor the frequency of care gaps closure within 30 days of an appointment, including lead, chlamydia, and osteoporosis screening (dual energy x-ray absorptiometry, or DEXA); pneumococcal immunizations; documentation of height and weight to capture body mass index; asthma questionnaire completion; and health education class attendance. These reports are e-mailed to regional leaders, medical center leaders, and local POE leads for identification of strengths and areas for improvement. Specialists in SCPMG have some of their at-risk moneys contingent on their performance on the Successful Opportunities Report. This has been an important step in getting the specialists involved in the POE.

The conclusions drawn from the analysis of these data reveal increased success in closing care gaps at every opportunity resulting in a 2% to 18.5% range of improvement in clinical quality for the conditions of diabetes, cancer, immunization, blood pressure, and smoking (Table 4).

**Future Potential for the Proactive Office Encounter**

In the outpatient setting, the POE allowed a shift from a reactive care-delivery model to one that is consistently proactive in addressing preventive and chronic care needs. Because SCPMG is part of an integrated system that includes Kaiser Foundation Health Plan and

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**Table 3. Proactive Office Encounter: successful opportunity care gap targets met for July 2009**

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</tbody>
</table>

*Data source: Permanente Online Interactive Network Tools (POE Reports). Successful Opportunity for each gap identified as a resulting test or procedure 30 days after appointment. Gray = POE Successful Opportunity rates are now as follows: retinal, Pneumovax, chlamydia, and DEXA at ≥25% per POE care gap identified. Diabetes Management health education departments at 10%, HbA1c, microalbumin, LDL, mammograms, Papanicolaou test, asthma, and smoking at ≥80% per POE care gap identified. BMI department at a rate of ≥80% per POE care gap identified. White = POE Successful Opportunity target not met. BMI = body mass index; BP = blood pressure; DEXA = dual energy x-ray absorptiometry; LDL = low-density lipoprotein cholesterol; POE = Proactive Office Encounter.
Proactive care is now an expectation of care delivery. Barriers encountered by the team were overcome through a collaborative approach, which involved labor partners, physicians, and leaders in the implementation from the early stages. Correlation data show a positive impact on the delivery of quality care.

**Table 4. Improvements on key quality measures since implementation of the Proactive Office Encounter**

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Diabetes lipid screening (profile) performed</td>
<td>88.6</td>
<td>91</td>
<td>90.4</td>
<td>90.6</td>
<td>2</td>
</tr>
<tr>
<td>Influenza immunization rate (members age ≥65 years)</td>
<td>60.2</td>
<td>62</td>
<td>62</td>
<td>62.5</td>
<td>2.3</td>
</tr>
<tr>
<td>Breast cancer screening (patients ages 52–69 years)</td>
<td>85.6</td>
<td>88.1</td>
<td>88.7</td>
<td>88.3</td>
<td>2.7</td>
</tr>
<tr>
<td>Diabetes glycated HbA1c testing</td>
<td>88.8</td>
<td>90.8</td>
<td>91.2</td>
<td>92</td>
<td>3.2</td>
</tr>
<tr>
<td>Cervical cancer screening</td>
<td>82</td>
<td>85.6</td>
<td>86.6</td>
<td>85.7</td>
<td>3.7</td>
</tr>
<tr>
<td>Diabetes blood pressure control &lt;140/90 mm Hg</td>
<td>76.1</td>
<td>74</td>
<td>79.5</td>
<td>82.6</td>
<td>6.5</td>
</tr>
<tr>
<td>Diabetes eye examination (retinal) performed</td>
<td>61.6</td>
<td>56.3</td>
<td>66.5</td>
<td>70.9</td>
<td>9.3</td>
</tr>
<tr>
<td>Controlling high blood pressure (patients ages 18–85 years)</td>
<td>70.4</td>
<td>72.8</td>
<td>79.6</td>
<td>82.6</td>
<td>12.2</td>
</tr>
<tr>
<td>Advising smokers to quit—January 2009</td>
<td>53</td>
<td>69</td>
<td>68</td>
<td>70</td>
<td>17</td>
</tr>
<tr>
<td>Colorectal cancer screening</td>
<td>52.5</td>
<td>65.5</td>
<td>69.7</td>
<td>71</td>
<td>18.5</td>
</tr>
</tbody>
</table>

Hospitals, there are more opportunities to expand and embed this approach throughout the organization where patients may seek care, from appointment call centers to hospital discharge.

In the near future, SCPMG intends to implement the POE in pharmacy and inpatient settings. Deployment in EDs and urgent-care settings is already in progress. Pre-encounter automated telephone calls were also piloted in 2008 and were deployed throughout SCPMG by year end. Automated pre-encounter calls target patients with HbA1c, lipid, and/or microalbumin laboratory care gaps and ask that they complete the necessary tests before their office visit to maximize their encounter with their clinician.

Implementing a proactive approach to care also involves continual improvement to the work flows already developed and requires refining the outpatient encounter with specialty-specific work flows, which are in development, for obstetrics, oncology, and nephrology.

With modification of the work flow training materials for SCPMG, other KP Regions could adopt a similar proactive approach, because other Regions have access to the same KP HealthConnect functionality and SmartTools required to support proactive care. Fully implementing this would require processes and structures for staff and physicians to use those electronic tools to close care gaps. That will require a comprehensive change in management approach, including a communication strategy and an extensive training program. More information and educational videos, job aides, and reference sheets are available from: http://proactivecare.kp.org.

KP’s Hawaii Region is now adopting a proactive care approach, embracing principles of the POE. In KP’s Mid-Atlantic Region, an ophthalmologist who saw an 82-year-old patient ordered a DEXA scan, which showed osteoporosis (Janice M Beaverson, MD, personal communication, March 2010). There is much external interest, including in community clinics in Southern California and professional and national health organizations.

**Conclusion**

The project’s impact has been widespread and positive, changing the organization’s culture and providing a powerful tool for physician’s, staff, and patients. Proactive care is now an expectation of care delivery. Barriers encountered by the team were overcome through a collaborative approach, which involved labor partners, physicians, and leaders in the implementation from the early stages. Correlation data show a positive impact on the delivery of quality care.

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**Disclosure Statement**

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

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**References**

Innovation

An Alternate Model for Medical Education: Longitudinal Medical Education Within an Integrated Health Care Organization—A Vision of a Model for the Future?

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Tim Grennan, MD, FACP
Howard Young, MD
Myra Hurt, PhD

Editor’s note: This article was developed as a hypothetical model from the June 2009 session of the Harvard Macy Institute—Program for Leading Innovations in Healthcare and Education on innovations in medical curriculum.

As the health care debate in the US rages on, we need also to examine whether our medical education system is keeping pace with the changing landscape of medicine and how well it will cope with the proposed changes in health care delivery. Are we graduating sufficient numbers of physicians in the correct specialties and in a timely manner? Are medical trainees being adequately trained for the molecular and digital revolutions in science and technology? Are there other models of medical education outside of the universities that we might explore for training outstanding physicians in America in the 21st century?

We propose situating a medical school program within one of the larger progressive, nonprofit, integrated, managed care organizations in the US. At first, this may appear an audacious suggestion. The recent health care reform legislation and current policy discussions suggest that these integrated delivery systems may become the model for future care delivery. It seems legitimate to try to use their strengths in seeking solutions to the country’s health care dilemmas. From this perspective, we suggest that situating modular and longitudinal medical education within a progressive integrated health care system such as a large, multispecialty group model, nonprofit health maintenance organization might provide a valid alternate stream of education and training for physicians (and other health care workers). It could draw its trainees from a broader but ultimately not less deserving pool of applicants and potentially also help alleviate certain health care worker shortages.

We conceive of this alternate medical education course operating alongside the traditional university-based medical schools rather than replacing them. We suggest the hypothetical name Kaiser Permanente School of Medicine (KPSOM) to exemplify the alternative model we describe. Kaiser Permanente (KP) is a large, integrated, prepaid Health Plan with 8.6 million members and more than 14,000 physicians in eight Regions. The organization has established for itself a solid reputation as a progressive health care delivery organization with a focus on preventive, patient-centered care and patient satisfaction.

The KPSOM for the training of health care workers would be one that 1) uses the existing structures of a progressive health care management organization (with existing graduate physician-training programs) and does not require the construction of new medical schools; 2) co-trains physicians, physician’s assistants, nurses, nurse practitioners, and potentially even health care administrators; 3) has a streamlined and less costly admissions process and functions alongside traditional university-based medical schools; 4) acknowledges the student-centric learning style and computer proficiency of the incoming Millennial Generation (or Generation Y) students; 5) maximizes human potential by taking into account differences in learning styles and accommodating self-paced modular learning; 6) increases the number of physicians (as well as other health care workers) by drawing on a
pool of applicants, some of whom may conventionally be considered underqualified for admission but will prove to be equally qualified after training; and 7) enhances opportunities for medical careers to students from economically disadvantaged backgrounds.

**Applicants to the Kaiser Permanente School of Medicine**

A central component of the school would be the admission and training of what we call the pluripotential health care worker. The baseline 1 to 3 years of learning in this school (depending on how the students pace their learning) would involve the training of a generic or pluripotential student apprentice who would be well versed in both basic science and basic medical skills at a level of competence necessary for medical students, physician’s assistants, and nurses or nurse practitioners.

Because baseline training before specialist training would be pluripotential, applicants could also be selected from a broader background of applicants. In particular, applicants from underprivileged and underserved areas might be accepted into the program because learning in the program is self-paced and modular in nature, with backup mentoring and academic support (as described in the following section). The school would be attractive to a diverse range of students, including those from resource-poor settings; students interested in a career in health care but undecided about the specific direction; students who prefer the option of self-paced learning; and students attracted by the option of remaining within a large organization for residency, fellowship, and subsequent employment opportunities.

An advantage of this hypothetical model would be that it could function without some of the current constraints that render the current admissions process to university medical schools cumbersome, expensive, and drawn out. Students applying to the KPSOM would not need to apply to and interview at numerous medical schools. The current highly competitive system is draining and costly and entails students crossing the country for multiple interviews and schools investing substantial time and money into screening applications and interviewing students—overall, an exhausting, time-consuming, and costly process. This new hypothetical institution might not require the MCAT (Medical College Admission Test) for admission, because it would conduct its own in-house evaluations, monitored by the Liaison Committee on Medical Education (LCME), of students it admits. These could take the form of an initial basic competency test, followed by formative and summative testing as students progressed through the modular self-paced learning system (see the next section).

This progressive admissions policy would allow applicants from a broader range of educational backgrounds, not only from elite schools but also from underserved areas. This would make for a healthy diversity among trainees. It has been recently noted that about 75% of US medical students come from the upper wage-earning quintile of the population. According to a report on the Web site of the Association of American Medical Colleges (AAMC), the Matriculating Student Questionnaire, All Schools Summary Report for the years 2006, 2007, and 2008, 69% to 71% of students reported that their parents’ gross income was $75,000 or more, and the average was between $149,779 (2006) and $164,483 (2008). In these same years, 15% or less reported that their parents’ gross income was less than $40,000. In keeping with the community mission of KP, this new training model could help redress this imbalance by accepting minority and less-privileged students. Recruitment from a wider pool of applicants would likely also increase numbers of medical, nursing, and physician’s assistant graduates and might have the added consequence of increasing the supply of qualified health care workers to underserved areas.

**Modular Self-Paced Learning**

Education and training at this new school would be modular and self-paced but would be buttressed with sophisticated academic support and mentoring. An organization the size of KP has ample resources to provide such academic support. Students would not study in lockstep with the entire class being at the same point in the curriculum at any one point, as in most current medical school curricula, but would instead pace their own learning. Coursework would be completed in modules, and trainees could be tested for competency at critical steps in their learning before being permitted to move on to the next learning module.

Modular learning in the basic sciences would be largely Web based. Because it would not be a classic university, this new alternative medical school would
not employ basic science faculty for lecture-style teaching. The school might partner with universities for parts of the basic science teaching. Students would be assigned (as apprentices) to KP clinical faculty members, many of whom are already clinical faculty members at local universities and are engaged in the teaching of graduate physicians. The students would shadow the faculty in clinics and hospitals while they also engaged in completing modules in clinical skills. Students would not be permitted to proceed to the next level of learning in the basic sciences or clinical skills until they had demonstrated adequate competency at each prior level of learning. Although the program would be self-paced, there would nonetheless be a limited time frame for completion of specific tracks (possibly five to seven years).

We envisage students learning the basic sciences concurrently with clinical skills so that concepts from these two spheres of knowledge would reinforce each other. The specifics of the school’s curriculum model would remain to be deliberated but would be based on recommendations of the AAMC for small interdisciplinary group teaching that would incorporate aspects of problem-based and team-based learning as well the more recent recommendations of the Carnegie Foundation’s 2010 report for supportive learning environments that encourage curiosity, encourage feedback improvement, and promote learners’ ability to work collaboratively in healthcare teams. As recommended in the Carnegie Foundation report, the KPSOM would also, through its apprenticeship model, incorporate more clinical experiences earlier in the curriculum. Examples of current curricula that may provide guidance are Harvard Medical School’s New Pathway MD Program (http://hms.harvard.edu/admissions/default.asp?page=pathway); the symptom-based curriculum of Calgary Medical School in Canada (www.medicine.ucalgary.ca/); and the new Paul L Foster Medical School in El Paso, Texas (www.ttuhsc.edu/elpaso/); and the “longitudinal integrated” clerkship curriculum of the Cambridge Health Alliance and Harvard Medical School (www.cha.harvard.edu/academics/integrated_clerkship.shtml) in Boston.

It is anticipated that the students would learn better and more quickly because the program would be embedded in an integrated health care system. While proceeding with their modules in the basic sciences, students would work at KP as clinician apprentices. Initially, they would do very basic clinical work while shadowing experienced physicians in clinics and hospitals, and only after demonstrated basic clinical competencies would they proceed to more self-reliant clinical work.

**Millenial Generation or Generation Y: Self-Based Style of Learning**

A curriculum of self-paced modular learning has a number of advantages. First, it would accommodate differences in students’ learning styles and would be advantageous to students from challenged backgrounds by allowing them to proceed through the program at their own learning pace (within certain time limits). Second, it would accommodate the self-based learning style of the “Millenial” or “Generation Y” students who are generally adept at computers and are swift at information retrieval from the Internet, who ostensibly have shorter attention spans than students in past generations, and who prefer to take charge and be at the center of their own learning. Third, it would take account of the exponential increase in medical knowledge by presenting it in modular form and allowing students to pace their learning.

**The Pluripotential Baseline Trainee**

The first benchmark phase of the KPSOM would be the training of a pluripotential health care worker who would subsequently proceed with more specific training along designated tracks toward becoming a physician, physician’s assistant, nurse, nurse practitioner, or health care administrator. Each track would have graduated levels of competency in training, and trainees would have to demonstrate adequate competency at each level before being admitted to the next.

Many students might know from the start which graduation track they wish to pursue, but all would initially go through the gatekeeping pluripotential track, during which they would also be tested for their natural learning styles, aptitude, and acquired competencies before being admitted to the graduation track of their choice. Such monitoring would maximize human potential because there would presumably be a closer fit between candidates’ aspirations and their true capabilities. A trainee who did not qualify for the physician track might still be offered the choice of the less demanding physician’s assistant track. After completion of the basic gatekeeping pluripotential track, the different tracks would, however, not be melded but would be separate and have strict competency attainment requirements. This hypothetical new school could afford having different tracks of health care professional training because unlike a university medical school, it would ultimately offer employment to most graduates in the different tracks.

Regarding administrative regulation of the school, the LCME—which currently appears to be interested...
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in innovative projects in medical education—would maintain its standard accrediting and regulatory role at all stages of the school’s development, as it does for all other US medical schools. Students would be required to pass the standardized National Board of Medical Examiners subject examinations as well as the US Medical Licensing Examination steps 1, 2, and 3 for licensure. In any case, in 2010, the centennial year of its groundbreaking Flexner Report, the Carnegie Foundation released another call for reform, Educating Physicians: A Call for Reform of Medical School and Residency, in which it drew attention to the need for reform with regard to admissions, accrediting, certifying, and licensing in medical education in a manner that resolves conflicts but ensures diversity of medical schools. The first two of the report’s seven recommendations read as follows:

1. AAMC and medical schools work together to revise premedical course requirements and admission processes, ensuring the diversity of those in medical schools.

2. Accrediting, certifying, and licensing bodies together develop a coherent framework for the continuum of medical education and establish effective mechanisms to coordinate standards and resolve jurisdictional conflicts.

Students as Reduced-Tuition Employees of the Organization

Tuition would be reduced because students would be admitted as part-time employees and would perform, in their roles as clinical apprentices, basic clinical service functions for the organization’s clinics and hospitals. Conceivably, as employees they might also receive a reasonable stipend to cover living expenses. Analogous education models exist within engineering schools in which students may spend half the year within the university and the other half employed by an engineering firm (Richard K Miller, personal communication, May 2009). The organization would ensure that appropriate supervision is provided at all times to guarantee that patient safety and quality of care is maintained.

Students of the new school would graduate with less financial debt than students of university medical schools and would therefore not be unduly influenced by considerations of the size of tuition loans in their choice of medical specialty training, as is happening with current medical school graduates applying for residency. Moreover, a less costly system may be enticing to students from disadvantaged educational backgrounds as well as to more accomplished students from better endowed institutions. This would enhance the diversity of the school’s student population and may ultimately also increase the numbers of physicians choosing to return to work in resource-poor settings.

