Mission: The Permanente Journal is published for physicians and nurses to create and deliver superior health care through the principles and benefits of Permanente Medicine.

Permanente Medicine is preventive, innovative, evidence-based, population care practiced by a multispecialty group, using an electronic health and medical record, and focused on patient relationships and outcomes.

Circulation: 10,000 print readers per quarter, and accessed by 390,000 unique web readers per year from 130 countries.

On the cover: “Sierra Drive” is an oil on canvas painting (25” x 19”) by Douglas Davenport, MD, of a house on the street where Dr. Davenport lives. These old-style construction homes were made to catch the cooling trade winds and the porches allowed for family gatherings and “sharing of aloha.” This house looks down on Diamond Head in Honolulu, HI. Dr. Davenport is an emergency medicine physician at the Moanalua Medical Center in Hawaii. He worked in ceramic for many years, starting his own pottery studio, Black Dog, in Makaha, Hawaii. A number of years ago he began painting, following a family tradition, and finds that it balances his life as a physician, father, and husband. It allows time for contemplation, meditation, and creativity. Another of Dr. Davenport’s paintings may be seen on page 63.

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CME Evaluation Form now online — see page 3 for details.
Quality through Sustainability and Transferability

The Vohs Award for Quality and The Lawrence Award for Patient Safety

By Tom Janisse, MD

Is an innovative practice that improves quality sustainable? Can it be transferred to other sites in a whole system of care for a large population? The future of American medicine depends on affirmative answers. This issue’s four Original Articles answer these more difficult questions about quality innovation through successful demonstrations. A good idea is not enough, and as noted by Arthur Huberman, MD, who chaired the Transfer of Successful Practices Workgroup of the Kaiser Permanente (KP) Care Experience Council: “The complexity involved in transferring successful practices is often underestimated. It involves much more than knowledge of the technical aspects involved. In fact, cultural issues usually present the most significant challenges.”

The organizational process that lifts the most successful of these practices into view and recognizes them includes the Vohs Award for Quality and the Lawrence Patient Safety Award. With this issue, The Permanente Journal has published 23 Vohs Award projects over a seven-year period, and five Lawrence Award projects over three years, representing many KP regions and most major medical specialties.

The Vohs Award

The James A Vohs Award for Quality is presented for the project(s) judged to best represent an effort to improve quality through documented, institutionalized changes in direct patient care. The innovation from the Colorado Region—“Chronic Care Coordination Program: Home-based Medication Reconciliation Following Discharge from a Skilled Nursing Facility”—is the recipient of the 2007 Vohs Award. Because of its relevance to the Original Articles in our upcoming Fall issue, we will publish this project then. In this Summer issue we publish the second-place selection, Northern California Region’s innovation—“Early Start: An Integrated Model of Substance Abuse Intervention for Pregnant Women”—which was successfully transferred first to multiple prenatal units, then to multiple medical centers and now multiple KP regions and even multiple non-KP county clinics.

The Lawrence Award

The David M Lawrence, MD, Chairman’s Patient Safety Award recognizes projects that advance the quality of care by improving the safety of care. The preferential project demonstrates a change in outcomes, involves members from various disciplines, and exhibits capability of replication interregionally. The innovation from the Northern California Region—“Promoting Patient Safety: The Rapid Medical Response Team”—received the 2006 David M Lawrence, MD, Patient Safety Award. The practice—a team of critical care experts to prevent, in nonICU patients, deterioration leading to resuscitation—has now been implemented in all 18 KP medical centers in Northern California.

Sustainability and Transferability

The two additional studies in the Original Articles section also demonstrate transferability. “Understanding Panel Management: A Comparative Study of an Emerging Approach to Population Care,” examines the practices of four different primary care teams in three regions; and “Church-Based Heart Health Project: Health Status of Urban African Americans” evaluates the effectiveness of transferring cardiovascular risk screening from clinic to the site of a community gathering of largely non-KP members.

Transferability of innovative practices is a necessary outcome for both local systems and national systems if we are to improve American medicine as a whole. Whereas each of the four studies in the Original Articles section present new data and discussion, the particular relevance for American medicine of publishing this set is as a studied perspective on sustainability and transferability of health care innovations.

Reference

1. Huberman A. The idea: innovation and transfer. Perm J 2005

Tom Janisse, MD, is the Editor-in-Chief of The Permanente Journal and publisher of The Permanente Press. E-mail: tom.janisse@kp.org.
2007 James A Vobs Award for Quality Second-Place Selection

Early Start: An Integrated Model of Substance Abuse Intervention for Pregnant Women

Abstract

Untreated perinatal substance abuse is associated with serious adverse maternal and neonatal outcomes. Historically, many barriers have prevented pregnant women from seeking treatment. Early Start (ES) breaks new ground by sidestepping these barriers with a fully integrated service delivery model.

ES is the largest HMO-based prenatal substance-abuse program in the United States targeting all pregnant women seen at Kaiser Permanente Northern California (KPNC) prenatal clinics, currently screening more than 39,000 women each year. The program is based on the premise that substance abuse is a treatable disease and addresses it in a nonjudgmental, accepting manner. A substance-abuse counselor is located in each obstetrics clinic providing accessible one-to-one counseling to pregnant women screened at risk for alcohol, tobacco, or drug use as part of the routine prenatal care package offered to all patients.