The financing of the school itself, which may require some additional infrastructure but little physical construction, may come from KP itself, particularly if it viewed the venture as a good investment. Because the school would attract students from resource-poor settings, additional financing might be obtained via the federal government, such as through new health care legislation, or through state support, or from large philanthropic organizations with an interest in education such as the Carnegie or Rockefeller Foundations.

The Lifelong Medical School: Residency, Fellowship, Cross-Training, and Continuing Medical Education

The KPSOM would continue and expand its own in-house residency and fellowship programs that encompass a number of medical specialties and subspecialties. Medical student trainees would apply from within the organization for specialty training at any one of its many hospitals.

Because the medical school and residency programs would be housed within the same organization, applications for residency would also be greatly facilitated. The drawn-out and costly process of the current residency application and cross-country interview process, which consumes the better part of the fourth year of medical school, would be obviated. This time saving could eliminate a year of medical training for the motivated, quicker-paced student or else provide the additional time required for the slower-working, self-paced student. During their ‘medical school’ training, students would be carefully monitored, evaluated, and assessed for their aptitudes and learning styles in deciding about residency. The processing of applications from within the organization would not only streamline the process but also might improve quality control and standardization of applications. Residency programs would also be largely modular in structure and self-paced for the learning of clinical competencies.

Although there might be some loss of diversity among residents who all derive from the same organization, compared with residents entering from a variety of different medical schools, the gain to the residency program would be in having a more carefully monitored, standardized, and appropriately matched (by aptitude, learning style, and intellectual capability) program of residents. Students would not be required, however, to...
complete all their clerkships and rotations within the school but would be encouraged to do rotations outside of KP, which already has formal affiliations with medical schools such as those with the University of California, San Francisco; Stanford University; the University of California, Los Angeles; the University of California, Davis; the University of Southern California; and the University of California, Berkeley (public health). Depending on their examination grades, performance, and recommendations, students from KPSOM applying for rotations, residencies, and fellowships outside of the organization should be readily competitive with students from other medical schools. Applications to outside programs should not present a compatibility problem, as KP already interfaces with several such residency programs.

The program might also admit a limited number of residents from other US medical schools as well as graduates of foreign medical schools, who would also be carefully assessed and then slotted into the appropriate phase of the training program. Currently, international medical applicants to US residency programs are required to repeat their entire residency training regardless of their prior training and competency. In this proposed alternative medical school, foreign residency applicants would nonetheless still have to pass US medical board examinations and satisfy all LCME accrediting requirements.

Applications to fellowship programs, which would also be in-house, would be similarly handled. The proposed KPSOM would also readily accommodate cross-training of its employed physicians into different associated subspecialties, a trend that is occurring increasingly as medical knowledge expands. For instance, the increasing role of invasive radiologic techniques and laparoscopic surgical techniques has changed management in a variety of surgical disciplines. Finally, continuing medical education programs would be easier to implement and monitor from within the organization, whereas the current system of accumulating continuing education credits is often seemingly haphazard and fragmented.

**Continuity of Care, Preventive Care, and Patient Satisfaction in the Lifelong/Longitudinal Medical School**

Because most trainees would continue their training within the organization initially as medical students, then as residents, fellows, and finally as fully employed physicians, they could provide better continuity of care for patients over this extended period of participation in the organization. This would lead to both enhanced patient care and, as a consequence, overall higher levels of patient satisfaction. Instead of experiencing continual disruptions in their care with frequent changes in physicians and hospitals, patients would continue to see the same physicians they initially encountered when these physicians were medical students or residents and who would therefore have a more substantial grasp of their ongoing health care needs over time.

In addition, with enhanced continuity of care, the organization could implement highly effective longitudinal preventive-care programs, which would lead to improved health outcomes and patient satisfaction. The integrated modular nature of this course would allow for flexibility in learning styles to be matched with the flexibility that would be needed of the future workforce. It would promote the concept of teamwork at an early stage, improve communication between trainees and teachers, and redefine the apprentice model in the 21st century.

**Summary**

In brief, the hypothetical KPSOM could be envisaged as a model of a lifetime medical school that would initially draw candidates from a diverse socioeconomic pool of applicants and guide them through a series of carefully monitored, modular, self-paced basic science and clinical skills learning programs, up to a phase where they would branch out into specialty programs leading to graduation as physician, physician’s assistant, nurse, nurse practitioner, or health care administrator.

Tuition would be less costly because students would also be employees of the organization and would likely remain in the organization throughout their extensive training careers, from medical school and into subspecialty certification—and possibly as full-fledged physician employees. This system would be satisfying to patients as well as students because it would provide more effective longitudinal and preventive care.

The model is offered as an alternate stream of medical education that would not supplant university medical schools but would operate alongside them. This alternate model might serve to increase the number of qualified physicians without the need to build more costly medical schools, and it would train a broader range of health care professionals from diverse backgrounds within the same organization. ✧

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References


The Most Essential
The most essential part of a student's instruction is obtained, as I believe, not in the lecture room, but at the bedside. Nothing seen there is lost; the rhythms of disease are learned by frequent repetition; its unforeseen occurrences stamp themselves indelibly in the memory.

—Medical Essays, “Scholastic and Bedside Teaching,” Oliver Wendell Holmes, 1809-1894, American physician, professor, and author
Gevork Mosesi, MD, is a Family Medicine Physician at the Bonita Medical Center in CA. Photography is one of Dr Mosesi’s passions because it allows him to capture beautiful moments; he feels that life around us is beautiful. His favorite subjects are landscapes, architecture, and his daughter.
**Innovation**

**The Northern California Perinatal Research Unit: A Hybrid Model Bridging Research, Quality Improvement and Clinical Practice**

**Abstract**

Kaiser Permanente (KP) has a long-standing commitment to conduct research and report publicly. Simultaneously, it faces a different imperative: harnessing information systems to leverage internal improvements in outcomes, efficiency, and costs. Now that KP HealthConnect, the KP electronic health record, is fully implemented, research challenges at KP are moving away from issues of data access and toward the mechanisms through which raw data create meaningful clinical knowledge that is based on rigorous research. In this report we describe a model for research—the Northern California Division of Research Perinatal Research Unit—that leverages internal and external resources to fulfill these twin missions.

The word *Irish* is seldom coupled with the word *civilization*.

—*How the Irish Saved Western Civilization*, by Thomas Cahill

The word *improvement* is seldom coupled with the word *research*.

—Gene Nelson, MD, Dartmouth University

**Prologue**

The principal investigator (PI) shares sensitive outcomes data in a meeting with the neonatology chiefs. The graphs clearly show that facilities A and C admit infants with suspected infections at rates that are two to three times higher than those for facility B, despite infant populations that are similar in terms of birth weight, severity of illness, and mortality. Data are stratified using the Score for Neonatal Acute Physiology (SNAP), forestalling a frequent response: “But my babies are sicker!” The meeting is challenging but goes well, establishing a pattern that continues to date: high-quality outcomes data, often combined with algorithms derived from federally funded research projects based at Kaiser Permanente (KP), are shared with clinicians, who respond by changing their admission criteria. Over time, admissions decrease by almost 8%, with no increase in neonatal mortality or morbidity. In addition, infants and their families are spared the disruption and stress associated with unnecessary admissions and separations. Reduced costs with potentially better care, along with an impressive publication record in the peer-reviewed literature—how did KP acquire the ability to have this type of dialogue and enable these kinds of informed, data-driven, evidence-based, operations decisions?

**Introduction**

Now that KP HealthConnect, the KP electronic health record, is fully implemented, research challenges at KP are moving away from issues of data access and toward the mechanisms through which raw data create meaningful clinical knowledge that is based on rigorous research. Studies have documented that an average of 17 years elapses between the creation of clinical knowledge and its general use at the front line of care. The average time for the entire cycle of knowledge creation—from research idea through funding, data collection, analysis, conclusions, publication, and finally, to broad dissemination—is even longer (Figure 1).

This article explores a model of research and operations analysis that has proven to be very effective: the Northern California Division of Research Perinatal Research Unit (PRU). This hybrid research model combines the best of traditional research capabilities with a rapid operations research function. As KP strives to improve outcomes by bringing...
research to bear directly on operational questions this unit provides an example of how KP can shorten the "time to using knowledge" cycle and effectively change clinical practice.

The Perinatal Research Unit Model

The mission of the PRU is threefold: research, reporting, and ad hoc analysis. PRU staff provide rapid-cycle summary and benchmarking data, as well as an excellent setting for conducting research. Among routine PRU outputs are annual data sets sent to the State of California on behalf of the six Northern California neonatal intensive-care units (NICUs), required for NICU certification by California Children’s Services. The group also generates analyses in response to ad hoc queries from clinicians, using the full array of available data at KP.2,4 Eileen Walsh, RN, MPH, PRU Project Manager, notes, “We take someone’s ‘I wonder …’, quantify it, and answer it accurately in a way that has meaning and can be generalized to our entire neonatal population.” Answers to operationally important questions posed by one NICU are often directly applicable to other units—and often serve as the starting point for manuscripts and federal grant applications.

The interdisciplinary staff at the PRU includes a PI, a project manager, a statistician or analyst, programmers,

This hybrid research model combines the best of traditional research capabilities with a rapid operations research function.

![Timeline from idea to actionable knowledge.](image)

Figure 1. Timeline from idea to actionable knowledge.

1 0.4-2.3 years from the time of application for funding until receipt of award (NIH tutorial: https://grants.nih.gov/grants/guide/p Policymakers. 2007. Clinical trials: design, conduct, and analysis. New York: Oxford University Press.

2 Average length of NICHD/NHLBI trials is 2.91 years (Meinert CL, Tonascia S. Clinical trials: design, conduct, and analysis. New York: Oxford University Press, 1986:40).


a research assistant, and other staff. The unit also partners with investigators at other institutions, including the University of California, San Francisco; the University of California, Santa Cruz; Harvard University; and the University of Pennsylvania. The PRU’s strong research team, with analytic and statistical expertise, is critical to the unit’s success.

The PI, Gabriel Escobar, MD, leads research activities and sets unit priorities. He brings several attributes to his role. Although he is a seasoned and successful traditional researcher, he also has the mind-set of a practicing hospital-based physician. As a clinician, he understands which questions are most pressing for operations and is driven to find answers. Straddling the worlds of research and operations, he is uniquely able to translate between them. His goals have always been to 1) improve the frontline delivery of care at KP and 2) conduct rigorous research. Because Dr Escobar is a physician who is translating research and embedding it into operations, his activities embody the concept of how research and quality improvement can be integrated into the broader KP community.

**A Key Partnership**

The work of the PRU is tightly integrated with the decision making of the neonatal chiefs in Northern California, a small specialty group whose visionary leadership has created a highly effective learning community. According to Allen Fischer, MD, Northern California’s Regional Director of Neonatology, the value of the PRU is that “their efforts inform our action. When we consider a change in practice, we ask the PRU, ‘What does the literature look like? What do KP outcomes look like?’” The PRU supports neonatologists as they work together to identify new practices by analyzing and showing them local data (baseline and postintervention), gathered from their own nurseries.

Figure 2 describes the interactions between the key groups involved in exploring and identifying changes in practice. Ideas for clinical practice research can come from the Neonatal Chief’s Group, the KP HealthConnect NICU/Newborn Governance Team, or the Neonatology Journal Club or “collaboratory,” whereby a community of practice uses shared data to improve knowledge and results. The Journal Club meets online one evening per month and draws an audience that includes neonatologists from Southern California and Hawaii as well as invited speakers from multiple universities. The needs of these groups drive much of the PRU’s work, and the Northern California Nursery Directors’ group, of which Dr Escobar is a sitting member, actively participates in setting PRU priorities.

Beyond the support that Dr Escobar provides to neonatologists to identify needed changes in clinical practice, he brings a hands-on approach to implementing changes in the NICUs. Dr Fischer says that Dr Escobar focuses on the question “How do you package new information so that it changes practice? As a practicing physician, he needs decision support himself, so he understands how to make it work for others.” Practice changes are facilitated through influence, as most of the key players in this process lack the line authority to mandate practice changes. However, widespread involvement of practicing clinicians with the PRU facilitates buy-in.

**Senior Operations Leadership Sponsorship**

The work of the PRU to improve operations has also been furthered through Dr Escobar’s relationships with regional operations leadership. He shares data and findings, as well as their implications, with senior leadership; in turn, senior leaders have consistently supported the PRU. A number of his colleagues have noted that Dr Escobar “cares about what leadership cares about.” He concurs: “Senior leaders tend to be interested in things that move the whole system, and that’s what I am interested in.” For example, Philip Madvig, MD, Associate Executive Director of The Permanente Medical Group (TPMG), sees the potential for the approach pioneered by Dr Escobar to bring value to medical specialties beyond neonatology. He and Donald Dyson, MD, Associate Executive Director of TPMG, are very supportive of closing the gap between emerging knowledge about effective practices and subsequent physician adoption.

**Areas of Demonstrated Success**

The PRU has demonstrated effectiveness in three dimensions: clinical research, operations analysis and improvement, and leveraging resources.

**Clinical Research**

With 92 peer-reviewed publications and 2945 citations during a period of 15 years, the PRU is con-
sidered an authority on newborn treatment management in many areas. For example, the National Institute of Child Health and Human Development (NICHD) views KP as a resource on data on newborns because of the principal PRU database, the Neonatal Minimum Data Set (NMDS). The NMDS is an application based on SAS statistical software (Cary, NC) populated with a standard set of data gathered on all infants admitted to Northern California NICUs. It contains a total of more than 46,000 infant records dated from 1993 to 2009; since 2000, enrollment averages 2969 infants per year. Full data collection for an infant who spends at least 72 hours in the NICU comprises approximately 150 data elements corresponding to maternal and infant demographics, maternal history, intrapartum and delivery details, NICU diagnoses and procedures, severity of illness, and disposition. Reliability of the NMDS data is enabled by ownership and strict quality control by the PRU and its partners. Although the NMDS is a state-of-the-art database and the defining product of the PRU, it sits with and is linked to a wide variety of KP data resources. Project-specific data sets are created for externally funded research studies.

PRU researchers are invited participants at NICHD conferences on jaundice and late-preterm infants. In a recent issue of Pediatrics focusing on jaundice, PRU researchers published a key article and were cited in five of six remaining articles, as well as in editorials. The official Centers for Disease Control Guidelines for Prevention of Perinatal Group B Streptococcal Disease cite a study based on a PRU population on “rule out sepsis.” The PRU’s H index (a measure of research productivity and impact) is 30, and its funding rate is roughly 50%.

Another stream of research conducted during a multiyear period centers on an issue that has not received rigorous research attention in the academic literature: respiratory distress in babies born at 34 weeks’ gestation or later. PRU work in this area resulted in the “Big Babies Breathing Hard” project. Central to this work is the Richardson score, which permits a rapid, quantitative assessment of the severity and the prognosis of respiratory distress. Additional areas of contribution are neonatal sepsis (identification, prevention, clinical management, outcomes), effects of maternal substance abuse during pregnancy, risk factors for rehospitalization among newborns, hyperbilirubinemia (effectiveness of screening and treatment strategies), and longitudinal outcomes for NICU survivors. An extensive bibliography can be found at http://dor-ent1.kaiser.org/staff/investigators/escobar.htm (password protected).

**Operations Analysis and Quality Improvement**

An equally important area of focus for the PRU is operations analysis and improvement. Driven by clinician questions, this work may or may not result in a publication, but it directly contributes to improved patient outcomes. PRU research on operational questions is conducted with the same data and the same resources for analytic rigor as clinical research and often uses the knowledge gained from traditional clinical research projects. The NMDS database, the PRU staffing structure, and strong analytic expertise all enable analysis. The queries that PRU receives from operations run the gamut from a low level of analytic complexity (eg, a clinician who requests simple counts of number of ventilated babies younger than 32 weeks’ gestation) to moderately complex (eg, a query about appropriate referral of mothers at risk of delivering late-preterm, multiple-gestation infants) and very complex (eg, research studying the effects of neonatal nosocomial infection on hospital length of stay and mortality). The response time to queries depends on the level of complexity. Most simple queries can be answered within days. More complex queries (eg, “Are the outcomes for respiratory distress in full-term infants the same across our units?”) often lead to more elaborate answers and sometimes lead Dr Escobar to submit a formal grant proposal. Because publishing can take a longer time, Dr Escobar accelerates knowledge sharing by circulating draft manuscripts internally with the Nursery Directors, instead of waiting for publication (up to two years).

Under a long-standing collaboration with the University of California, San Francisco, the PRU has also played an important role in how KP clinicians manage neonatal hyperbilirubinemia. Working with a nationally recognized jaundice expert, Thomas Newman, MD, the PRU initially contributed considerable data, consultation support, and paper tools to efforts by the Chiefs of Pediatrics and Nursery Directors to implement the American Academy of Pediatrics clinical practice guideline for hyperbilirubinemia. These efforts continue, but the PRU is now shifting its emphasis to KP HealthConnect, where it played a major role in developing and implementing an automated hyperbilirubinemia assessment tool embedded in the electronic health...
The Northern California Perinatal Research Unit: A Hybrid Model Bridging Research, Quality Improvement and Clinical Practice

.record. Currently in beta testing, this tool will be rolled out to the Northern California Region this year.

Leveraging Resources

Ongoing support for PRU activities comes from KP and external grants. Between 2000 and 2009, Kaiser Foundation Hospitals and Health Plan provided an average of approximately $600,000 per year in direct support for the NMDS database, whereas TPMG provided approximately $200,000 per year in support for programming and consultation. Since 2000, the PRU has also averaged $1 million per year in external funding from the federal government, foundations, and industry. Clearly, grantors have benefited from Dr Escobar’s operational insights and relationships, and KP has benefited from the research conducted for external sources. Everyone wins.