A 2006 ES study, sponsored by the Kaiser Foundation Research Institute, evaluated program effectiveness in terms of its impact on neonatal and maternal outcomes. Preliminary results that included 49,986 KPNC patients indicate that compared with pregnant women whose results on screening for substance use were positive but who were untreated, ES-treated women had significantly lower rates on a number of outcome measures.

The originality and transferability of ES has led to both local and national recognition. Universal screening of all pregnant women with access to an integrated model of substance-abuse treatment should be the standard of care for every prenatal patient because of the significant benefits for mothers and their babies.

Introduction

In the early 1990s, two prevalence studies confirmed that prenatal substance abuse was a significant problem among Kaiser Permanente Northern California (KPNC) patients. An internal prevalence study conducted by neonatologist Marc Usatin, MD (Walnut Creek), from 1989 to 1990 tested newborn meconium for prenatal exposure to street drugs but not alcohol. An overall exposure rate of 3.2% was found for all KPNC birthing facilities. Shortly thereafter, the California Department of Alcohol and Drug Programs conducted a study that included five KPNC hospitals and found rates of perinatal alcohol and drug exposure ranging from 10% to 18% of all births (two KPNC sites had rates higher than the statewide average of 11.35%).

This information, coupled with a body of literature documenting adverse neonatal outcomes such as placental abruption, fetal death, premature delivery, and babies born small for gestational age, prompted the development of a new approach to treating this population.

Historically, pregnant women at KPNC who were identified as having substance abuse problems were referred by their prenatal clinician to existing internal or community-based treatment programs. These efforts were largely unsuccessful; only a fraction of the women referred by these programs attended them. Several clinicians, concerned about the poor outcomes and poor intervention record with this approach, explored other successful prenatal substance abuse intervention models, all of which were in the public sector at that time.

To capitalize on KPNC’s strength and history as a vertically integrated program, the clinicians identified models that would further integrate services. Experts from Born Free, an integrated program, the clinicians identified models that would further integrate services. Experts from Born Free, a program in Contra Costa County that routinely screened pregnant women at KPNC who were identified as having substance abuse problems were referred by their prenatal clinician to existing internal or community-based treatment programs. These efforts were largely unsuccessful. 

Historically, pregnant women at KPNC who were identified as having substance abuse problems were referred by their prenatal clinician to existing internal or community-based treatment programs. These efforts were largely unsuccessful. 

Historically, pregnant women at KPNC who were identified as having substance abuse problems were referred by their prenatal clinician to existing internal or community-based treatment programs. These efforts were largely unsuccessful.
all pregnant women for alcohol, tobacco, and other drug use and referred them to an on-site substance abuse specialist, as well as administrators for programs that were integrating a variety of mental health and behavioral health services with primary care, were consulted.

Through a Garfield Memorial Fund sponsored grant, KPNC began an obstetric, clinic-based perinatal substance abuse intervention program known as Early Start (ES) and piloted the program at the Oakland Medical Center from 1990 to 1993. At the same time, the multidisciplinary Perinatal Substance Abuse Task Force was initiated. The innovative aspect of ES was stationing a licensed substance abuse expert, or ES specialist (ESS), within the Obstetrics Department to work as part of the prenatal care team. The role of the ESS was to assess, educate, and provide ongoing counseling to at-risk women. The ES model also implemented universal substance use risk screening and education for all pregnant women and ongoing professional education, consultation, and training for obstetrics/gynecology (Ob/Gyn) clinicians and staff. The Early Start Intervention Specialists are listed in Table 1.

Evaluation of the pilot project found that 92% of the patients who were referred to the ESS by their clinician accepted the referral. For 81% of these women, the ESS diagnosed moderate to severe substance abuse problems. These women were regularly tested for alcohol and other drugs during their prenatal care. Subsequently, 69% had negative findings on toxicology screens by the 32-week point in their pregnancies, and their babies had significantly better birth outcomes and shorter hospitalizations compared with women who continued to use alcohol and street drugs (Boddum A, Chin V, Gordon, N, Soghikian, K. Unpublished final report to Garfield Committee: a model system for early identification and management of substance abuse during pregnancy. August 1992).

Surveys of prenatal clinicians involved in the pilot project indicated that they were very satisfied with the model and felt that it enhanced their clinical practice. Prior to the ES program, clinicians indicated that they were not likely to identify substance-abusing patients. After the in-service training and implementation of ES, these same clinicians reported that they were much more likely to obtain a substance abuse history and make a referral if appropriate. All but one of the 15 clinicians involved in the pilot project felt that it was very important to have the substance abuse specialist located in the Ob/Gyn department rather than to only be able to refer to the chemical-dependency treatment program at the facility.

In 1994, after these successful pilot results, the Perinatal Substance Abuse Task Force lobbied The Permanente Medical Group (TPMG) board of directors and regional Kaiser Foundation Hospitals (KFH) to transfer the program to four new sites and to hire a regional coordinator. ES rolled out at 16 additional sites during the next 10 years through local TPMG funding and seed money from Regional Successful Practices. In 2003, KFH and TPMG leadership agreed to jointly fund the program for full regional implementation (see Figure 1).

**Objectives**

The KPNC ES program created four objectives that are the core of the program:

- To decrease substance abuse in pregnant women
- To reduce negative birth outcomes and medical costs associated with prenatal substance abuse

---

**Table 1. Early Start Intervention Specialists**

<table>
<thead>
<tr>
<th>Name, Title</th>
<th>Facility(ies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheryl Anderson, MFT</td>
<td>Napa</td>
</tr>
<tr>
<td>Dori Anderson, LCSW</td>
<td>Sacramento, Davis</td>
</tr>
<tr>
<td>Lagen Biles, PhD</td>
<td>Gilroy</td>
</tr>
<tr>
<td>Theresa Brees, LCSW</td>
<td>Santa Teresa</td>
</tr>
<tr>
<td>Cathryn Brompton, LCSW</td>
<td>Hayward</td>
</tr>
<tr>
<td>Terri Crochetti, MFT</td>
<td>Rancho Cordova, Fair Oaks, Folsom</td>
</tr>
<tr>
<td>Helen Coupe, MFT</td>
<td>Roseville, Lincoln</td>
</tr>
<tr>
<td>Ellie Ehrenhaft, LCSW</td>
<td>Oakland</td>
</tr>
<tr>
<td>Lois Everitt-Krause, MFT</td>
<td>Clovis</td>
</tr>
<tr>
<td>Laura Fleischmann, MFT</td>
<td>Daly City</td>
</tr>
<tr>
<td>Electa Gentry-Goodwin, LCSW</td>
<td>Deer Valley, Martinez, Livermore</td>
</tr>
<tr>
<td>Edith Givens, MFT</td>
<td>Fremont</td>
</tr>
<tr>
<td>Debbie Goldman-Hall, LCSW</td>
<td>Milpitas</td>
</tr>
<tr>
<td>Nancy Grover, LCSW</td>
<td>Petaluma, Novato, San Rafael</td>
</tr>
<tr>
<td>Monica Haimowitz, LCSW</td>
<td>Santa Rosa</td>
</tr>
<tr>
<td>Donna Kelley, LCSW</td>
<td>Vallejo</td>
</tr>
<tr>
<td>Marisa Leto, MFT</td>
<td>Richmond</td>
</tr>
<tr>
<td>Christine Lyng, ACSW</td>
<td>Walnut Creek, Shadelands</td>
</tr>
<tr>
<td>Linda Mackinson, LCSW</td>
<td>Pleasanton</td>
</tr>
<tr>
<td>Lucille Norwood, LCSW</td>
<td>Oakland</td>
</tr>
<tr>
<td>Nona O’Keefe, LCSW</td>
<td>South Sacramento</td>
</tr>
<tr>
<td>Michelle Raines, MFT</td>
<td>Elk Grove</td>
</tr>
<tr>
<td>Katie Richards, MFT</td>
<td>Roseville</td>
</tr>
<tr>
<td>Stephanie Roessler, LCSW</td>
<td>Vacaville</td>
</tr>
<tr>
<td>Joanne Rudinskas, LCSW</td>
<td>Santa Clara</td>
</tr>
<tr>
<td>Marilyn Scott, LCSW</td>
<td>Antioch</td>
</tr>
<tr>
<td>Marilyn Sponza, MFT</td>
<td>Redwood City</td>
</tr>
<tr>
<td>Lynette Statham, LCSW</td>
<td>Fresno</td>
</tr>
<tr>
<td>Barbara Taylor, MFT</td>
<td>Santa Teresa</td>
</tr>
<tr>
<td>Paula Tucker, LCSW</td>
<td>Modesto, Manteca</td>
</tr>
<tr>
<td>Chandra Williams, LCSW</td>
<td>Fremont</td>
</tr>
<tr>
<td>Karen Winter, MFT</td>
<td>Fairfield</td>
</tr>
</tbody>
</table>
• To improve access to substance abuse services for pregnant women
• To enhance clinician satisfaction and efficacy.

Scope and Significance
ES is the largest HMO-based prenatal substance abuse program in the United States. ES targets all pregnant women seen at KPNC prenatal clinics, currently screening more than 39,000 women each year. In 2006, ES provided over 13,900 patient visits to more than 7600 KPNC patients (Table 2).

Although this program focuses on obstetrics, a pilot program was recently launched at the KPNC Richmond facility that links ES mothers and babies to pediatrics with the goal of providing them with seamless services.