Although the NMDS database was initially expensive to build and maintain, it provides value to KP on multiple levels. Ready access to this database—with pilot data ready in days—makes the PRU very competitive in securing external grants. The results of research using the NMDS have answered clinical questions and provided real benefit to KP in “rule out sepsis,” jaundice, dehydration, outcomes for late-preterm infants (Escobar GJ [PI]: Sepsis and critical illness in babies at 34 weeks gestation and longer. Study in progress; funded by the National Institute for General Medical Sciences), and respiratory distress in full-term babies.

The Challenge of Bridging Research and Operations

Serving the two masters of research and operations is not without challenges. The benefits to KP of the PRU’s ready and rigorous response to clinical questions are clear, but the close association between research and operations may also raise concerns. For instance, allowing operations leaders to influence the choice of research topics may be perceived as impinging on a PI’s intellectual integrity. However, Dr Escobar finds interesting clinical research topics and contributes in meaningful ways without jeopardizing his reputation or the integrity of the research. Both the PI and KP operational leaders have a common goal (improved clinical care), so there is much less potential conflict of interest than in other, more conventional relationships, such as between researchers and pharmaceutical companies.

Equally important is the PRU’s policy of transparency about research results. Results from studies approved by the institutional review board are always submitted for publication, even if they make clinicians uncomfortable. This was the case with an Escobar study on neonatal “sepsis workup” that found that only 78% of newborns who met the study’s definition for “critical illness” had been treated with systemic antibiotics. Initial reaction to this finding was consternation, but after the results were confirmed by a repeat audit, the neonatologists took a different stance: They changed the guideline for such infants. On the other hand, because the PRU aims at systematic knowledge, it handles incidental findings during the course of a study in a different manner. For example, a study-required record review might reveal an instance of apparently inappropriate care. Because the PRU is not charged with local quality assurance, this information is not published—nor is it suppressed. In these situations, the PRU simply refers the case to the appropriate facility authority (usually, the Nursery Director).

In the end, no attempt at any kind of organizational censorship of the published study has occurred, and the Neonatology Chiefs’ culture of transparency allows them to improve care and to establish a precedent for performance improvement.

Conclusions: What Differentiates the Perinatal Research Unit Model

A number of factors differentiate the PRU model and contribute to its success:

• Data with high integrity and granularity
• Statistical and analytic expertise and capacity
• A PI with dual goals of improving patient care and building a research reputation
• Partnership with specialty and clinical leaders that includes visionary specialty leadership and a self-examining, data-driven learning culture
• Senior operations leader sponsorship.

Not all research units engage in answering clinical and operations questions with such agility, nor are many regional operations analysis units set up to manage the subtle and clinical nature of some of these questions. The PRU brings to knowledge creation an effective balance between rigor of methodology and speed. Rigorous research work and research capability are leveraged to inform questions of day-to-day clinical practice in a more timely way.

The work of the PRU is enabled by aligned interests and
strong partnerships with clinicians, medical leadership, and regional executive operations leadership. The PRU has made a substantial contribution to Northern California neonatology’s reputation as among the best in the state. The model has now been extended to adult hospital care in Northern California, and a similar model is being explored in Southern California.

The PRU has developed a synergistic approach to using internal and external funding sources while effectively meeting the requirements of both. Dr Escobar has maintained the highest standards of scholarship while exploring issues that directly affect operations. Most importantly, the leadership, transparency, and partnership demonstrated by Northern California research, operations, and neonatology have resulted in demonstrably better care and outcomes for the mothers and babies of KP Northern California.

* Those outside the Kaiser Permanente organization may send questions concerning investigators to dorhelpdesk@doc.kaiser.org.

Disclosure Statement

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

Acknowledgments

We are sincerely grateful for the open access to information and insights provided by Gabriel Escobar, MD, and Eileen Walsh, RN, MPH. We also appreciate the time and wisdom contributed by senior TPMG leadership. Finally, we thank the physicians and staff of the Northern California perinatal services in their continuing efforts to improve care for our patients.

Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

References

Overview of Emerging Concepts in Metabolic Surgery

Michel Murr, MD, FACS
Arash Rafiei, MD
Habib Ajami, MD
Tannous K Fakhry, MD

Introduction

There is now a worldwide epidemic of obesity. According to the Centers for Disease Control and Prevention, the prevalence of obesity among all age groups has increased significantly since 1990; about two-thirds of US adults are overweight or obese.2

Obesity is classified according to body mass index (BMI); overweight is a BMI of 25 to 29.9 kg/m², class I obesity is a BMI of 30 to 34.9 kg/m², class II obesity is a BMI of 35 to 39.9 kg/m², and class III obesity is a BMI of ≥40 kg/m².

The 1998 National Heart, Lung, and Blood Institute guidelines recommended a combination of low-calorie diet, exercise, and behavioral therapy as first-line treatment for obesity. Such a comprehensive approach results in weight loss of 8% to 10%; nonetheless, weight regain is common after two years.5

Metabolic or bariatric surgery induces durable and sustainable weight loss. The 1991 National Institutes of Health Consensus Conference Statement defined the criteria for bariatric surgery as a BMI of ≥40 kg/m² or of ≥35 kg/m² with comorbidities (Tables 1 and 2).6,7

The most recent guidelines of the American Diabetes Association8 state that “bariatric surgery should be considered for adults with BMI >35 kg/m² and type 2 diabetes, especially if the diabetes is difficult to control with lifestyle modification and pharmacologic therapy.” Surgical candidates must have tried other weight-loss modalities (diet, exercise, etc) before consideration of bariatric surgery. It is estimated that about 3% of the US population, or approximately five million people, meet the weight criteria for bariatric surgery.9

The prevalence of serious comorbidities such as metabolic syndrome is 39% among patients undergoing bariatric surgery.10 More importantly, among individuals with type 2 diabetes, 85% are overweight and 55% are obese.11 The Nurses’ Health Study demonstrated that individuals with a BMI of 35 kg/m² had a 40-fold increase in their likelihood of developing diabetes.12 The link between diabetes and obesity is due to induction of insulin resistance by excess adipose tissue and generalized low chronic inflammation.

The role of metabolic surgery in the treatment of obesity is well established.13 The Swedish Obese Subjects (SOS) study demonstrated that metabolic surgery induces remission of diabetes in 69% of obese-diabetic patients.14 Furthermore, in a meta-analysis of 136 studies, the proportion of patients who had diabetes before surgery (median, 11%; range, 3%–100%) and who showed fewer effects from or resolution of diabetes after surgery ranged from 64% to 100% (median, 100%).15 Improvements in insulin sensitivity within the first few days after Roux-en-Y gastric bypass (RYGB), before any measurable weight loss, is commonly observed, and has been maintained at

<table>
<thead>
<tr>
<th>Table 1. Comorbidities associated with obesity</th>
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<tr>
<td><strong>Category</strong></td>
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<tr>
<td>Neurologic</td>
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<td>Pulmonary</td>
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<tr>
<td>Circulatory</td>
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<td>Gastrointestinal</td>
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<td>Genitourinary or gynecologic</td>
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<tr>
<td>Musculoskeletal</td>
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<tr>
<td>Metabolic</td>
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<td>Psychiatric</td>
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| **Comorbidity**                               |
| Pseudotumor cerebri                          |
| Obstructive sleep apnea                      |
| Obesity hypoventilation syndrome             |
| Hypertension                                 |
| Cardiomyopathy                               |
| Pulmonary hypertension                       |
| Deep venous thrombosis                       |
| Gastroesophageal reflux disease              |
| Cholelithias                                 |
| Nonalcoholic steatohepatitis                 |
| Stress urinary incontinence                  |
| Polycystic ovary syndrome                    |
| Mechanical arthropathy                       |
| Diabetes mellitus                            |
| Hyperlipidemia                               |
| Hypercholesterolemia                         |
| Metabolic syndrome                           |
| Depression                                   |
| Binge-eating disorder                        |
| Somatization disorder                        |
| Body dysmorphic disorder                     |

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The remission of obesity-related comorbidities such as metabolic syndrome after bariatric surgery is accompanied by increased longevity.

12 months after surgery. Similarly, in a randomized study, laparoscopic adjustable gastric banding (LAGB) was far superior to standard nonsurgical therapy in inducing remission of diabetes.

The remission of obesity-related comorbidities such as metabolic syndrome after bariatric surgery is accompanied by increased longevity. The SOS study, metabolic surgery reduced overall mortality by 29%. In a larger cohort of patients who underwent RYGB, deaths from coronary artery disease were reduced by 56%, cancer-related deaths decreased by 60%, and more importantly, disease-specific mortality from diabetes decreased by 92%.

Surgically induced weight loss reduces other markers of metabolic syndrome such as serum triglyceride and cholesterol levels, as well as hypertension in at least 62% of patients. In addition, metabolic surgery significantly improves obstructive sleep apnea, gastroesophageal reflux disease, mechanical arthropathy, fatty liver, fertility problems, and urinary incontinence.

Moreover, metabolic surgery reduces obesity-related costs and use of health care resources. It is estimated that the cost of surgical interventions for class II to class III obesity is offset by the subsequent reduction in pharmaceutical and hospitalization cost within the first two years after bariatric surgery.

Additionally, surgical treatment of obesity improves quality-of-life measures. The SOS study found a positive correlation between improvement in quality of life and the degree of weight loss. This was echoed by another study, in which 95% of those who had undergone bariatric surgery had improvements in their quality of life.

Physicians who care for patients after bariatric surgery need to be familiar with common postoperative syndromes that result from specific nutrient deficiencies: protein, vitamin, and trace-element (iron, zinc) deficiencies. Nutritional consequences of bariatric surgery could lead to anemia, neurologic disorders, visual disorders, skin disorders, and edema. Therefore, patients who have undergone bariatric surgery require indefinite, regular follow-up care by their primary care physicians. The surgical mortality rates are 0.1% for LAGB and 0.5% for RYGB.

Types of Metabolic Procedures

Bariatric procedures fall into two categories: restrictive procedures, such as LAGB and sleeve gastrectomy (SG), which limit the amount of oral intake, and diversionary procedures that divert nutrients from the stomach and duodenum and use the Roux anatomy in combination with either mild restriction, such as in RYGB, or malabsorption, as in biliopancreatic diversion/duodenal switch. The vertical banded gastroplasty and jejunoileal bypass are no longer undertaken, owing to insufficient weight loss and devastating malabsorptive sequelae, respectively.

LAGB was first introduced in Europe during the 1990s and was approved for use in the US by the Food and Drug Administration in 2001. It involves placing a band around the cardia of the stomach. The inner diameter of the band can be adjusted during an outpatient office visit by injecting normal saline into a subcutaneous reservoir. Several studies suggest that LAGB is associated with fewer complications and a lower mortality rate (0%–0.7%) than are other restrictive procedures.
Overview of Emerging Concepts in Metabolic Surgery

or diversionary procedures, however, it is associated with a higher likelihood for reoperation. A meta-analysis of 136 studies showed that weight loss after LAGB ranged from 40% to 54%.

SG, another restrictive procedure was introduced in 1993. It is a form of unbanded gastroplasty involving a subtotal vertical gastrectomy (Figure 2). Complication rates range from 0% to 24%, and the mortality rate is 0.4%. Resolution of comorbidities at 12 to 24 months after SG has been satisfactory, but long-term data are still lacking.

RYGB is the most common bariatric procedure undertaken in North America. The stomach is divided to make a small pouch (15–30 mL) from the cardia. The midjejunum (Roux limb) is anastomosed to the gastric pouch. Gastrointestinal tract continuity is reestablished by anastomosing the biliopancreatic limb to the midjejunum forming the common channel where digestion and absorption occurs (Figure 3). RYGB is associated with an overall complication rate of 10% and a mortality rate of 0.4%. Early complications include anastomotic leak (3%), deep vein thrombosis or pulmonary embolism (3%), bleeding (3%), and wound infection (4%). Late complications include anastomotic strictures (5%), ulcers (2%), and incisional hernia or small bowel obstruction (2%).

The foregut and hindgut hypotheses have been proposed to explain the resolution of diabetes after RYGB. Rubino et al offered the foregut hypothesis: that when food bypasses the duodenum and proximal jejunum after bariatric surgery, a so-called anti-incretin or decrétin factor that is yet unknown is inhibited and thus insulin resistance is decreased and glucose tolerance improves. Cummings et al and Patriti et al proposed the hindgut explanation, suggesting that the quick transit of nutrients to the distal bowel improves glucose metabolism by stimulating secretion of glucagon-like peptide-1 and peptide YY. Insulin secretion is increased and glucose tolerance improves, affecting body weight and food intake.

Most patients undergoing bariatric surgery have some degree of hepatic steatosis: Approximately 25% have
nonalcoholic steatohepatitis, and 1% to 3% have cirrhosis that is incidentally found in the operating room. All studies using standard RYGB have consistently demonstrated decreased steatosis on follow-up liver biopsy. The alteration in the gut hormone’s response after RYGB—namely, the upregulation of glucagon-like peptide-1—has been shown to decrease the nonalcoholic fatty liver disease induced by obesity.

Biliopancreatic diversion (BPD) and biliopancreatic diversion with duodenal switch (BPD/DS) involve a partial gastric resection and a short common channel (Figure 4). Consequently, the likelihood of protein-calorie malabsorption approaches 7%; a smaller number of patients will require additional operations to lengthen the common channel. In comparison to other bariatric procedures, patients who undergo BPD or BPD/DS have rapid and greater long-term weight loss that exceeds 70%.

In our practice, we recommend RYGB for patients with diabetes or those with a BMI of >50 kg/m². Our experience suggests that patients with a BMI of >50 kg/m² who undergo LAGB may not lose enough weight to overcome their comorbidities and achieve the BMI of <40 kg/m² that is supported in the literature. Diabetes decreases immediately after RYGB, whereas the reduction of diabetes after LAGB depends on how much weight is lost.

**Preoperative Evaluation**

A multidisciplinary and comprehensive approach is preferred for the management of morbid obesity. All patients who are considering bariatric surgery should be evaluated and screened by an interdisciplinary team that includes a bariatric surgeon, a bariatrician, a nutritionist, a psychologist, and an exercise physiologist. In addition to conducting a routine assessment, the interdisciplinary team should aim at reducing perioperative risks specifically in patients with a BMI of >50 kg/m², hypertension, or previous history of thromboembolism as well as in men and in patients older than 45 years. Risk reduction may be achieved by preoperative weight loss, prophylactic inferior vena cava filter, and smoking cessation. More importantly, the preoperative evaluation lays the foundation for healthy eating habits and lifelong behavior modification.

**Postoperative Care**

Patients with severe cardiac disease, diabetes, or severe obstructive sleep apnea are monitored in an intermediate or intensive care unit. Tachycardia is an important indicator of postoperative complications and should be addressed promptly and treated accordingly. In our practice, β-blockers are given immediately after surgery to patients who were taking them before surgery and to selected high-risk patients. We initiate continuous positive airway pressure or bilevel positive airway pressure early in the recovery room by using the patient’s own equipment. Oral food intake is initiated after an upper gastrointestinal tract study for fast tracking.

**Follow-up Care**

Restrictive procedures are not associated with alterations in intestinal continuity. As a result, nutritional deficiencies are uncommon. The anatomic changes because of diversionary surgical procedures, however, increase the likelihood of various nutrient deficiencies; therefore, we prescribe multivitamins with iron, vitamin B₁₂ injections, calcium, and vitamin D supplements. Additionally, protein supplements should be given as soon as patients can tolerate oral intake.

The first postoperative office visit is scheduled two to three weeks after the procedure. By this time, most patients can tolerate semisolid food, and therefore it is important to differentiate between excessive oral intake, anastomotic strictures, and ulcers that also manifest as intolerance to food, nausea, and vomiting. The frequency of follow-up visits depends on the type of procedure. Patients who undergo LAGB usu-

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Figure 4. (A) Biliopancreatic diversion. (B) Biliopancreatic diversion with duodenal switch.

ally need their first band fill between four and eight weeks after surgery and every two months thereafter. Patients who have undergone RYGB are scheduled for follow-up visits every three to four months in the first year and twice yearly thereafter.

A complete blood count and liver function tests are conducted once or twice yearly, and levels of total serum protein, electrolytes, blood urea nitrogen, creatinine, and albumin are measured on this schedule too. Additionally, we recommend measuring levels of parathyroid hormone, vitamins D and B₁₂, folic acid, iron, and ferritin every one to two years after bariatric surgery or as needed.

The Future of Metabolic Surgery

The future of metabolic surgery lies with the innovative approaches of surgeons and the ever-expanding understanding of obesity by nonsurgeons. Several studies that are now examining the benefits of metabolic surgery in class II obesity are promising. Endoluminal applications and device interventions now in phase 1 and 2 studies are other exciting areas of research. In addition to preventing comorbidities, metabolic surgery may be used as a primary tool for the treatment of diabetes and obesity.