The ES program changed the existing service delivery care model to one that improves quality and access for patients. Some of these clinical and operational changes include:
• Adding a substance abuse specialist to the prenatal care team and physically stationing the specialist in the prenatal clinic (the most innovative aspect of the program model)
• Educating all pregnant women about the risks of alcohol, tobacco, and other drugs through various media and at multiple points in pregnancy (information is included in published newsletters, given orally at prenatal group visits, available on the national help line and the ES Web site, and provided individually through customized educational pamphlets and one-to-one counseling)
• Screening for risk at the first prenatal visit by a self-administered questionnaire and by urine toxicology testing (with signed consent)
• Intensive training (eg, using addiction-medicine physicians and other specialists) for obstetric clinicians about the medical aspects of prenatal

<table>
<thead>
<tr>
<th>Table 2. Regional Early Start patient care metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>Number of women screened by Early Start (questionnaires)</td>
</tr>
<tr>
<td>Number of women served by Early Start (assessments)</td>
</tr>
<tr>
<td>Number of total patient contacts (all assessments and return visits)</td>
</tr>
</tbody>
</table>

Figure 1. Early Start: growth and critical events. AMGA = American Medical Group Administrators; CMI = Care Management Institute; ES = Early Start; KFRI = Kaiser Foundation Research Institute; KP = Kaiser Permanente; NCAL = Northern California; TPMG = The Permanente Medical Group.
substance abuse and techniques for effective referrals
- Ongoing counseling and case management for pregnant women identified as being at risk, with the option for continued care for up to one year after childbirth
- Multidisciplinary training, consultation, and work groups with relevant departments, including pediatrics, chemical dependency, psychiatry, and social services
- Maintaining an underlying philosophy that prenatal substance abuse and addiction are diseases that should be addressed, just as any other complication of pregnancy
- Partnering with the KPNC Division of Research to conduct program evaluation, research projects, and report development
- Aligning with the organizational goal of providing quality, personalized care, and specialized services for women.

The ES model provides nontargeting, accessible, clinic-based substance abuse counseling to pregnant women. At the time of the first prenatal office visit, at-risk patients are referred by the prenatal care clinician directly to the ESS, who has a confidential office space in close proximity to examination rooms within the obstetrics clinic. The ESS completes a thorough psychosocial assessment with the patient, educates her about risks, and provides support, resources, and referrals to appropriate services. With an emphasis on abstinence, the ESS and patient work collaboratively to achieve behavioral-change goals related to the patient’s substance abuse patterns. Follow-up ES appointments occur throughout the pregnancy in conjunction with the medical prenatal visit. The ES program boldly embraces innovation, supplanting typical obstacles to care to successfully provide uniquely tailored services to this high-risk group of patients.

**ACOG Ethics Committee Opinion**

In May 2004, the American College of Obstetricians and Gynecologists Committee on Ethics wrote:

*Abuse of alcohol and drugs is a major health problem for American women across differences in socioeconomic status, race, ethnicity, and age, and it is costly to individuals and to society. Obstetrician-gynecologists have an ethical obligation to learn and use a protocol for universal screening questions, brief intervention, and referral to treatment. … This is the clinically appropriate professional action, both medically and ethically … and it results in a mean net savings of $4644 in medical expenses per mother/infant pair, … [Although] few treatment programs focus on the needs of pregnant women … there are successful models for prevention and treatment for women and their families (AR-Cares, Choices, Safeport, Early Start and Mom/Kid Trial).*

**Quality Measures**

With the implementation of ES, KPNC is poised as the quality leader in the field. The 2006 ES study, sponsored by the Kaiser Foundation Research Institute and conducted by the Division of Research, evaluates program effectiveness in terms of its impact on neonatal and maternal outcomes.

Preliminary results indicate that compared with pregnant women whose results on screening for substance use were positive but who were untreated, ES-treated women had significantly lower rates on a number of outcome measures (see more detail in the Design and Methodology section).

In 2000, a cost–benefit analysis of ES was conducted as part of a business case to promote full regional implementation. The analysis showed a savings in variable direct costs of $1504 per baby whose mother received ES intervention, compared with babies of mothers who

**Table 3. 2005 Early Start clinician satisfaction survey (n = 631)**

<table>
<thead>
<tr>
<th>Survey statement</th>
<th>Strongly agree/agree (%)</th>
<th>Undecided (%)</th>
<th>Somewhat disagree/strongly disagree (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am satisfied with the Early Start program</td>
<td>90.4</td>
<td>5.5</td>
<td>4.1</td>
</tr>
<tr>
<td>I understand the services provided by the Early Start program</td>
<td>96.8</td>
<td>1.7</td>
<td>1.5</td>
</tr>
<tr>
<td>Our ESS is competent</td>
<td>93.6</td>
<td>4.1</td>
<td>2.3</td>
</tr>
<tr>
<td>Having an ESS saves me time</td>
<td>90.1</td>
<td>5.5</td>
<td>4.4</td>
</tr>
<tr>
<td>It’s easy for me to have my patients see our ESS</td>
<td>85.5</td>
<td>7.9</td>
<td>6.7</td>
</tr>
<tr>
<td>Our ESS communicates appropriately and is responsive</td>
<td>93.0</td>
<td>4.9</td>
<td>2.0</td>
</tr>
<tr>
<td>Our ESS is responsive to and coordinates the needs of patients</td>
<td>91.6</td>
<td>5.5</td>
<td>2.9</td>
</tr>
</tbody>
</table>

ESS = Early Start specialist.
abused substances and received no intervention, after six months of follow-up monitoring after delivery. The business case conclusion was that regional implementation would be highly cost effective, providing a simple return on investment of >30%.