Disclosure Statement
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References

Josh Schechtel, MD, is a hospital-based Pediatrician and Chief of Professional Staff Education at the Oakland Medical Center in CA. He has been drawing, designing gardens, and fabricating tile mosaics for many years and started painting about three years ago. This painting is one of a series of abstracts based on aerial views of crops on Moloka‘i.
Thiazolidinediones: A 2010 Perspective

Ashok Krishnaswami, MD, FACC
Shalini Ravi-Kumar, MD
John M Lewis, MD

Abstract
A large number of cardiology clinical trials have mortality as an endpoint unless adequate surrogate endpoints are available. Although there are nine classes of agents used in the treatment of diabetes mellitus, none have shown a mortality benefit in clinical trials. The United Kingdom Prospective Diabetic Study was the first to suggest that metformin given for diabetes mellitus had a trend toward lowering mortality. The accidental discovery of peroxisome proliferator-activated receptors (PPARs) led to the introduction of the thiazolidinediones (TZD), a PPAR agent with a suggestion of a promise for the future. As the incidence of cardiovascular complications related to diabetes mellitus increases, there is a sense of urgency to produce antidiabetic medications that achieve not only nontoxic glycemic control but also improved cardiovascular outcomes. The goal of this review is to aid the clinician to appropriately assess the benefits and risks of TZD use when prescribing for patients.

Introduction
It is well known that microvascular disease in type 2 diabetes mellitus can be halted with aggressive glycemic control. Even with nine classes of antidiabetic agents currently on the market, only the biguanide metformin has shown a trend toward decreasing macrovascular disease. The goal so far, understandably, has been focused on glycemic control. However, with the abundance of hypoglycemic agents on the market, medications will have to be chosen to not only achieve glycemic control but also decrease cardiovascular mortality.

The thiazolidinediones (TZDs) are the first group of antidiabetic medications that attempted to scale this pinnacle of reducing cardiovascular mortality within a highly competitive arena. In July 2008, the US Food and Drug Administration (FDA) convened a meeting to discuss the question of whether there should be a requirement that any antidiabetic medications without a concerning cardiovascular safety signal during early-phase clinical trials be further studied in a long-term cardiovascular trial. The answer was resoundingly in the affirmative for the need to have future antidiabetic medications achieve a beneficial cardiovascular mortality profile before FDA approval is given.

TZDs are a class of medications currently approved by the FDA to treat type 2 diabetes mellitus. However, there is significant debate surrounding its safety. Troglitazone, the first TZD to be approved by the FDA to treat type 2 diabetes mellitus was withdrawn in the year 2000 because of idiosyncratic hepatotoxicity. Currently there are two TZDs on the market: rosiglitazone (Avandia) and pioglitazone (Actos). Because they improve insulin sensitivity and carry a low risk of causing hypoglycemia, they have been quickly incorporated into clinical practice and represent as much as 25% of total prescriptions for oral hypoglycemia medications. However, the TZDs—specifically, rosiglitazone—have faced a great deal of criticism because of the discovery of worrisome adverse affects. This has affected TZD prescribing patterns within Kaiser Permanente Northern California (KPNC) (Table 1). The most debated side effect is whether rosiglitazone causes heart attacks. The aim of this review is to shed light on the overall understanding of TZDs. Subsequently, we hope that it provokes a healthy discussion regarding the appropriate use and placement of TZDs (specifically, pioglitazone) within the KPNC PHASE (Prevent Heart Attack and Stroke Every day) program.

Biology of Peroxisome Proliferator–Activated Receptors
Peroxisome proliferator-activated receptors (PPARs) are a family of intracellular receptors for fatty acids and fatty-acid derivatives. Three types of PPARs are expressed in a variety of metabolic tissues: PPAR-α, PPAR-β/δ, and PPAR-γ. PPARs, unlike other receptors, are located within the cell nucleus, where they are thought to exert their effect of regulating gene transcription directly within the cell. Each receptor has unique locations and functions. PPAR-α is expressed in metabolically active tis-
sues such as the liver and plays a large role in lipid and lipoprotein metabolism and also in suppressing vascular and systemic inflammation. Fenofibrate and gemfibrozil are some important examples of ligands for this receptor. PPAR-δ is the most widely distributed PPAR. Its exact role is yet unclear, but it too plays a role in lipid metabolism; it also plays a role in cholesterol homeostasis in macrophages, embryo implantation, and cell proliferation. PPAR-γ is mostly expressed in adipose tissue (adipocytes). It is also found in skeletal muscle, hepatocytes, intestinal tissue, endothelial cells, cardiac muscle, the renal collecting duct, and in macrophages.

The primary role of PPAR-γ appears to be in regulating adipogenesis along with glucose and lipid metabolism. PPAR-γ is thought to enhance the actions of insulin and decrease resistance to insulin. Ligands for PPAR-γ include free fatty acids, certain prostaglandin derivatives, non-steroidal anti-inflammatory agents, and TZDs. All TZDs have varying selectivity for each PPAR receptor and thus have a variety of effects on the human body besides their primary action.\(^5\) (Table 2).

**Effects of Thiazolidinediones on Diabetes Mellitus, Lipids, and Adipocytes**

TZDs have additional effects besides their primary role as antihyperglycemics. They typically reduce glycated HbA\(_1c\) by 1% to 2% when compared with placebo. This is similar to the hypoglycemic effects of the sulfonylureas and metformin.\(^8\) They do this primarily by increasing skeletal muscle glucose uptake and less by decreasing hepatic production of glucose. They also are thought to preserve β-cell function; this effect has been shown in animal models as well as in human studies.

They have varying effects on lipid metabolism. Both TZDs increase high-density lipoprotein (HDL) cholesterol and low-density lipoprotein (LDL) cholesterol. A variation between the two TZDs has been noted in respect to their effects on LDL particle concentration and size, producing an overall shift to a larger, more buoyant LDL particle. Triglyceride levels are also decreased with both TZDs, with there being a larger decrease with pioglitazone. These effects may be related to pioglitazone’s effect on hepatic PPAR-α.

TZDs also increase body weight by differentiation of preadipocytes to adipocytes and increasing adipocyte mass. Although it is known that increased levels of adiposity increase the propensity of cardiovascular risk, other features of TZDs are thought to perhaps attenuate this risk. One such example is redistribution of fat from visceral to subcutaneous depots, a pattern that is thought to be associated with decreased risk for cardiovascular disease (CVD).\(^3\) This pattern of change is also associated with increased adiponectin and decreased tissue-necrosis factor-α levels. Both are associated with favorable changes in CVD risk profile. TZDs also decrease circu-

### Table 1. Crude thiazolidinedione (pioglitazone and rosiglitazone) use within Kaiser Permanente Northern California in two contiguous years

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<thead>
<tr>
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<tbody>
<tr>
<td>Pioglitazone prescriptions</td>
<td>84,882</td>
<td>83,011</td>
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<tr>
<td>Total number of patients taking pioglitazone</td>
<td>29,507</td>
<td>28,049</td>
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<tr>
<td>Rosiglitazone prescriptions</td>
<td>2227</td>
<td>737</td>
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<tr>
<td>Total number of patients taking rosiglitazone</td>
<td>851</td>
<td>276</td>
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Data from written personal communication from Jim Chan, PharmD, PhD, September 30, 2008.\(^\dagger\)

### Table 2. The beneficial and harmful effects of thiazolidinediones

<table>
<thead>
<tr>
<th>Beneficial effects</th>
<th>Harmful effects</th>
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<tr>
<td>Improvement in cardiac function</td>
<td>Increase in body weight</td>
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<tr>
<td>Improvement in cardiac metabolism and glucose uptake</td>
<td>Fluid retention</td>
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<tr>
<td>Coronary vasodilation</td>
<td>Possible congestive heart failure</td>
</tr>
<tr>
<td>Regression of left ventricular hypertrophy</td>
<td>Possible macular edema</td>
</tr>
<tr>
<td>Improvement in vascular insulin resistance</td>
<td>Fractures</td>
</tr>
<tr>
<td>Decrease in blood pressure</td>
<td>Increase in LDL-cholesterol</td>
</tr>
<tr>
<td>Improvement in endothelial function</td>
<td>Highly debated risk of myocardial infarction(^\dagger)</td>
</tr>
<tr>
<td>Increase in HDL cholesterol and decrease in triglycerides</td>
<td>Increases in HbA(_1c) by 1-2%</td>
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\(\dagger\) Exact risk is unknown. Prospective randomized clinical trial planned by GlaxoSmithKline, producer of rosiglitazone halted by the US Food and Drug Administration.

LDL = low-density lipoprotein; HDL = high-density lipoprotein.
lating free fatty acids, with resultant favorable effects on the liver and skeletal muscle.

**Effects of Thiazolidinediones on Inflammation and Endothelial Function**

Vascular inflammation is a fundamental component in the process of atherosclerosis. This process, with subsequent thrombosis, is lengthy and complicated, developing usually over decades. The final rupture of the atherosclerotic cap, with spillage of the highly thrombogenic infracap contents into the coronary vessel lumen, is the explanation for most fatal coronary thromboses. However, for coronary plaque progression to occur, continued inflammation is needed. Numerous mediators of inflammation are expressed, such as adhesion molecules and growth factors, whereas release of chemoattractants and elaboration of cytokines weaken the fibrous atherosclerotic cap. It is thought that transcription factor nuclear factor (NF)-κB mediates many of the inflammatory processes that occur during the development of atherosclerosis. Multiple studies have suggested that PPAR activation favorably modulates NF-κB action.

TZDs also favorably affect coronary and peripheral vasodilation, along with minimally improving blood pressure. These effects are thought to be mediated by increasing endothelial release of nitric oxide, increased expression of vascular endothelial growth factor, and decreased expression of endothelin-1. TZDs also partially inhibit voltage-gated L-type calcium channels. These channels are the mechanisms of action on the nondihydropyridine calcium-channel blockers. Although the effect of blood pressure reduction is minimal, epidemiologic estimates suggest that this small change may provide a significant decrease in the risk of stroke and myocardial infarctions.

**Data Favoring Thiazolidinediones (the Good or Neutral)**

The Diabetes Control and Complications Trial (DCCT) conclusively demonstrated that tight glucose control in persons with type 1 diabetes significantly decreased microvascular complications such as retinopathy, nephropathy, and neuropathy. After a follow-up period of 7 to 9 years of 1205 persons with well-controlled type 1 diabetes who were involved in the DCCT study, the Epidemiology of Diabetes Interventions and Complications study showed decreased macrovascular complications (coronary calcification).

A decrease in microvascular complications in persons with type 2 diabetes mellitus is thought to be backed up by reasonably strong data. Although it was shown in 1982 that intensive glycemic control decreases microvascular complications in type 1 diabetes mellitus, there is yet no conclusive proof that a current FDA-approved treatment can reduce the risk of macrovascular complications in persons with type 2 diabetes mellitus. The University Group Diabetes Program actually showed that tolbutamide increased cardiovascular mortality. The United Kingdom Prospective Diabetes Study was the first study to suggest that a diabetic medication had a favorable CVD risk profile. It showed a nonsignificant reduction (p = 0.052) in myocardial infarction in patients treated intensively with insulin or sulfonylureas. It also showed a reduction in diabetes-related death and all-cause mortality in a substudy of 342 overweight persons given metformin. In a 10-year post-trial observational follow-up assessment, the reduction in these CVD events became statistically significant.

Numerous studies have assessed the role of TZDs in persons with type 2 diabetes mellitus. Small controlled studies using surrogate markers such as carotid intimal-media thickness (IMT) have shown a decrease in the progression of carotid IMT in persons treated with a TZD. Protective effects against restenosis after percutaneous intervention in TZD-treated patients have also been noted. Large randomized, controlled trials that have assessed the effects of TZDs on major CVD events that are completed or ongoing are described in the following paragraphs. In evaluating the results of all these trials, one should distinguish those that compare TZDs with placebo as an add-on therapy to those that compare TZDs with other hypoglycemic drugs.

PROactive was the first study to suggest that a diabetic medication had a favorable CVD risk profile. It showed a nonsignificant reduction (p = 0.052) in myocardial infarction in patients treated intensively with insulin or sulfonylureas. It also showed a reduction in diabetes-related death and all-cause mortality in a substudy of 342 overweight persons given metformin. In a 10-year post-trial observational follow-up assessment, the reduction in these CVD events became statistically significant.

Numerous studies have assessed the role of TZDs in persons with type 2 diabetes mellitus. Small controlled studies using surrogate markers such as carotid intimal-media thickness (IMT) have shown a decrease in the progression of carotid IMT in persons treated with a TZD. Protective effects against restenosis after percutaneous intervention in TZD-treated patients have also been noted. Large randomized, controlled trials that have assessed the effects of TZDs on major CVD events that are completed or ongoing are described in the following paragraphs. In evaluating the results of all these trials, one should distinguish those that compare TZDs with placebo as an add-on therapy to those that compare TZDs with other hypoglycemic drugs.
or stroke) was significantly reduced in the pioglitazone group (301 patients in the pioglitazone group and 358 in the placebo group; p = 0.027). It is noteworthy that the time to permanent insulin use was significantly decreased in the pioglitazone group.

ADOPT16 (A Diabetes Outcome Progression Trial) was a multicenter, randomized, double-blind, controlled clinical trial that sought to answer whether monotherapy with either rosiglitazone, metformin, or glyburide was sufficient to maintain euglycemia in persons in whom type 2 diabetes mellitus had recently been diagnosed and who had not taken any diabetes medications before. The primary outcome was the time to monotherapy failure (plasma glucose >180 mg/dL after an overnight fast). Analysis of the outcomes showed a cumulative incidence of monotherapy failure at 5 years of 15% with rosiglitazone, 21% with metformin, and 34% with glyburide. This was a 32% greater risk reduction for rosiglitazone compared with metformin, and a 63% greater risk reduction compared with glyburide (p < 0.0001 for both comparisons). However, some important limitations of the study should be mentioned: 1) the study was an efficacy and safety trial and not a primary cardiovascular endpoint trial; 2) there was a large withdrawal rate; and 3) patients with type 2 diabetes mellitus were in a very early stage in this study, and thus they may not represent the general population of patients with type 2 diabetes mellitus. Preliminary cardiovascular safety findings had not detected a significant difference in cardiac ischemic event rates between rosiglitazone and metformin or glyburide, but many believe that an increased risk cannot be ruled out.1 There were understandably more patients with heart-failure events with rosiglitazone than with placebo arm) and followed for a median of 3.0 years. Rosiglitazone was titrated to a maximum dose of 15 mg/d and ramipril was titrated to a maximum dose of 15 mg/d in a 2 × 2 factorial design. The primary outcome was a composite of incident type 2 diabetes mellitus or death. The results of the study showed that fewer individuals experienced the composite primary outcome in the rosiglitazone group compared with the placebo group [306 (11.6%), 686 (26.0%); p < 0.0001]. One-half of the individuals in the rosiglitazone group and approximately one-third of the placebo group achieved normoglycemia [1350 (50.5%), 798 (30.3%); p < 0.0001]. Also among individuals with impaired fasting glucose or impaired glucose tolerance, taking ramipril for 3 years significantly increased regression to normoglycemia but did not significantly decrease the incidence of type 2 diabetes mellitus or death.

The ACT NOW17 trial, presented at the American Diabetes Association 2008 meeting, randomized participants to placebo or pioglitazone titrated to 45 mg/d. Pioglitazone decreased the rate of progression to type 2 diabetes mellitus (1.5% per year) compared with placebo (6.8% per year; hazard ratio [HR], 0.19; p < 0.00001). The risk of fracture, heart failure, and other adverse events was similar except for a higher rate of edema in the pioglitazone group compared with placebo (22% vs 15%).

In April 2008, results of the PERISCOPE18 (Comparison of Pioglitazone versus Glimepiride on Progression of Coronary Atherosclerosis in Patients with Type 2 Diabetes) trial were published. PERISCOPE was a coronary intravascular ultrasound (IVUS) study in 547 patients with type 2 diabetes mellitus who underwent coronary angiography for clinical indications with a “target vessel” for IVUS that had a stenosis of <50% in an area of 40 mm or longer. The primary endpoint was change in percent atheroma volume (PAV) from baseline. They were then randomized to receive either glimepiride or pioglitazone, which was then titrated to a maximum tolerated dose. If a patient required cardiac catheterization for a clinical indication at a point between 12 and 18 months, a follow-up IVUS study was performed. Only 181 patients in the glimepiride group and 179 patients in the pioglitazone group were included in the primary analysis (66% of the initial cohort). The least-squares mean of the PAV increased in patients taking glimepiride and decreased in patients taking pioglitazone (0.73 vs −0.16; p = 0.002).

RECORD (Rosiglitazone Evaluated for Cardiovascular Outcomes in oRal agent combination therapy for type 2 Diabetes) was a multicenter, open-label, noninferiority trial that randomized persons who had inadequate glycemic control with metformin or sulfonylurea to either receive add-on rosiglitazone or not. An interim analysis19 to assess for increased rates of myocardial infarction with rosiglitazone is the biggest and most heated debate.

... the unknown risk of myocardial infarction with rosiglitazone is the biggest and most heated debate.
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infarction was not conclusive. The final analysis\textsuperscript{20} again noted no differences in the primary endpoint, with 321 events in the rosiglitazone group and 323 events in the control group (HR, 0.99; 95% confidence interval [CI], 0.85–1.16). As suspected, there was an increased risk of congestive heart failure (HR, 2.10; 95% CI, 1.35–3.27) and fractures (HR, 1.57; 95% CI, 1.12–2.19).

The APPROACH\textsuperscript{21} (Assessment on the Prevention of Progression by ROSiglitzagone on Atherosclerosis in diabetes patients with Cardiovascular History) trial, the results of which were published recently, was an IVUS trial that randomized patients presenting to a cardiac catheterization laboratory who had at least one area in their epicardial coronary arterial system that contained an atherosclerotic plaque that was not intervened upon prior with a stenosis of 10-50%. This trial noted no change in the primary endpoint (PAV), whereas one secondary outcome, normalized total atheroma volume, was significantly reduced (–5.1 mm\textsuperscript{3}; 95% CI, –10.0 to –0.3; \( p = 0.04 \)).