In 2005, Ob/Gyn clinicians were surveyed about their satisfaction with the ES program, and their responses exceeded the already high ratings from a similar survey done in 2004. With a 58% response rate, 90% of clinicians across the region agreed or strongly agreed with the statement that the program “saves me time,” and 92% to 94% agreed or strongly agreed that the ESS was competent, communicated appropriately, and was responsive to and coordinated solutions for patient needs (Table 3).

ES met both of the 2005 quality and access performance goals of increasing consistency of service delivery across the region through assessment and return visits for both high-risk and at-risk populations. Preliminary analysis of rates for 2006 shows that ES also met the 2006 assessment rate goal of 77% (Table 4).

ES exceeds the recommendations of the 2004 American College of Obstetricians and Gynecologists Committee on Ethics Opinion9 and addresses two top priorities for the Healthy People 2010 initiative,10 which has a national goal (See Sidebar: Healthy People 2010) of increasing the percentage of pregnant women who achieve abstinence from alcohol to 94%, and to 100% from street drugs.

### Design and Methodology

A follow-up study to the first ES retrospective study, which was reported in 2003,11 was conducted in 2006 and produced similar results. The KP Community Benefit-funded 2006 ES retrospective study included 49,986 KPNP patients who completed the ES prenatal substance abuse screening questionnaires between January 1, 1999, and June 30, 2003; underwent urine toxicology screening tests; and had either a live birth or an intrauterine fetal death.12

Four groups were then compared on neonatal and maternal outcomes: 1) substance abusers screened, assessed, and treated (SAT); 2) substance abusers screened and assessed who had no follow-up treatment (SA); 3) substance abusers who were only screened (S); and 4) control study subjects whose screens had negative results.

### Results

The study showed that SAT women had statistically significantly lower rates than S women for placental abruption, preterm labor, and stillbirth and often had outcomes that compared favorably with those of the control study subjects.

For most major neonatal outcomes such as assisted ventilation, low birth weight, and preterm delivery, a similar trend was observed, with control study subjects having the lowest rates, followed by SAT and SA women, with S women having the highest rates. In most cases, the rates for the S women were significantly higher than those for the control study subjects. This pattern persisted in multivariate analyses controlled for maternal age, ethnicity, and amount of prenatal care.

To assess possible bias caused by self-selection and severity of illness, the three groups of substance-abusing women were compared regarding available risk factors (such as smoking and family history) and variables indicative of severity of substance abuse (such as frequency of use and poly-drug use). The assessed and treated women had similar or higher rates for these factors than did the women in the nonintervention group, indicating that their problems were no less severe.

The investigators concluded that substance abuse treatment for pregnant women that is integrated with prenatal care significantly benefits newborns and their mothers.

### Clinical Impact

Prior to ES, many barriers prevented pregnant women from attending traditional addiction treatment programs,
The originality and ease of replicability of ES has led to considerable local and national recognition for the program model and its research efforts.

including lack of transportation, lack of child care services, intensive time requirements, additional costs and copayments, stigma, and lack of services tailored to meet their needs. ES breaks new ground by sidestepping these barriers with a fully integrated service delivery model. The multidimensional nature of prenatal substance abuse requires a multidisciplinary approach and the commitment of the entire Ob/Gyn Department.

Early Start is based on the premise that substance abuse is a treatable disease and addresses it in a nonjudgmental, accepting manner. Accordingly, all women are screened through a confidential prenatal screening questionnaire and are expected to undergo urine toxicology screening, although they can decline the latter (but the vast majority do consent). The purpose is to cast a wide net such that no woman who abuses street drugs or alcohol will be missed. At the first prenatal office visit, patients whose questionnaire or toxicology screening results are positive are referred by the prenatal clinician directly to the ESS. The ESS completes a thorough psychosocial assessment with the patient, educate her about risks, and provides support, resources, and referrals. After the assessment, the ESS works hand in hand with the clinician to coordinate the patient's care throughout pregnancy. If the ESS determines that the woman has chemical dependency, substance abuse, or increased risk for substance abuse, then follow-up ES appointments are continued throughout the pregnancy in conjunction with the medical prenatal visit.

The program at each clinic is managed by the ES team, composed of a physician or nurse practitioner “champion,” an Ob/Gyn nurse manager, an ES medical assistant, and the ESS. The ES medical assistant continues to monitor, book, and reschedule appointments for ES patients throughout the pregnancy. The assistant works very closely with the ESS to coordinate care and assists with case-management needs. All prenatal clinicians are trained with standardized scripts to assist them in talking with and referring patients to the ESS, and the ES champion at each site is actively involved in their training, education, and support. The Ob/Gyn nurse manager is also a key player, maintaining well-coordinated and streamlined ES systems. The teams meet monthly at their sites to review their quality goals, improve systems, and celebrate successes. Twice a year, these teams meet with all of the other ES teams regionwide to address obstacles and to share and develop best practices. The local sites are supported by a multidisciplinary regional team with endorsement from the regional women’s health leader and sponsorship and joint financial support from TPG and KFH executive leadership.