Recently published findings of three clinical trials—Action to Control CardiOvacular Risk in Diabetes (ACCORD),\textsuperscript{22} the Veterans Administration Diabetes Study,\textsuperscript{23} and the Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes (BARI 2D)\textsuperscript{24}—showed no firm causal association between rosiglitazone and ischemic heart disease (IHD) events.

**Data Not Favoring Thiazolidinediones (the Bad)**

Known adverse effects that occur with the use of TZDs are discussed in the following sections. Some of these are thought be unique to a particular TZD, and others may be thought of as a class effect. Some have a more robust backing of scientific data; others have less. The most-recognized adverse effects include peripheral edema, heart failure, macular edema, and fractures. The overall medical community now is well aware of the effects of TZDs on peripheral edema and heart failure. However, the unknown risk of myocardial infarction with rosiglitazone is the biggest and most heated debate.

**Edema**

The incidence of new or worsening edema is noted to occur in 2.5% to 16.2% of persons with type 2 diabetes mellitus. This risk increases with increasing age, higher doses, female sex, and increasing creatinine levels, with concomitant use of insulin. Two mechanisms are thought to contribute to this problem with TZDs. The first is increasing sodium retention and plasma volume expansion because of the presence of PPAR-\( \gamma \) in the epithelium of the renal collecting duct. There is some thought that amiloride or spironolactone could decrease this effect. The second is the similarity of TZDs to perhaps the dihydropyridine type of calcium-channel blockers (eg, nifedipine, nicardipine, amlodipine) that exert their effects through L-type calcium channels that may cause an increased fluid permeability.\textsuperscript{3,25}

**Heart Failure**

The second and more serious problem of heart failure is thought to occur much less frequently, in 0.25% to 0.45% of persons with type 2 diabetes mellitus per year.\textsuperscript{3,25} In May 2007, the FDA recommended, on the basis of clinical data, that TZD use in patients with any degree of heart failure be avoided. It is of interest, however, that no TZD has shown a harmful effect on cardiac structure or function. In fact, some small studies have shown improvement in hemodynamic values such as stroke volume index and cardiac index. One small randomized study assessed the effect of rosiglitazone versus placebo in patients with New York Heart Association class I and II heart failure and with a left ventricular ejection fraction of <45%. This trial showed an increase in peripheral edema in the rosiglitazone group compared with the placebo group (25.5% vs 8.8%; \( p = 0.037 \)). There was no deterioration of systolic function and perhaps an improvement in diastolic function.\textsuperscript{26}

In the PROactive study, nonadjudicated heart-failure events were more common in the pioglitazone group, but no evidence of increase in heart failure mortality was noted.\textsuperscript{27} A similar finding was noted in the interim analysis of the RECORD study.\textsuperscript{28} These studies’ results suggest an overall low but distinct risk of hospitalizations for heart failure.

**Macular Edema**

Although there have been case reports,\textsuperscript{29} and retrospective studies\textsuperscript{30–34} in the literature suggesting the association of macular edema with use of a TZD, the overall evidence either proving or disproving it is fair at best. However, most experts in the field believe that TZDs probably exacerbate macular edema and that with discontinuation of TZDs, macular edema may decrease or abate completely. A case example is given in Figure 1.

**Bone Loss**

Another important aspect of TZDs is its effect on bone. Early basic science and preclinical work have shown that TZDs decrease osteoblast differentiation...
and increase osteoclast formation, suggesting overall bone loss. The mechanism of TZD effect on bone has not been completely elucidated but again appears to be due to its effect on PPAR-γ. There is hope that eventually selective PPAR-γ modulators may overcome the undesirable extraglycemic effects. In 2006, the ADOPT group published a separate analysis of the fracture risk associated with rosiglitazone in comparison with metformin and glyburide. Rosiglitazone had an increased relative risk (RR) of 1.81 compared with metformin and 2.13 compared with glyburide. A sex-based association of risk was noted, with women having an increased risk for both upper and lower limb fractures; men did not have an increased risk in this study. The risk ratios calculated showed the largest increases in fracture risk for the foot (RR = 3.3), the hand (RR = 2.6), and the proximal humerus (RR > 8). There was an insufficient number of fractures of the hip and spine to assess the risks for these fractures.31,32 Pioglitazone carried a similar risk for all clinical fractures (1.9 per 100 person-years).

Significant research is needed in many areas in this field. Specifically, there is a need to further define which subgroups are at high risk and also to determine the effects of osteoporosis treatment in persons with type 2 diabetes mellitus who are taking a TZD.

The Ugly?

The possible association of TZDs with myocardial infarction came to light after a Peto fixed-effects meta-analysis, published in 2007, of 42 clinical trials concerning rosiglitazone use in approximately 28,000 patients suggested an odds ratio (OR) of 1.43, or a 43% greater risk, for myocardial infarction and an OR of 1.64, or a 64% greater risk, for cardiovascular death compared with placebo or other antidiabetics.33 A subsequent editorial suggested that there were numerous limitations to this meta-analysis, including possible misclassification, ascertainment errors, and a variability of entry criteria and outcome definitions among the original studies. A subsequent editorial suggested that there were numerous limitations to this meta-analysis, including possible misclassification, ascertainment errors, and a variability of entry criteria and outcome definitions among the original studies.

Whether any risk is due to an individual drug or a class effect is not known. Another meta-analysis of randomized trials concerning pioglitazone use was undertaken that suggested that pioglitazone decreased rather than increased adverse CVD events. This study evaluated 19 clinical trials, with a total participant enrollment of 16,390. The duration of treatment was between 4 months and 3.5 years. Death, myocardial infarction, or stroke occurred in 4.4% (375 of 8554) of participants receiving pioglitazone and 5.7% (450 of 7836) of participants receiving control therapy (HR, 0.82; 95% CI, 0.72–0.94; p = 0.005).

An excellent overview of the safety of TZDs in relation to IHD risk is provided in a recent scientific advisory reported by Kaul et al.36 The advisory statement addressed 1) rosiglitazone and IHD risk, 2) pioglitazone and IHD risk, and 3) pioglitazone versus rosiglitazone and IHD risk. Their conclusions were that 1) an association between rosiglitazone and IHD outcomes has not yet been firmly established, but sufficient safety signals have emerged to raise concerns; 2) the majority of published study findings do not positively correlate an increased risk for IHD in patients treated with pioglitazone, and hence there has been no black-box warning issued for pioglitazone; and 3) current evidence suggests that TZDs should not be used with the expectation of benefit with respect to IHD events.

Figure 1. Results of optical coherence tomography (OCT) and fluorescein angiography in a man with diabetes.34

Foveal thickness and macular volume are noted for each date. On August 2, 2007, only the right eye was scanned. Rosiglitazone was stopped after the visit of May 11, 2007. Because of residual symptoms, the right eye was treated by laser on August 2, 2007; follow-up evaluation on October 8, 2007, showed significant resolution. OCT uses a laser in a technique similar to ultrasound to obtain information about the macula. Laser light reflected from the retina is detected, and because of the partial transparency of the retina, different layers reflect differing amounts of laser light. A computer-reconstructed scan is produced that allows very accurate measurements of macular contour and thickness. OCT is extremely useful in the diagnosis and evaluation of diabetic macular edema and can be used to monitor the effect of treatment on retinal thickness. OD = ocular dextra (right eye); OS = ocular sinistra (left eye).

*Figure available in color at: www.thepermanentejournal.org/images/Fall2010/p69.jpg.*
Update

In June of 2010, Nissen and Wolski published yet another meta-analysis: Rosiglitazone Revisited.37 The conclusion of this meta-analysis including data from the RECORD study noted an increased risk of myocardial infarction (OR = 1.28; 95% CI 1.02-1.63, p = 0.04) but not cardiovascular mortality (OR = 1.03; 95% CI 0.78-1.36; p = 0.86). Excluding the RECORD trial yielded qualitatively similar results but quantitatively higher odds ratio disfavoring rosiglitazone.37 The firestorm over TZDs has continued and led to an FDA advisory committee meeting again on July 14, 2010 to decide the fate of Avandia. Numerous presentations were made from many leaders in the academic community as well from GlaxoSmithKline.38 Two decisions were made. The first was to keep Avandia on the market but recommend stricter warning labels. The second was that the postmarketing trial known as TIDE (Thiazolidinedione Intervention with vitamin D Evaluation) be placed on partial clinical hold.39 Under the partial clinical hold no new patients may be enrolled into the trial until further notice from the FDA. Patients already enrolled in the trial will be allowed to continue to participate.

Conclusion

In medicine, as in many other areas of innovation, initial enthusiasm is usually tempered with the realities of subsequent knowledge. The evolution of TZD development is a prime example. Once seen as holding a promise of mortality reduction, TZDs are currently used with a focus on additional glycemic control, with careful patient selection to avoid possible toxicities.

The primary prevention of type 2 diabetes mellitus and cardiovascular mortality in persons with type 2 diabetes mellitus is of the utmost importance. The current PHASE program at KPNC addresses this exact need of improving the outcome in these high-risk patients. Without current data suggesting any benefits of prescribing a TZD except for improving glycemic control, care should be taken to avoid subgroups of patients who may have a higher risk of developing edema, congestive heart failure, fractures, and possibly macular edema. These subgroups may include patients of advancing age, those taking higher doses of a TZD, women, those with renal insufficiency, and those who also take insulin. The type 2 diabetes mellitus treatment algorithm currently proposed may need to be further refined to balance adequate glycemic control, costs, and expected future risks in individuals (Figure 2-4).40

Figure 2. The diabetes mellitus portion of the current Kaiser Permanente Northern California PHASE (Prevent Heart Attack and Stroke Everyday) program.

Cr = creatinine; HF = heart failure; LFT = liver function test; NPH = neutral protamine Hagedorn (insulin); SMBG = self-monitoring of blood glucose; SQ = subcutaneous; ULN = upper limit of normal; bid = twice daily; hs = at bedtime; q2days = every 2 days.

### Figure 3. Proposed antihyperglycemic strategy in the patient with type 2 diabetes mellitus and coronary artery disease.

<table>
<thead>
<tr>
<th>HbA1c ≥ 7.0%</th>
<th>HbA1c &lt; 7.0%</th>
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<td>Metformina</td>
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<td>+ Pioglitazoneb</td>
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<td>HbA1c ≥ 7.0%</td>
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*Because of the risk of lactic acidosis, metformin should be avoided in patients whose coronary artery disease is complicated by acute or unstable heart failure.

*Because of the risk of fluid retention, pioglitazone should be avoided in patients whose coronary artery disease is complicated by heart failure; it is contraindicated in those with New York Heart Association class III to IV symptoms. Because of recent concerns regarding the increased risk of myocardial infarction with rosiglitazone, this drug is best avoided in coronary artery disease patients until further safety data become available.

*Secretagogues include the sulfonylureas and the nonsulfonylurea glinides. Certain sulfonylureas (eg, glyburide) may impair ischemic preconditioning and are probably best avoided in patients with active coronary insufficiency.

*Insulin can be added to or substituted for oral agents at any point in the disease course. When more advanced regimens are used, insulin secretagogues traditionally are discontinued. Reprinted with permission from Inzucchi SE, McGuire DK. New drugs for treatment of diabetes: part II: Incretin-based therapy and beyond. Circulation 2008 Jan 29;117(4):574-84, Figure 1.
Aleglitazar, a promising novel dual PPAR agent that is currently being tested in a phase III clinical trial, again brings hope to this field. We will await the results of this and other ongoing studies of diabetes medications that can now enter the market only if a favorable cardiovascular risk profile is attained.

Disclosures

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

Acknowledgments

We sincerely thank Saul Cenuth, MD, Principal Investigator and Director of the Diabetes Management Center of the BARI 2D study, Case Western Reserve, Cleveland, Ohio, for reviewing our manuscript.

Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

References


Figure 4. Proposed antihyperglycemic strategy in the patient with type 2 diabetes mellitus and heart failure.

* Secretagogues include the sulfonylureas and the nonsulfonylurea glinides. Certain sulfonylureas (eg, glyburide) may impair ischemic preconditioning and probably are best avoided in patients with active coronary insufficiency.

* Metformin is no longer contraindicated in this setting and may be used cautiously, but only in stable, compensated heart failure patients with normal renal function and acid-base status.

* Insulin can be added to or substituted for oral agents at any point in the disease course. When more advanced regimens are used, insulin secretagogues traditionally are discontinued. Because of the sodium-retaining properties of insulin, the lowest effective dose should be used, and the dose should be titrated carefully. Reprinted with permission from Inzucchi SE, McGuire DK. New drugs for treatment of diabetes: part II: Incretin-based therapy and beyond. Circulation 2008 Jan 29;117(4):574-84; Figure 2.
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ECG Diagnosis: Hypothermia

Joel T Levis, MD, PhD, FACEP, FAAEM

An Osborn wave (also referred to as the J wave) is a characteristic ECG finding for hypothermia consisting of an extra deflection on the ECG at the terminal junction of the QRS complex and the beginning of the ST-segment takeoff. Osborn waves usually occur when the core body temperature falls below 90°F (32°C), and are believed to result from an exaggerated outward potassium current leading to repolarization abnormality. They can also be found in other conditions such as hypercalcemia. Other ECG findings in patients with hypothermia can include prolongation of the PR, QRS and QT intervals, T wave inversions, and various dysrhythmias including atrial fibrillation, sinus bradycardia, atrioventricular block, and ventricular fibrillation. Fatal ventricular fibrillation or asystole can occur in hypothermic patients when core body temperature falls below 82.4°F (28°C).

References
Image Diagnosis: Interesting Chest Radiographs from the Emergency Department

L Paige Sokolsky, MD
Gus M Garmel, MD, FACEP, FAAEM

Figure 1. Left upper lobe pneumonia
Lobar pneumonia seen on chest x-ray results in a somewhat homogenous opacification of the lung with ill-defined margins. Air bronchograms are present in the image on the left. The lateral film demonstrates decreased retrosternal clear space and increased opacity at the level of the aortic arch (image on right).

Figure 2. Right middle lobe pneumonia
A “silhouette sign” is present when an infiltrative process lies adjacent to a solid organ or tissue, such as the heart or diaphragm. This is seen as the loss of the right heart border in the image on the left. Margins are well defined where the consolidation abuts an interlobar fissure. Both images demonstrate an opacity overlying the heart and a pronounced right oblique fissure.

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This chest x-ray in a patient who fell 15 feet demonstrates mildly displaced right third and fourth lateral rib fractures, a displaced right clavicle fracture, and a widened mediastinum. Rib fractures can be subtle (or nonexistent) findings on chest radiograph, and point tenderness with pleuritic chest pain should be considered a rib fracture despite a lack of radiologic evidence. Dedicated rib views seldom add relevant clinical information. In children, greater force is required to fracture a rib because of increased compliance. Thus, children may have a pulmonary contusion without rib fractures. Etiologies of rib fractures include blunt trauma, severe coughing, physical abuse, and certain sport movements (throwing, swinging).1

A pneumothorax on chest x-ray results in the loss of peripheral lung markings with a straight white pleural line parallel to the chest wall that does not pass outside the chest cavity. Skin folds, bed linens, and the medial scapular border may mimic this condition.4 Classification schemes include small and large pneumothoraces, with large defined as being greater than 2-3 cm from the chest wall to visceral pleura, which correlates to 20% to 30% decreased lung volume. Contrary to popular belief, the most appropriate view to initially screen for pneumothorax is an upright inspiratory (not expiratory) film because of the greater thoracic cavity size.5 A small primary pneumothorax does not generally require treatment, but a large primary or any size secondary pneumothorax requires treatment and close monitoring.5

This chest radiograph demonstrates air in the soft tissues of the neck and upper chest (seen in the myofascial planes), in addition to air outlining the mediastinum and superior pericardium. These findings occurred in a teenage girl who presented with chest pain and “crunchy” skin (Hamman’s sign) after vigorous coughing against a closed glottis. In this case, these findings did not result in hemodynamic compromise, although may in some cases. Other causes of pneumomediastinum or pneumopericardium include blunt or penetrating chest trauma, heavy lifting, mechanical ventilation, rupture of the esophagus, trachea, bronchus or alveoli, perforated vescus, and barotrauma. Treatment ranges from reassurance, observation, or release of air, depending on signs, symptoms, and amount of air.

References
HAITI: The Kaiser Permanente Experience—Part 1

Sarah Beekley, MD

“It is one of the beautiful compensations of life, that no man can sincerely try to help another without helping himself.”
— Ralph Waldo Emerson

Our cause is health, our passion is service, and we are here to make lives better. This is the social mission of Kaiser Permanente (KP), and the personal mission of the staff whose stories are shared in this collection of essays. Each volunteered their time, sacrificed their personal safety and comfort, and challenged themselves to extend well beyond their normal limits both personally and professionally. And each of them would say that they gained more than they gave.

Why is volunteering such an elevating human experience? Why is being of service to someone who cannot repay you so profoundly rewarding? Perhaps it is legacy, knowing that one has truly made an invaluable contribution to the lives of others. Perhaps it is mastery, the challenge of testing one’s expertise, resilience, and resourcefulness in an unfamiliar and austere environment. Perhaps it is gratitude, the recognition that we live and work in a community of extraordinary wealth and privilege, and that with this privilege comes the opportunity, even the responsibility, to give back. Perhaps it is just the human desire to connect in an authentic and noncontractual way. These stories give us a glimpse into the many factors that motivate us.