Transferability Results

As seen in Figure 1, the ES program was funded for full regional implementation in 2003 on the basis of the results of a business case that was developed with support from ES research.11 The program continues to be implemented and expanded throughout all of Northern California. In 2003, ES was one of the successful transfer practices studied for a research project completed by Kaiser Permanente’s (KP’s) Care Experience Council. In 2004 the program was the first to be endorsed for national transfer by the Care Management Institute Maternal and Newborn workgroup, and in August 2006 the program officially transferred to the Hawaii Region.

The pioneering practices of ES have also been successfully adopted by the KP Southern California Bellflower obstetrics clinic and by San Bernardino County (the largest county in the state). Using ES as the model, San Bernardino County successfully secured March of Dimes funding to support hiring substance abuse specialists for the four major prenatal practices serving county patients. The ES model is currently being studied by Contra Costa, Alameda, Solano and Santa Clara counties for implementation.

The originality and ease of replicability of ES has led to considerable local and national recognition for the program model and its research efforts. Early Start:

- Was given the Models of Excellence for High-Risk Patient Management Award by the American Medical Groups Association, 2000
- Was chosen as one of four women’s health priorities targeted by KPNC for full implementation in the Northern California Region, 2001
- Was included as a model of care in the American Association of Health Plans publication Improving Maternal Child Health: Innovation Program Approaches for Health Plans, 2001
- Was given the Silver Hera Award by the American Association of Health Plans, recognizing significant improvement in women’s and children’s health outcomes, 2003
- Was chosen as priority to transfer programwide by the Care Management Institute Maternal Newborn Health Group, 2004
- Was included as a successful model for pregnant women by the American College of Obstetrics and Gynecology Committee on Ethics Opinion, 2004.

ES has two comprehensive Web sites with resources for internal (http://kpnet.kp.org/california/earlystart) and
facing the future
Providing specialized services to meet the identified needs of our young clients will help them face the future and its responsibilities.

— Biddle KK. The Young Mother’s Club: A program designed for the special needs of pregnant adolescents. Perm J 1997 Fall;1(2):30-2.

Conclusions
ES exemplifies the four cornerstones that constitute the KP promise: The ES outcomes research clearly demonstrates that implementation of universal screening practices and providing substance abuse treatment for pregnant women that is integrated with prenatal care creates “quality that you can trust,” resulting in significant beneficial effects on newborn and maternal health. Locating the ESS in the obstetrics clinic and providing a unique one-to-one counseling experience focuses attention on the individual needs of our patients, addressing KP’s commitment to “caring with a personal touch” and making services “convenient and affordable.” Ensuring that ES appointments are linked with routine prenatal care and that copayments are waived for ES appointments and laboratory visits meets the goal of providing affordable services.

ES is a national model of choice for prenatal substance abuse intervention and will continue to benefit our patients, KP, and the broader community for generations to come.

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

References
Understanding Panel Management: A Comparative Study of an Emerging Approach to Population Care

By Esther (Estee) B Neuwirth, PhD
Julie A Schmittdief, PhD
Karen Tallman, PhD
Jim Bellows, PhD

Abstract

Context: Panel management is an innovative approach for population care that is tightly linked with primary care. This approach, which is spreading rapidly across Kaiser Permanente, represents an important shift in population-care structure and emphasis, but its potential and implications have not been previously studied.

Objective: To inform the ongoing spread of panel management by providing an early understanding of its impact on patients, physicians, and staff and to identify barriers and facilitators.

Design: Qualitative studies at four sites, including patient focus groups, physician and staff interviews, and direct observation.

Findings: Panel management allows primary care physicians to use dedicated time to direct proactive care for their patients, uses staff support to conduct outreach, and leverages new panel-based information technology tools. Patients reported appreciating the panel management outreach, although some also reported coordination issues. Two of four study sites seemed to provide a more coordinated patient experience of care; factors common to these sites included longer maturation of their panel management programs and a more circumscribed role for outreach staff. Some physicians reported tension in the approach’s implementation: All believed that panel management improved care for their patients but many also expressed feeling that the approach added more tasks to their already busy days. Challenges yet to be fully addressed include providing program oversight to monitor for safe and reliable coordination of care and incorporation of self-management support.

Conclusion: Subsequent spread of panel management should be informed by these lessons and findings from early adopters and should include continued monitoring of the impact of this rapidly developing approach on quality, patient satisfaction, primary care sustainability, and cost.

Introduction

Kaiser Permanente (KP) has long been committed to population care—using a systematic approach to identify and address members’ unmet chronic and preventive care needs. Panel management, an innovative approach to population care that is tightly linked with primary care, has been rapidly spreading across KP. Early reports on panel management from innovation sites were promising and garnered a great deal of attention within KP. For example, one innovation site, which had ranked among the lowest-performing regional KP medical centers on Health Employer Data and Information Set measures of diabetes care in 2002, became a top performer in the region in the control of low-density lipoprotein levels within two years of panel management implementation. These and other successful experiences of innovators inspired the spread of panel management to a host of early adopter sites. By early 2007, six of the eight KP Regions and Group Health Cooperative of...
Puget Sound (in Washington State) had initiated regionally sponsored activities to support the dissemination of panel management. Implementers pursued three related goals: improving performance on quality measures, strengthening patients' relationships with their primary care physicians (PCPs), and optimizing the use of nonphysician staff in population care. The spread of panel management across KP has been enabled by the availability of flexible information technology tools for population care.

We synthesize here the findings from a qualitative national quality improvement study aimed at understanding staff, physician, and patient experiences of this approach to population care within KP. The purposes of this study were to provide a rapid assessment of early panel management implementation, to provide timely information to subsequent adopters, and to inform later quantitative evaluations of the practice.

**Definition of Panel Management**

Although panel management is a term that can potentially describe a number of approaches to patient care, we define panel management as a set of tools and processes for population care that are applied systematically at the level of a primary care panel, with PCPs directing proactive care for their empaneled patients. Two features distinguish panel management from KP's previous implementation of population care: 1) processes to identify and address unmet care needs are more tightly linked with primary care practices and 2) less-intense, individualized outreach and follow-up are provided for more patients via telephone contact with panel management assistants (PMAs), who communicate physician recommendations to patients. Some regionalized services continue concurrently (such as individualized care management for high-risk members), but panel management shifts emphasis and resources to supporting PCPs and providing many “light touches” (low-intensity contacts) to patients with unmet care needs.

Panel management is aligned with recommendations for strengthening patients' “primary care home” and is also closely related to total panel ownership (TPO), which has been described in this journal. We conceptualize panel management as a component of TPO. Whereas TPO is a broad set of practices and an overarching philosophy of physician accountability for access, care, and service for all members in their panels, panel management refers to a narrower and more specific set of tools and processes for outreach purposes.

**Larger Context: Shifts in Structure and Emphasis of Population Care**

Population care has undergone a broad evolution within KP. KP first implemented structured population care programs in the 1990s, with an emphasis on building needed capabilities within its delivery system. Similar health care systems, particularly integrated delivery systems, also took this approach; other organizations have used alternative approaches, especially contracting with external “disease management” companies to provide supplemental services outside the traditional health care system.

KP's initial approach to population care was shaped strongly by recognition that PCPs were already stretched by a large and growing list of expectations. Many KP population care services were implemented as regionalized support services, separate from primary care practices and teams, and most were focused on patients with major chronic conditions, such as asthma, diabetes, and cardiovascular disease. Implementation details have varied among locations and over time, but regionalized services have typically included registries to track patients with chronic disease and identify care gaps relative to evidence-based protocols, automated outreach by mail or phone to inform patients of needed tests or treatment, provision of patient education materials and one-to-many health education classes, and “in-reach” systems to flag unmet care needs whenever registry patients presented for care. Risk-stratification methods, supplemented by physician referrals, identified a small subset of high-risk patients. These patients were offered individualized services from care managers, typically specially trained registered nurses who played a strong, relatively independent role in managing care for high-risk patients, seeing them in person and contacting them by phone to assure that their care conformed to evidence-based protocols and to provide self-management support. Care managers were typically enabled, acting under protocol and within their professional scope of practice, to order routine tests, titrate medication dosages, and perform other routine clinical tasks.

This approach yielded very substantial improvement over time on chronic care quality metrics. However, in recent years KP has sought to reinvigorate its slowing improvement on publicly reported performance measures, find ways
to realize greater cost savings than were observed in previous chronic conditions management programs, and more fully integrate chronic conditions management within primary care. It is within this larger context of changing organizational needs and the desire to optimize and improve the delivery system that panel management emerged. We provide information here on physician, staff, and patient experiences with panel management to inform successful program adoption and spread.

Methods
Between January and September 2006, we collected qualitative data on four study sites. Data was collected from three distinct sources: 1) direct observation of panel management practices, 2) physician and staff interviews, and 3) patient focus groups. Data from all sources were transcribed and coded using the principles of rapid assessment and qualitative data analysis.

Prior to study data collection, we interviewed 15 leaders and potential adopters from across KP to identify their priorities and needs. These initial interviews also guided the study team in selecting four study sites in three KP regions. Chosen sites had full implementation across an entire facility or area.

Across the four sites, 40 semi-structured interviews (45–90 minutes long) were conducted with operational leaders, physicians, and staff. Interviewees were selected by a representative from each site who was given a list of sampling criteria from the study project lead. A concerted effort was made to interview both avid supporters of panel management and those more tentative about or critical of this approach. Observation focused on staff communication with patients, physician-staff communication, handoffs between staff and physicians, workflow and program processes, and department- or program-specific meetings.

We conducted one patient focus group at each study site. Patients were selected and recruited by site staff on the basis of the following inclusion criteria: at least one out of 10 patients; many were long-term members whose conditions (primarily diabetes) had been diagnosed at least three years earlier. Topics for discussion included patient expectations and experiences of chronic condition care at KP, preferences for outreach regarding chronic condition care, preferences for the type of staff conducting outreach, and overall experience of panel management communication (phone, letters, physician follow-up, outreach staff follow-up, etc).