Every physician and nurse who worked in Haiti did so because colleagues and family at home made it possible. These stories are written both to inform and to express gratitude to the many silent partners that made this work possible. Many are extracted from letters, blogs, or e-mails written while in Haiti or soon after returning to the US. They are written to honor the people of Haiti, suffering or healed, living or dead. They are written to acknowledge the courage, the sacrifice, and the skill of those who continue to dedicate themselves to making lives better.

Because the desire to share the stories was as great as the outpouring of compassion, this collection is being published in two parts. This first part is an introduction and commentary on the experience, the need, and the organization of answering the need. The second part, in the Winter 2011 issue, will be the personal stories, triumphs and failures of some of those who traveled to Haiti whose lives were changed.

Tribute

Robert Pearl, MD

Kaiser Permanente (KP) began when Sidney Garfield, MD, went into the Mojave Desert to provide care to the workers building the California Aqueduct. He went there out of a sense of mission to deliver quality medical care to people in need. That spirit remains vibrant and powerful today in our many relief efforts from the tsunami in Southeast Asia to Hurricane Katrina to Haiti. The stories of these brave volunteers serve as an inspiration to all of us. I am grateful to all of the people of KP who make sacrifices to help others, whether in our local communities or across the globe. I hope all of us will take the time to read about the work they did and the impact they had.

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I went to Haiti in late January as a member of an Operation Rainbow surgical team which comprised both Kaiser Permanente (KP) and non-KP team members. As background, my own medical charity, Medical Exchange International (www.medicalexchangeintl.org), had partnered with Operation Rainbow in the past to provide anesthesia equipment for several surgical missions in the developing world. In Haiti, we had an opportunity not only to provide pulse oximeters and anesthesia supplies, but also to help out on the clinical front line. As an anesthesiologist with a background in medicine and critical care, I split my time about half and half between the operating rooms and the intensive care unit (ICU), both of which were intense and busy. Whereas I could write at length about what we did and how we coped with severely constrained resources, I want to focus this article on an important “epiphenomenon”: the catalytic action of the earthquake tragedy to create a new inflection point in the long history of Haiti-Dominican Republic relations.

Although we experienced the startling devastation in Port-au-Prince when we went into the city to deliver a pulse oximeter, our clinical work took place entirely at the Buen Samaritano (or Bon Samaritain in French) makeshift hospital in the town of Jimani, one mile east of the Haitian-Dominican border in the Dominican Republic. Before the earthquake, the facility was a yet-to-open complex comprising a chapel, an orphanage, and a dental clinic. After the earthquake, the chapel and the orphanage were rapidly converted to hospital wards, and the dental clinic became our acute care venue including a 4-room operating suite. We estimated we had about 250 patients on site, almost all of whom were injured Haitian refugees. We did between 20 and 50 surgical cases a day in 4 converted dental consultation rooms. The vast majority of our surgical cases were orthopedic and plastics procedures, as expected. In our makeshift ICU, I cared for 5 to 10 patients on any given day, and we also opened up a perinatal ward when we suddenly found ourselves doing C-sections (if you build it, they will come …). The facility was staffed by volunteers from all over the world. We worked closely with our own superb Operation Rainbow orthopedic surgeons, including our mission lead Dave Atkin, MD, from San Francisco and pediatric specialist Chris Comstock, MD, from Corpus Christi, Texas, and with surgeons from around the US and around the globe. In the ICU, I worked closely with an excellent emergency/critical care team from Barcelona (and by closely I mean cross-covering to maintain 24/7 on-site care—the real thing). Nurses and pharmacists from all over the world worked together, and I remember being particularly touched when I saw a group of Israelis help an Arab team unload several tons of food that was brought in by the United Arab Emirates. All this is to say that there was a tremendous and truly inspiring internationalism—a deep humanism was in full bloom here.

This leads me to my main point: I witnessed first-hand an extraordinary stepping-up-to-the-plate by the Dominican government and the Dominican people. From the moment we arrived, we saw that the Dominicans had dedicated their major international airport in Santo Domingo to international relief efforts. Because Haiti’s airports were marginally functional at best,
From Tragedy, Opportunity—A New Beginning for Haiti and the Dominican Republic

this was crucial to the immediate relief efforts. The short aid corridor between the Dominican Republic border and Port-au-Prince was active 24/7 with an endless stream of trucks laden with food, water, tents, coal, firewood, blankets, medical supplies, and more from dozens of countries and with a very notable contribution from the Dominican Republic itself. For example, the Dominican Republic sent 15 mobile cafeterias serving 100,000 meals a day into Haiti. Santo Domingo Water Corporation sent dozens of tank trucks, each containing 2000 gallons of water. Estimates of total

Dominican Republic aid for Haiti to date have exceeded $17 million, no small sum for a small island republic that is itself a developing nation. We witnessed the Dominican army conspicuously keeping the Dominican side of the relief corridor safe and functional until the United Nations (UN) Peacekeeping Force (which fortuitously had been in Haiti prior to the earthquake) took over on the Haitian side to assure the relief lifeline kept flowing. Thankfully, the Dominican authorities allowed thousands of Haitian refugees to cross the border eastward into the Dominican Republic to seek care in our emergency relief hospital and in other Dominican hospitals.

At Buen Samaritano, I noted that many of the drugs we used, and a hefty component of the supplies we used such as oxygen masks, epidural kits, and IV catheters, came from the Dominican Republic. The Dominican personnel presence was huge, literally hundreds of Dominicans representing the Dominican Public Health Department (known by its Spanish acronym of SESPAS), the Dominican Food Aid Program, the Dominican Republic’s major emergency relief organization (known as URN for Unidad de Rescate Nacional), as well as Dominican representatives from countless humanitarian programs such as the Pan-American Health Organization (PAHO), US Agency for International Development, the UN World Food Program, and Ninos de las Naciones. The Dominican-based ARS Humano provided the trailers we used for our tuberculosis isolation ward and our spinal cord injury care unit. Dominican interpreters navigated the tricky Creole-French-Spanish language challenges for us. The Dominican government allowed US military transport choppers as well as those of several private US entities into their airspace to help us evacuate some of our most critically ill patients to the USNS Comfort hospital ship. The Dominican army was on-site day and night in Jimani, keeping us safe and keeping the peace amidst the influx of refugees. The Dominican charity Esperanza provided transportation and meals for our team. Last but certainly not least (from an anesthesiologist’s standpoint), the Dominican Red Cross filled our rapidly depleting oxygen tanks every few days—life-giving assistance, literally and figuratively.

This Dominican largesse would be worthy of praise and worth relating in and of itself. But what makes it all the more heartening and extraordinary, in fact truly “game-changing” if one can apply that adjective to international relations, is that it opens a new era in the long history of tense and violent relations between these two neighboring nations. Columbus landed on the island of Hispaniola on his first voyage to the New World in 1492 and promptly claimed it for Spain. But it did not take long for the French to wrest half of the island from the Spanish, thus establishing
two separate but equal colonies with political, cultural, and economic disparities that persist to this day. The Dominicans still resent a period of Haitian occupation from 1822 through 1844, though some Haitian scholars insist that the Haitians were “invited” in to ensure abolition of slavery in post-Spanish Dominica. Little known to most outsiders, the Dominicans ultimately had to win their independence not from Spain but from their Haitian overseers. The Dominicans repaid the favor in kind with a brutal retaliatory massacre of over 20,000 Haitians by the despotic Trujillo regime in 1937. To make matters worse, the persistent sharp contrast in prosperity, and some say an inherent racism in the Dominican Republic—have continued to fuel the fires of hatred, fear, and mistrust. The Dominican Republic ranks a respectable 90 out of 182 countries on the UN’s Human Development Index, a composite measure of wealth, health, and educational indices. Haiti comes in at a miserable 149, just a hair above Sudan. The Dominican economy has long profited from cheap Haitian labor: more than 90% of the country’s sugar workers are of Haitian origin. The average Dominican can expect to live into his or her 70s, whereas 61 is the average life expectancy for Haitians and this is now surely reduced as a result of the earthquake. All of this makes it understandable that Haiti rejected an offer of over 3000 Dominican troops which was tendered the week after the quake with the intent of assisting the UN battalion in securing the aid corridor in eastern Haiti. To many Haitians that offer was similar to the idea of having Russian “peacekeepers” come into the Ukraine.

But that long and mostly ugly relationship which has prevailed for centuries may now be coming to an end. The opening was there after January 12, 2010, and the Dominicans took it. Some say it is in their interest to prevent a “failed Haiti” (if that is not already the case) and that the Dominicans are just pragmatists working to stem the tide of refugees. No doubt there is, as always, an element of public relations at work here and in fact the Dominicans have received some good press for their efforts. But having seen it in action, on the front lines, the Dominican effort by my observation is more than pragmatic and more than PR. It is huge and robust, carefully thought out, and thoroughly genuine.

Time will tell if this represents a true turning point and ushers in a new era for these two countries that uneasily share an island in our own backyard. Haiti’s tragedy is the costliest natural disaster in recorded history according to the Inter-American Development Bank. But as with any great tragedy, there is great opportunity inherent in the rebuilding phase, and the Dominicans seem to have grasped that. The Dominican effort and the healing of Haiti-Dominican Republic relations may turn out to be a very major ingredient in the formula for Haiti’s long-term (and I use the word advisedly) reconstruction. ❖

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**No Need to Wait**

How wonderful it is that nobody need wait a single moment before starting to improve the world.

— *Diary of a Young Girl, Anne Frank, 1929-1945, Jewish-German diarist and holocaust victim*
When Haiti suffered one of the worst natural disasters ever to occur in the Western hemisphere, people from all over the world responded with donations of time and money. The first response was excellent—although at times overwhelming the fragile infrastructure—it was substantial and well intended.

In the past The Permanente Journal (TPJ) has chronicled the experiences of health professionals responding to disasters, including the Katrina flooding and the Bande Aceh tsunami. Here, TPJ shares the stories of those who responded to the earthquake in Haiti and of those who support them; more stories will appear in the Winter 2011 issue.

As important as these stories are, they are only the first chapter in the story yet to be told of Haiti’s recovery: The story of a country almost completely destroyed and the story of a people caring for each other and coping with their present difficult situation. The story yet to be written will be of the massive rebuilding and relocation that must be supported by people and finances from around the world.

During my recent trip to Haiti with a health care team, I had several community leaders describe how immediately after the earthquake, groups from several countries and agencies provided food, living supplies and health needs. After the initial response, care from outside Haiti has markedly decreased and now there are only a precious few volunteer short-term teams, most faith-based, assisting the Haitians. Haitian leaders wonder: Have Americans forgotten their plight already? There is excellent ongoing support by several large agencies, but the challenge is just too great to meet the basic living needs of the Haitians. The destruction in Haiti is more widespread and devastating than imaginable. Having been part of a medical relief team in Bande Aceh, I have seen destruction and the plight of displaced people. Although the challenges in Haiti are quite different, it is my opinion that the long-term relief needs in Haiti will actually be greater than Bande Aceh.

Living conditions for most Haitians were bad before the earthquake, now the conditions are unspeakable. Thousands of Haitians are living in tents creating clusters that look like refugee camps. Fortunately, large-scale disease outbreaks have been avoided because international agencies have provided clean water and scores of port-a-potties. Tent life is awful. Several Haitians I know who are living in tents tell me of the difficulties of their present living conditions, especially during the heavy rains of May when water would flow through the floors of their tents. One friend of mine lives in a tent with 15 family members. People are hungry. Initially, rice and beans were delivered, now only rice is being made available. Without jobs, many walk aimlessly around these camps. Finally, there are no regular communications from the Haitian government. Nobody knows what to expect.

I’m certain talented people at the United Nations, World Health Organization and US Agency for International Development are making plans to help the Haitian people. InterAction, a coalition of aid organizations, planned to divide their available funds for immediate relief and for long-term rebuilding. It can only be assumed that holding funds in reserve must reflect the belief that no further major inflow of relief funds is expected. If that is in fact the case, then the overall funds available will be tremendously inadequate. The funds donated for Haiti relief in the first 4 months was $1.3 billion, which is significantly less than the donations in the first 4 months to either 9/11 ($2.3 billion) or Katrina ($3.4 billion).

Several major needs over the next decade will include: orphan
Haiti—Forgotten Already?

COMMENTARY

Haiti—Forgotten Already?

care, medical and dental care, optical support, microenterprise development, and, of course, light and heavy construction. People and money will be badly needed for years to come.

So What Can Be Done?

First, the extent of this ongoing disaster and the immediate needs of the Haitian people must return to the awareness of the world, especially those of us in North America. Champions are needed to advocate for the Haitian people, beginning with President Obama and then others who can influence Americans, such as celebrities.

Second, major funding far in excess to what has already been donated is needed. Giving must be considered an ongoing need and not an isolated fundraising event. I remember the time when the tragedy of the African AIDS epidemic eventually made such an impact on the world that we started to see regular fundraisers, documentaries, and other ongoing reminders of the needs of the African continent. The living conditions of the Haitian people need to be raised to a similar level of awareness.

Finally, we must make certain that some of our erroneous assumptions do not blunt relief responses. The history of corruption in the Haitian government doesn’t change the need. Past living conditions do not make current conditions any more tolerable: the majority of Haitians are living in great uncertainty and in much poorer living conditions.

The Haitians are a wonderful people, a highly literate people, a caring people. Now they are a people in need.

How would you answer the question asked by the Haitian leaders? Have we already forgotten them?

References

Mes Quatre Fils (My Four Sons)

Watershed: a chiefly British term that means the crest or dividing line between two drainage areas or bodies of water. In American English, this term has come to mean an important point of division between two phases or conditions. In early 2010, I was badly in need of a watershed. My life had become a complicated morass of the personal and professional, and in my late 30s, a watershed moment was needed to restore balance and perspective as I moved into my next decade. As I remember the call I received on Sunday morning, February 7, 2010, asking that I come to Haiti, tears sprung to my eyes, because at precisely that moment, a watershed began.

Why would answering a call to humanitarian duty lead to such an important inflection point in one’s life? How could a mere two weeks create the transition that only a watershed moment can establish? For those who have been part of relief efforts in the past, the answer is clear: the unique relationships in which one participates in this kind of intense situation are the answer. In particular for me, a unique family that I built with four interpreters who had lost their parents, siblings, and many friends, Christophe, Robenson, Hilaire, and Wilson helped to refine my perspective and re-align my life with my personal moral values.

As an only child without siblings, my experience of family is of intimate isolation, not of the broad, sweeping ties that a large extended family grants and for which I have often pined. The many Haitians who lost their families and were left without children, siblings, and parents were relegated to a condition both alien and devastating. Indeed, the loss of family was perhaps one of the greatest tragedies of the event. For me, my distance from my partner and 19-month-old son was also alien and challenging. In this catastrophic period in Haitian history, these personal and environmental factors collided in a way that was unexpected, but extremely enriching.

Humanity is defined by relationship. Loss of physical health, economic prosperity and even basic needs such as food and water, are tolerable when our fellow men and women help to nurture us through the chaos. For Haitians, as for many societies worldwide, the basic unit of relatedness is the family or the family of choice: a source of advice, reinforcement, guidance, and support. As I arrived in Haiti and experienced the temporary loss of my own family, distant from my own support system and alone in a foreign land, I needed that same support and strength. In a way, my experience with these four interpreters taught me that I cannot live in a vacuum anymore than they.

Although I had not experienced their profound loss, I understood their need for companionship. Our very different experience of aloneness led to our mutual need for a surrogate family.

On February 28, 2010, this family was disrupted, and the difficulty of separation from my adopted, Haitian family had its own special level of intensity. Leaving these four young men when I wondered if I could have done more for them was tempered only by the realization that in a short day, I would be reunited with my own family. As I ascended from Haiti on the jet that would carry me back to my daily routines, familiar personal life, and career aspirations, I realized the importance of intense personal relationships with strangers in a unique situation: not just with my adopted sons, but also with the volunteers, dedicated relief workers, and Haitian nationals who had helped to create the watershed moment for me.

Life-changing experiences breed intensity and a unique brand of relational intimacy, the essence of which is felt forever. My experience in Haiti was indeed a watershed moment. As a young woman named Dominique, another interpreter at the hospital told me: “Haiti is a land of contradictions and paradoxes, as it holds you tightly in her arms and never lets you go, even as you may try to leave her. Haiti Pou Tou Tan (Haiti Forever) is how we refer to our Mother Land.” Indeed, Haiti will live in my mind and heart forever.

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Our collective organizational response and my personal experience in Haiti were different from any prior disaster response in which I have been involved.

I have had the fortune to be involved with Kaiser Permanente (KP) volunteers and disaster relief efforts during large-scale disasters since we sent the first teams to Southeast Asia after the 2004 tsunami. In addition to the more than 40 people we sent in relief efforts to Sri Lanka and Indonesia for the tsunami, multiple KP physicians volunteers traveled to Kashmir after the earthquake in Pakistan in late 2005 to work as part of Relief International’s program. KP physicians collaborated with the Department of Health and Human Services to provide medical care in the Gulf Coast after Hurricane Katrina in 2005. Another KP physician and I volunteered with Doctors Without Borders after postelection violence broke out in early 2008.

In the years since we first sent volunteer disaster medical relief workers to provide aid after the tsunami, many changes have occurred within KP’s Global Health and volunteer programs that have resulted in better support for this distinctly important and rewarding work. Under the sponsorship of The Permanente Medical Group leadership, we have:

- Created a framework to support physician volunteerism by coordinating the efforts of the Assistant Physician-in-Chief of Health Promotion, Community Benefit, Public Affairs and dedicated physicians at each facility via the KP Cares program.
- Developed relationships with multiple medical relief organizations including Doctors Without Borders, Relief International, International Medical Corps, Medshare, and others.
- Created a KP National Volunteerism Web site (www.KPCares.org) for all employees of the Northern California, Mid-Atlantic and Georgia Regions. This enables all KP staff to both post and search volunteer opportunities. In addition, it allows staff to register in a comprehensive disaster response database that was used, with the invaluable support of Program Office’s Community Benefit, to identify skilled clinicians immediately after the Haitian earthquake. This database continues to serve as a resource should a disaster occur in our own local communities.
- Developed and delivered several Continuing Medical Education courses on the topics of disaster medical relief and humanitarian medical work in austere environments.

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In total, these efforts created a KP response to the Haiti earthquake unlike any response we have mounted in the past. A small number of KP staff traveled to Haiti with organizations they had identified on their own immediately following the earthquake, or reconnected with relief organizations with which they had worked in the past. The greatest impact however, was via KP’s contribution as the main contributor of medical personnel and logistical support to Relief International’s disaster response (see www.RI.org). We used the KPCares.org Web site to gather information on interested volunteers, and in the first month alone sent over 30 physicians and nurses to Haiti with Relief International. In the first few weeks we staffed a team of emergency physicians, nurses, and medics who largely delivered trauma care. Our subsequent waves of volunteers ran the spectrum of Family Medicine, Pediatrics, Ob/Gyn, Internal Medicine, and Mental Health. They represented the Regions of Northern California, Southern California, and the Mid-Atlantic. All donated at least two weeks of their time with the support of their departments and colleagues. We are now also involved with the Relief International long-term capacity building project in Haiti, and contribute about two medical volunteers at a time for their efforts to run five community clinics, staffed primarily by Haitian medical personnel. Our volunteers provide teaching and educational support for the Haitian national staff.

On a personal level, as intense and chaotic as the first few weeks of the relief effort were, I was deeply inspired by the successful development of our new capability to respond. KP now has the ability to mobilize our volunteers and their expertise to assist in future humanitarian disasters. I could not be more proud to work for an organization that supports volunteer and community service efforts in such a comprehensive and systematic way. There is no greater reward than to be of service in a time of need in a way that honors the principles of our professional commitment to medicine.

Father and son.

Photo by Hernando Garzon, MD.

**Full of Grace**

Everybody can be great. Because anybody can serve.
You don’t have to have a college degree to serve.
You don’t have to make your subject and your verb agree to serve ….
You don’t have to know the second theory of thermodynamics in physics to serve.
You only need a heart full of grace. A soul generated by love.

— The Reverend Dr Martin Luther King, Jr, 1929-1968,
Baptist minister, civil rights activist, 1964 Nobel Laureate for peace
After the earthquake struck Haiti’s most populous area in and around Port-au-Prince, and just before the rainy season started, several Kaiser Permanente (KP) physicians moved in to coordinate the medical arm of the Malaria Emergency Technical Operational Response (MENTOR) program. Traditionally, MENTOR has focused on malaria in war zones and after major natural disasters. Several KP physicians initially worked with this French Nongovernmental Organization (NGO) after the 2004 earthquake and tsunami in the Indian Ocean on the Island of Sumatra in Indonesia. These physicians shared shifts for several months assisting in the rebuilding with a focus on vector-borne disease reduction and control. Since then, they have assisted MENTOR in other natural disasters. After the 2008 Cyclone Nagris in Myanmar, MENTOR implemented programs for not only malaria but also for other vector-borne diseases, such as dengue. Between those disasters, KP physicians have also worked as trainers for MENTOR workshops on clinical program management of malaria and other vector-borne diseases in such places as Uganda, Kenya and Japan and even New York and Mill Valley, CA.

Haiti’s earthquake was the sixth deadliest natural disaster in recorded history (ranking just after the 2004 tsunami) and is estimated to have killed 230,000 people. Importantly, this event displaced over one million people, leading to large scale movements and increasing risks of insect-borne diseases. This risk is amplified by three factors: exposure, migrations, and infrastructure disruption. In Haiti, the population has increased exposure as they are now living in densely populated tent camps with little between them and the elements. Rainy season starts in April and vectors burgeon. Second, when people move from areas of low endemicity to areas where disease rates are high, there are more susceptible people at risk. This also works in reverse to the disadvantage of a population when individuals who are infected move into zones that have no disease but the mosquito vectors are established and can spread the disease into the nonimmune and previously unaffected majority population. The third risk element is simply the disruption of public health systems that can coordinate the prevention of disease. The public health system was arguably underfunded and ineffective before the earthquake as the deadly Plasmodium falciparum and mosquito-borne parasitic disease, lymphatic filariasis continued to thrive in Haiti, one of the few places in the Americas it is still observed.

The KP-MENTOR initiative focuses on clinical trainings, vector assessments and control using indoor residual spraying and larviciding. We coordinate with the health sectors of many of the 391 registered health NGOs in Haiti to build capacity around vector-borne disease recognition, diagnosis, and treatment. We collaborate with the Ministry of Public Health and Population to promote guidelines and develop strategy for managing these often silently persistent diseases that put a major drag on human comfort and progress.

**Mentoring About Vector-borne Disease Control**

D Scott Smith, MD, MSc, DTM&H

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Twilight on Tuesday, January 12, 2010 in Port-au-Prince, Haiti: about 40 seconds of chaos 7.0 magnitude. Buildings begin to crack and the sound makes people think of the gunfire that is all too frequent in the downtown area. For safety, people run inside. Buildings, shoddily constructed, crumple, trapping those inside. One of the best hotels, the Montana, on a verdant hillside overlooking the steaming plain of lowland Port-au-Prince, pancakes entombing more than 300 people. The air is thick with heat and the dust of concrete.

Afternoon on Tuesday, January 12, 2010 in Oakland, CA: news on the car radio tells me I will make my fourth trip to Haiti sooner than planned. During 2009, I had worked in and around Port-au-Prince as a volunteer anesthesiologist on three separate Smile Train-funded surgical mission trips. I had stayed at the Montana. I had walked through the Cité de Soleil. My friends and colleagues lived in Delmas, now largely destroyed. We had operated on nearly 200 children and adults with congenital cleft lips and palates, tumors, and burns, after seeing and screening several hundreds more. Because of the poverty, neglect and lack of long-needed medical services, many more adults needed our teams’ attention. Despite the dire living circumstances and lack of resources, locals were unfailingly polite, helpful, and grateful for our efforts. I loved this Pearl of the Antilles with its vibrant culture and people, rara music, voodoo, and native art. Despite Haiti’s turbulent history, the indigenous spirituality and resourcefulness were unparalleled by any country that I have traveled to.

I check my ready bag that evening and prepare to depart. My Disaster Medical Assistance Team (DMAT) is on call in January and all members are on standby for deployment. DMATs and International Medical Surgical Response Teams (IMSuRT) are groups available for national disasters and emergencies such as 9/11 and Hurricane Katrina. Recently the National Disaster Medical Service (NDMS) had been preparing DMAT and IMSuRT groups for work on a global scale. Months of team meetings involving disaster response and planning, equipment training and orientation, and numerous deployments have prepared team members to provide triage, evaluation, and first-response treatment of populations in times of disaster.

Wednesday, January 13, 14:53 pm: simultaneous cell phone text, e-mail, and voice mail set us in motion. By the grace of our Kaiser Permanente departmental scheduler and the generosity of my departmental chief and colleagues, I commit as a rostered team member, and leave the following day for Atlanta. After an overnight briefing, including DMAT teams from Massachusetts, Florida, and New Jersey, we board a government charter aircraft and fly directly into Touissant L’Overture airport in Port-au-Prince, landing Friday, January 15.

Long distance disaster relief is seldom smooth. Teams arrive before the equipment caches. Security cannot be guaranteed in the logical hospital sites where patients are. Infrastructure and transportation are nonexistent. Running water, electricity, cell phone, and Internet service are absent. An alphabet soup of international and federal agencies (PAHO, UN, USAID, and CDC) as well as the pre-existing nongovernmental organizations are in disarray. Air traffic control and the airport terminal are destroyed. The one runway, unlit, is not built for receiving overloaded flights.

All these issues become secondary once the teams find their sites and equipment and supply lines are
established. The Petionville Country Club becomes a triage and day treatment center for the tent city that forms on the nearby golf course. The Quisquiya School in Port-au-Prince adjacent to the Ministry of Public Health’s Gheskio HIV clinic becomes a mobile field hospital with surgical and obstetric capability for the tented camp built on the neighboring soccer field. Federally deployed US teams of medical volunteers from different states are working cooperatively in a single encampment.

The teams quickly adapt to the heat and insects, the lack of running water, the MREs (“meals refused by enemy”), and to each other. Day and night shifts alternate sleeping on cots in tents and battling mosquitoes and heat rash. The US Army’s 82nd Airborne establishes a helicopter landing zone across from the soccer field and ensures a steady flow of the most critical patients evacuated from the University Hospital and the surrounding neighborhood. The cases shift from week-old orthopedic crush injuries and long bone fractures to gunshot wounds and day-old babies with sepsis and respiratory failure. We deliver 11 babies and operate on 30 patients. We can run 2 simultaneous operations, but are limited by the lack of oxygen and supplies for spinal or nerve block anesthesia. There seem to be babies and children everywhere. A respiratory therapist hand-ventilates a tiny premature infant overnight before she can be helicoptered out to the USNS Comfort. A pharmacist cradles a child while dispensing medication. A warehouse supply logistician comforts a boy who has lost his leg.

The work is constant, grueling because of the heat and uncertainties, and often hopeless. Bright spots appear in the camaraderie of shared adversity and in the unexpected resilience of a particular patient. Guil­lame, not expected to live, gets hope in the form of an oxygen tank delivered by his brother’s motorcycle. Micheline, upon being told she is paraplegic and will never walk again, finally consents to a much needed amputation of her gangrenous lower leg. Robert, a lost child, is re-united with an uncle. Patient #361 gets the next available spot for air evacuation out to Florida. At night and on Sunday morning, the hymns of prayer and gratitude from the people in the adjacent tent city rise above the generator’s drone and float back to us through the warm heavy air. Arms are raised in supplication, and thanks are given for the “it could be worse” scenarios. Small groups of team members pray together. The scent of garlic and peppers being cooked mingles with the acrid smoke of burning trash and decay.

After two weeks, word arrives that a plane is to take the first teams back to the US. Landing and equipment resupply schedules remain highly variable and uncertain. However, replacement teams are en route to relieve us. The transition is rapid but thorough, with shifts overlapping and orientations completed. We had been cocooned inside the surgical field hospital where we had arrived in darkness, isolated within and guarded by the 82nd Airborne, so it was a shock to transit through the main streets of the still-ruined city. Daily activity, as I had seen in my previous travels to Haiti, is returning. Strangers were helping each other and it is good.
March 10, 2010

After leaving Haiti and returning to my life in the Bay Area, I felt as if I returned to another world. The orderly rows of lights as I descended into Miami airport were a stark contrast to the haphazard state of Port-au-Prince. There are few similarities between the scene I left and that to which I returned. But, what if the same tragedy happened in our own country? I learned many lessons during my five-week mission to Haiti, and will share a few of them here so that we can be better prepared to respond to future events on our own soil.

We have all heard the statement, “Communication is always the biggest problem during a disaster.” In retrospect, I realize I never truly understood the implications of this statement until now. When I arrived in Haiti, local phone coverage was intermittent, at best. Even when calls went through, the reception was often so bad that it was more frustrating than helpful. Satellite phones were unreliable and generally unusable. Surprisingly, my iPhone seemed to send and receive text messages and e-mail without much problem. Although this was good for simple communications, texting proved too time-consuming, and time was a luxury I did not have. Coordinating relief operations via any electronic means proved to be difficult, and face-to-face communication became invaluable. As a lesson learned, I would urge everyone to become adept at text messaging so that you are better prepared for times when communication is limited.

I heard many stories of trapped victims texting their friends and family. Through this communication alone victims were rescued. Although helpful, the time delay and content limits of text messages made me realize how important it is to be self-sufficient and decisive during the aftermath of a disaster. “Be prepared,” is another commonly heard statement in disaster readiness. Before I left for Haiti, I read *The Unthinkable, Who Survives When Disaster Strikes—and Why* by Amanda Ripley. She describes human response to disasters and discusses ways in which we can react better to such situations. Ms Ripley writes that the people around you during a disaster are the critical component to whether you survive it. In Haiti, several days passed before international aid arrived. Before then, the Haitians could rely only on those around them. Preparation makes a difference not only in how effective the response is, but ultimately in how many lives are saved. As a lesson learned, each and every one of us should think of how we will help our neighbors during a disaster. The more times you run through scenarios in your mind or in a drill, the better you will react in a real event. Now when you hear “Be prepared,” don’t just consider the supplies you might need, but also think of what role you will play in the hours or days after a disaster without communication.

The next lesson is one that became a hot topic after Hurricane Katrina: “Crisis care guidelines,” previously: “crisis standards of care” or “alternate standards of care.” During the management of disasters, resources are limited, and patients will not be able to get the same quality of care that they would get during an average, non-disaster-stricken time. Crisis care guidelines were developed to help medical professionals navigate through these difficult times. For instance, if there are too few ventilators for patients who require one,

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which patients get the ventilators? Similarly, mass casualty triage is another form of crisis care management. In Haiti, the baseline country standard of care was generally not to intubate critically ill patients. As disaster responders it is imperative that we have a grasp of the current standards of care.

What also became apparent is that these standards change rapidly depending on the resources available. For instance, when the German Red Cross set up a tent hospital 15 minutes away from our clinic with ventilator and intensive care unit capability, our clinic’s standards of care changed. Similarly, when the hospitals around us filled up and stopped taking critically ill patients, our standards changed. This occurred day by day, and sometimes hour by hour. This accentuated the fluid nature of disaster work, and is something that should be considered when we consider crisis care guidelines in our own hospitals and within our own communities.

Finally, the last lesson is organization. In a blog, I mentioned the chaos in Haiti during the emergency response. This is not unique to Haiti, and is expected after any catastrophic event. Whereas I seem to thrive in chaotic environments, I also recognize the importance of trying to minimize chaos to improve efficiency and productivity. During visits to several different hospitals in Port-au-Prince, I witnessed American physicians, nurses, and medical support volunteers arriving unannounced and offering their expertise. Similarly, many donors sent large quantities of supplies to various hospitals in Haiti. Although these gestures are very much appreciated, the proper coordination of these activities would allow for better productivity of volunteer medical staff and better management and use of supplies. Similarly, better coordination would allow for better safety, security, and planning. The lesson learned from this is that if anyone is interested in participating in future disaster efforts, signing up now to be a health care volunteer is the best approach. You may do this through your hospital, www.kpcares.org (available to any Kaiser Permanente employee nationally), your county or state professional associations, or various nongovernmental organizations. If you wish to donate money or supplies to future relief efforts, donate to organizations that you trust now so that they can appropriately coordinate their efforts and be prepared and ready for the next disaster. If everyone followed these simple steps, I am convinced that the level of chaos would be more manageable and the efficiency of response efforts would improve.

The people of Haiti may seem like they live in a different world, but as Amanda Ripley describes in her book, “Fear is a primitive response.” Humans, no matter where they are, will have the same fear response. If we stand ready for disaster, we will fear it less, and we will come together and manage it. Let us learn from this tragedy and prepare ourselves, so that this historic tragedy will not repeat itself.

Thank you for your tremendous support.

Reference
And The Beat Goes On

Pattie Palmer-Baker

Autumn licks the maple’s outer
Branches where green heaves
With desire for the sunlight smashing
Stained-glass windows with red;
That long-wave extreme of the spectrum a heart pumps,

Red wave after wave. But my heart flutters
Like a weak fist clinching, opening
As wide as a cracked door. Blood backs up, thickening
Into a sticky red-black pool where tiny fists might float.
The doctor’s fear: one will break loose and hurtle
To my brain, punch a black hole that sucks words, moons, worlds.

Only a little dangerous, although.
Not like atrial fibrillation, a serial-killer; pumps
Wild, erratic, erotic. I would die for that beat.
But this heart flutter beats weakly, organizes
Into a saw-toothed pattern; perfect for me, a woman
Clutching her heart for fear of.

I accede to the doctor’s order: an anticoagulant to thin
Syrupy black-cherry blood until watery red races
In my veins, pumping up
Centers in the purple flowers my skin blooms.

A medical warning; my new blood,
High on thinners, might amass
Red until it ‘bleeds out.’
But why should I care? I am seasoned
In autumn. Color-drunk,
I welcome death for a dripping slice of life.
Dear Editors and Readers,

Effects of 12- and 24-Week Multimodal Interventions on Physical Activity, Nutritional Behaviors, and Body Mass Index and Its Psychological Predictors in Severely Obese Adolescents at Risk for Diabetes
Fall 2010, page 29

The approach taken in the current obesity article by James J Annesi, MD; Ann M Walsh, MS, RD; and Alice E Smith, MS, MBA, RD is so different than our observations gleaned from a quarter-century of experience treating obesity that some useful insight might be gained by comparison. Their essential conclusion from their carefully described and well-executed study is that a major treatment effort focusing on diet and exercise as the key treatment modalities failed to reduce weight meaningfully in a group of morbidly obese adolescents. Because the concepts of diet and exercise reflect conventional thinking about a problem whose treatment is rife with difficulty, we propose that they are describing a treatment approach whose basic premise is flawed.

The concept that obesity is the result of nutritional ignorance, while appealing, has no more demonstrable validity than does the supposition that poverty results from an inability to count money. Each, however, provides the comforting opportunity to busy ourselves in teaching rather than in understanding a more disturbing causality.

It is axiomatic in medicine that etiologic diagnosis is antecedent to treatment. Otherwise, we end up treating cough instead of Gram-positive bacterial pneumonia, or do not differentiate the shortness of breath of pulmonary embolism from that of anxiety. The question not addressed by Annesi et al (and by many others) is Why these children became obese, understanding that this is not to be confused with How they became obese. In what ways do their obese patients differ from demographically similar adolescents who do not significantly overeat? As we point out in our article in the Spring 2010 issue of The Permanente Journal (TPJ), with very rare exception, no one is born fat. Thus, the age at which weight gain first begins is a useful start in the differential diagnosis of the physical sign of obesity. Family history is also important, not because of genetics, but because it allows us to see how others in the same household have responded to life’s stresses, whether internal to the family or external to it.

In a number of places Annesi et al hint at these stresses (“… self-concept, general self, and overall mood”) but avoid exploration. Their conclusion thus rings particularly true: “… and attention to participants’ self-concept and mood may be important treatment considerations.” Indeed, the psychoactive benefits of eating for the treatment of various levels of depression are profound. These benefits underlie the fact that almost every single “diet pill” has been a stimulant that has had antidepressant activity. So too, physical activity has antidepressant properties, just as inactivity is a commonplace marker for depression.

It is not our intent to engage in a polemic, sportive though that is in topics of difficulty and uncertainty. Rather, we propose that readers interested in the origins and treatment of obesity go to the TPJ Web site and review the Pre-Program Questionnaire (www.thepermanentejournal.org/files/Obesity/Preprogram-Questionnaire.pdf) that we have developed and used in San Diego during the past quarter-century. Having a few obese patients fill out that questionnaire at home will provide the information base underlying the needed new direction of our approach to obesity. Nutrition and arithmetic are both important subjects, but the one is no more relevant to the treatment of obesity than the other is to the resolution of poverty.

The change in direction that we propose will undoubtedly be resisted because it significantly raises the performance bar for those choosing to be involved. The article by Annesi et al has merit because it illustrates the ineffectiveness of the usual approach to obesity. Hopefully, it will lead to explorations of other possible treatment approaches for obesity that incorporate awareness of the benefits of overeating in unconsiously treating problems that are unrecognized, often distant, and almost never explored. Additionally, those approaches must incorporate an understanding of the benefits of obesity, which are not at all in conflict with the manifest risks of obesity. Indeed, in biological systems, the simultaneous existence of varying levels of opposing forces is the norm of all our control systems.

Vincent J Felitti, MD, FACP
Retired Internist from the Department of Preventive Medicine, Clairemont Mesa Medical Office, San Diego, CA; Senior Editor for The Permanente Journal

Reference
Dear Editor,

Congratulations to Dr. Felitti and colleagues for publication of the article “Obesity: Problem, Solution, or Both” in the Spring 2010 issue of The Permanente Journal (TPJ) as well as continued success for their weight loss program in San Diego. I believe that readers of TPJ and individuals contemplating participation in similar programs might appreciate a different perspective, evidence, and context regarding the use of Very Low Calorie Diets (VLCD) for weight management.

1. Caloric restriction strategies for weight loss using less than 1000-1200 calories daily should only be undertaken with supervision of a physician or other clinician with significant expertise. Marked fluid and electrolyte shifts can occur and result in complications such as potentially life-threatening arrhythmias, syncope, and hypotension. Many individuals will experience side effects such as fatigue, constipation, and cold intolerance.

2. Evidence-based practice guidelines from the National Institutes of Health discourage use of diets providing less than 800 calories daily. Studies comparing diets of 800 calories daily or more to diets of less than 800 calories daily show that sustained weight-loss outcomes are similar, though risk and side-effect profile are increased with diets using less than 800 calories daily.1

3. Metanalysis of VLCD meal replacement programs indicate mean weight loss of 17.9 kg (16%) at six months,1 significantly lower than that reported in this study. Recent work has elucidated counter-regulatory biologic mechanisms that decrease weight loss accrued from caloric restriction over time.

4. Weight regain after use of VLCD and similar programs are rapid and substantial. More than 50% of accrued weight loss is likely to be regained within two years after program participation.2,4 Individuals contemplating these programs need to understand the high likelihood of weight regain, and that long-term participation in behavioral group treatment, continued use of meal replacements, and high levels of physical activity are the best strategies to mitigate this risk.

5. Overall costs and “cost per pound lost” is much higher in VLCD program as compared to other noninvasive strategies for weight loss.3 This is because of the need for medical supervision, laboratory monitoring, and purchases of food products, all services generally excluded (whether appropriately or not) from health insurance benefit packages.

Keith Bachman, MD
Clinical Lead for Kaiser Permanente’s Care Management Institute
Weight Management Initiative

References


Response:

We are pleased to respond to Keith Bachman, MD’s comments on our recent description of our extensive experience with treating obesity in the Southern California Permanente Medical Group San Diego area. Dr. Bachman’s comments represent the usual views about treating obesity, a serious problem that is generally not handled easily or well.

1. There is no question that unsupervised Very Low Calorie Diets (VLCDs) are dangerous, which is the point we made with our example of the Irish Hunger Strikers. Indeed, Optifast is not even available by prescription, but only in physician-supervised programs. Because we actively supplement with potassium, and monitor weekly, our impression is that our patients on an absolute fast supplemented with Optifast have fewer electrolyte problems than patients taking prescription diuretics.

As separate and minor issues, distinctly fewer bowel movements are the natural consequence of not eating. Cold intolerance and fatigue will be experienced by a few as commonplace stress responses to not being able to de-stress by eating, but most patients report increased energy levels.
and reduced asthma attacks and other allergic processes. The psychophysiology of this improvement has not yet been described.

Our San Diego Positive Choice Program, developed as the result of many years experience, differs markedly from the program supplied by the manufacturer of Optifast. That program, although safe and well intentioned in our opinion, does not adequately pursue the psychological underpinnings of obesity, thus needlessly limiting the effectiveness of their product. Dr. Bachman accurately notes this limitation in his Point 3.

2. Considering the approach usually given to treating obesity, the National Institutes of Health cautions are appropriate to most of these circumstances. However, with capable medical supervision of electrolyte balance and related biomedical matters, risk is not an issue, as we have illustrated in our 30,000 cases. Our experience with treating these patients over 25 years demonstrated that maintaining weight loss has nothing to do with calorie intake in the weight-loss phase. Maintenance is totally a function of what is accomplished or not accomplished in the accompanying program, which needs to be psychologically and nutritionally oriented. This point has further been demonstrated by those patients who have been able to eat their way out of bariatric surgery, as we illustrated by the quote in our article, “The antidote [sic] to bariatric surgery is Karo Syrup.”

3. The whole point of our article centers on our having outcomes better than usual. That said, weight loss in any program is a function of patient compliance, which is a function of the support provided by the program. This, in turn, will be a function of how well the issues underlying any given patient’s obesity are understood, by the program and the patient. This is not an easy concept to grasp if one persists in misunderstanding the caloric origins of excess poundage as the crux of the problem. That misconception mistakes mechanism for cause, a common error. We believe that our better-than-normal outcomes are the result of the support from our program, in conjunction with the VLCD.

4. Indeed, rapid regain sometimes occurs, and is a blight in some programs, just as it sometimes occurs after bariatric surgery. The question is why does it occur in these instances? How do these individuals differ from those who do not regain? The answer to this question has absolutely nothing to do with calorie intake in the weight-loss phase, a point made clear in our article. It is the program that is the key determinant of long-term outcomes. Our program has been slow in development because we repeatedly tripped over counterintuitive aspects of obesity, such as the hidden benefits of obesity and the consequent threat of major weight loss to many individuals.

5. This statement does not incorporate the cost savings to our patients in not buying any food or caloric beverages for 5 months. Thus, while our cost-neutral charge to the patient is approximately $2500 for the Program, including Optifast for 5 months and the Maintenance Program for the next 12 months, when corrected for food not purchased and dinners not eaten out, the actual net cost for most people will be only a few hundred dollars for a 17-month Program. On the other hand, to the degree that a person on a VLCD is also eating on the side, the economic costs of failure will indeed be high. The major reduction in office visits that we documented during and in the year subsequent to the Program were an additional benefit, either to the patient or to the health care system. Beyond this, the details of insurance programs other than Kaiser Foundation Health Plan were not examined.

Although we believe we made these points clearly, we also understand that they lie sufficiently outside conventional thinking about obesity that they perhaps need restatement in different ways. To that end, one of us (AR) has extended an offer to Dr. Bachman to again visit the San Diego Positive Choice Program to see in action what we are describing.

Any major revision of commonly held ideas is difficult, uncomfortable, and sometimes threatening. The philosopher, Eric Hoffer, explored this problem well in his small monograph, The Ordeal of Change.2 In that regard, The Permanente Journal offers us all in Kaiser Permanente an important sounding board for the introduction of new thinking into an old problem that is obviously getting worse in the face of usual approaches, even though those approaches are supported by august governmental agencies.

Vincent J Felitti, MD, FACP, Kathy Jakstis, Victoria Pepper, RD, Albert Ray, MD

References
BOOK REVIEW

Obese from the Heart: A Fat Psychiatrist Discloses
by Sara L Stein, MD

Review by Vincent J Felitti, MD, FACP

This is an unusual book. It is an autobiographical approach to obesity, written by a perceptive and unusually open psychiatrist who describes herself as fat since second grade, and still fat. Its great virtue is that it focuses on basic emotional causality, not avoidantly escaping this by discussions of consequent intermediary biochemical mechanisms. Moreover, Obese from the Heart is highly readable and easily understood, equally useful for physician as well as patient. A free chapter can be read at the Web site: http://obesefromtheheart.com/

The tone is set in the early pages: "The only difference between the food addict and the alcoholic or cocaine addict or gambler or the shopaholic or the sex addict is the drug of choice: Food."1p11 Sara Stein, MD, then goes on to point out repeatedly that something is being treated and that the treatment almost works—at least for a brief while. That something typically is depression: "This isn’t a story of genetics. This is a story of separation and loss. And the bottomless hole it leaves inside of you. Is it possible that the genetics of food addiction are related more to our family stories than to our chromosomes?"1p16

Various short chapters help one understand the role of eating in dealing with trauma, anxiety, anger, stress, and grief. Most of us are not comfortable discussing these in ourselves, much less with patients. That’s where the value of this book lies: it is an exemplar, it bears witness to what we might do in everyday practice. When did we last ask a patient how they felt about having cancer or a stroke or dying? What is the price that we each, as doctor or as patient, pay for this?

Reference

Grandparenting a Child with Special Needs
by Charlotte E Thompson, MD

Review by O D Collins, MD, PhD

This unique book, written by a highly experienced and caring pediatrician, addresses the important role of grandparents in raising children who have special needs and has information valuable for those grandparenting normally developing children. There is also much information useful to the parents of both. It is written in an appealing, informal way with frequent anecdotes gleaned from the author’s long years of pediatric practice and her role as a mother and grandmother. Given the difficulty of raising any child to his or her full potential, skilled, practical assistance is an invaluable asset. Many physicians will thus welcome this book as a referral source for those caring for these difficult patients.

In addition to its extensive text covering topics from diagnosis to divorce, to dressing, and to social occasions like parties, Grandparenting a Child with Special Needs provides extensive appendices of US state-by-state resource locations and contacts, as well as contact information for American associations and societies helping with problems ranging from abuse through osteogenesis imperfecta to visual impairment. Web sites are listed for children’s resources both in the US and in the UK. Those raising children with special needs, and the involved grandparents helping with those children, will welcome referral to this book, a copy of which might be a useful addition to the waiting room of any pediatrician.
CME Evaluation Program

Kaiser Permanente physicians (NUID required) may earn up to 4 AMA PRA Category 1 credits for reading and analyzing the four designated CME articles, by selecting the most appropriate answer to the questions below, and by successfully completing the evaluation form. Other clinicians for whom CME is acceptable in meeting educational requirements may report up to four hours of attendance. Please return (fax or mail to the address listed on the back of this form) to The Permanente Journal by December 30, 2010. Forms may also be completed and submitted online at: www.permanentejournal.org. You must complete all sections to receive credit. (Completed forms will be accepted until December 2011. Acknowledgment will be mailed within two months after receipt of form.)

Section A.

Article 1. (page 4)
Factors Contributing to Door-to-Balloon Times of ≤90 Minutes in 97% of Patients with ST-Elevation Myocardial Infarction: Our One Year Experience with a Heart Alert Protocol

All of the following have been identified as strategies to improve door-to-balloon times for percutaneous coronary intervention (PCI) in patients presenting to the Emergency Department (ED) with ST-elevation myocardial infarction except:

a. Emergency Medicine physician activation of the Cardiac Catheterization Laboratory (CCL) with a single call to a central page operator
b. preparation of the CCL team within 20-30 minutes of the ED activation call
c. consultation of the case with the on-call cardiologist prior to ED activation of the CCL
d. real time case feedback to ED and cardiology staff
e. a team-based approach

Which of the following additional strategies can contribute to further improvements in door-to-balloon times?

a. ECG acquisition and interpretation from patients presenting with potential Acute Coronary Syndromes (ACS) prior to complete triage and patient registration
b. use of Emergency Medical Services (EMS) prehospital ECGs for CCL activation before patient arrival in the ED
c. breakdown of the door-to-balloon time into clinically relevant intervals with continued quality analysis of each interval to evaluate for areas of improvement
d. use of a pre-PCI medication box for rapid medication procurement and administration during the CCL activation-to-CCL door time interval
e. all of the above

Please return completed form by December 30, 2010

Article 2. (page 12)
Reasons for Not Meeting Coronary Artery Disease Targets of Care in Ambulatory Practice

The main reason patients failed to achieve risk factor goals was because:

a. the patient failed to come back for follow-up care
b. physicians believe treatment of acutely ill patients is preferable to secondary prevention treatments
c. the patient came in for a visit and the care team failed to address an unmet target
d. the patient was resistant to offered therapy

e. all of the above

Which of the following statements is inaccurate?

a. lists generated for quality reporting have limited age ranges
b. lists generated on a quarterly or monthly cycle are acceptable and do not rapidly become out of date
c. care teams often overlook the chronic care needs of patients
d. lists generated from real-time analysis using tailored reporting tools by the care teams are preferred

### Article 3. (page 57)
**Overview of Emerging Concepts in Metabolic Surgery**

Which of the following is true regarding the remission of type 2 diabetes mellitus after Roux-en-Y gastric bypass (RYGB):

a. when food bypasses the duodenum and proximal jejunum, insulin resistance is decreased and glucose tolerance improves
b. the quick transit of nutrients to the distal bowel improves glucose metabolism by stimulating secretion of GLP-1 (Glucagon-Like Peptide-1) and PYY (Peptide YY) levels
c. the resolution of type 2 diabetes mellitus is solely because of the restrictive and malabsorptive properties of RYGB
d. all of the above
e. a and b

Which of the following is inaccurate regarding the laparoscopic adjustable gastric band (LAGB):

a. in comparison with other bariatric procedures, it is associated with fewer complications and lower mortality rates
b. in comparison with other bariatric procedures, it is associated with a lower likelihood for reoperative surgery
c. it is not the procedure of choice for uncontrolled severe type 2 diabetes mellitus
d. weight loss after LAGB ranges from 40 to 54%
e. none of the above

### Article 4. (page 64)
**Thiazolidinediones: A 2010 Perspective**

All the following are known risks of Thiazolidinedione (TZD) use except:

a. foot fracture
b. hand and humerus fracture
c. weight gain
d. severe hypoglycemia
e. fluid retention with possible congestive heart failure

At the end of a long office visit, a 55-year-old man employed as an engineer who recently was diagnosed with type 2 diabetes mellitus asks: “Doc, of the diabetes medications we talked about, which has shown to prevent heart attacks and to make me live longer?” You answer:

a. Pioglitazone has been shown to decrease deaths and heart attacks
b. Insulin, because it will help your diabetes the most efficiently
c. so far no medications that are used for diabetes has been shown to prevent heart attacks and help people with diabetes mellitus live longer. However, metformin (glucophage) has been the closest without achieving it
d. combination of glipizide, exenatide and Insulin
e. none of the above

### Objectives
1. to inculcate the use of evidence-based medicine as part of the science of medicine
2. to stress the art of medicine via enhanced patient-physician communication, improved care experience for patients, and more satisfying caregiving experience for physicians and staff through better teamwork
3. to review appropriate updates on the diagnosis and treatment of clinical conditions
4. to describe infrastructure and systems improvements that lead to improvements in outcomes and patient care experiences

### Section B. Referring to the CME articles and the stated objectives, please choose your level of agreement next to each statement as appropriate.

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- The article covered the stated objectives.
- I learned something new that was important.
- I plan to use this information as appropriate.
- I plan to seek more information on this topic.
- I understood what the author was trying to say.

### Section C. What change(s) (if any) do you plan to make in your practice as a result of reading these articles?

- __________________________
- __________________________
- __________________________
- __________________________
- __________________________

### Section D. (Please print)

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