Findings
Program Characteristics: Similarities and Differences
We found wide variation in program implementation characteristics. Basic characteristics—similarities and differences—of the panel management approaches at the four study sites are summarized in Tables 1 and 2. We identified four common components of program implementation: (See Sidebar: Key Components of Panel Management)

1) dedicated physician time for directing clinical decision making related to panel management work; 2) dedicated staff and/or staff time for supporting physicians to complete the work; 3) information technology tools for sorting patients into clinically appropriate groupings and identifying patients requiring outreach; and 4) structured work processes completed on a routine basis. At all four sites, the panel management process included the steps outlined in Figure 1. Although implementation approaches to each of these steps differed across the sites studied, all process steps outlined in Figure 1—except for patient status review and treatment decisions—were primarily carried out by nonphysician staff.

All four sites had some practices and implementation experiences in common (see Table 1). PCPs directed the clinical decision making, whereas nonphysician staff carried out physician orders. Physicians had

### Table 1: Identification of Patients with Unmet Care

<table>
<thead>
<tr>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
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<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>No</td>
<td>No</td>
<td>No</td>
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### Table 2: Preparation for Review of Patient Status

<table>
<thead>
<tr>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
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<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

### Figure 1. Panel management process steps.

1. Identification of patients with unmet care
2. Preparation for review of patient status
3. Patient status reviewed and treatment decisions made
4. Follow-up on PCP instructions (communication with patient)
Follow-up on PCP orders
- Communicate with patients by phone or mail
- Per PCP orders, provide patients with information to address care gaps
- Provide some self-management support

Panel management has changed my practice by giving

- Mostly implemented without new funding
- Provide some self-management support
- Wide-scale dissemination throughout entire facility or area

Resource allocation
- Many appreciated outreach and reminders
- Mostly implemented without new funding
- Resources shifted to support new activities

Spread
- Wide-scale dissemination throughout entire facility or area

Table 1. Similarities in implementation across study sites

PCP = primary care physicians

designated time to review patient medical record information (eg, two or three 15-minute appointment slots per week blocked off for panel management activities). The implementation of panel management was widespread throughout the facility or area. The shift to panel management involved an operational decision to shift resources from traditional care management or from other programs to support panel management activities.

In three of the four cases, panel management was implemented without new funding. Two sites redirected resources primarily from care management to support panel management implementation. Another site redirected clinic resources to support panel management. The one site that did add resources had been regionally identified as being underfunded for population care management.

Numerous differences between the four sites, illustrated in Table 2, make the inferences about any single factor difficult. The sites varied by size, amount of time the program was fully operational across the facility or area, and/or speed of implementation (incremental versus rapid). Other differences included type of staff used for outreach, previous experience of outreach staff, staffing ratios, whether the program was located within or outside the module, and whether support staff were assigned to panel management only or had other responsibilities as well (eg, rooming patients). Some programs used former care managers for the PMA role; others used former clinic-based staff.

Physician and Staff Experiences

Most physicians reported that they were satisfied with these programs and believed that they were “the right thing to do” for patients. At the same time, many also believed that panel management added more activities to their day; this tension between wanting to do the right thing and desiring to have a sustainable practice came up frequently in interviews with PCPs. Another challenge expressed by physicians concerned the initial implementation process. Some physicians explained that transitioning to a panel management approach required a change in their practice style and thinking. However, over time many (See Sidebar: In Their Own Words: Kaiser Permanente Physicians on Panel Management) also came to believe that panel management could better leverage their time during office visits because the program’s outreach targeted the nonurgent needs of their patients. Several physicians reported that implementing panel management encouraged them to be more proactive with more of their patients.

The nonphysician staff described a wide range of experiences. For medical assistants who were formerly in a clinic, many found that their role in panel management offered opportunities for job growth—most medical assistants interviewed welcomed the new responsibilities. For staff formerly in traditional care management programs, panel management programs represented a major change in their roles, as patient contact shifted from face-to-face interaction to telephonic outreach. These former care managers generally expressed satisfaction with the program, but several expressed dissatisfaction with the lack of face-to-face interactions with patients that they were used to having.

Patient Experiences

Overall, patients were extremely pleased with their care. They were particularly pleased with their PCPs. They appreciated the reminders, attention, and monitoring related to panel management outreach.

In Their Own Words: Kaiser Permanente Physicians on Panel Management

- “Panel management doesn’t make my day any easier, but it makes my day better. It improves quality . . . it is better for the patient, but it can add to your day.”
- “Panel management has changed my practice by giving me hope that some of my more difficult patients might actually turn around their health status. It has made me more optimistic in approaching these patients; now I work to maximize the number of outreach efforts that occur both from my office and from the panel management staff.”
activities and generally believed that the outreach helped them better manage their condition. Many patients wanted more self-management support in addition to the panel management outreach communications, which tended to center on medications and laboratory results. They wanted more written materials, tailored support especially concerning diet, and classes. In general, patients were open to communications about their care from PMAs. They were generally unsure (but unconcerned) whether outreach staff were nurses, medical assistants, or receptionists. Overall, nonphysician staff were most valued when they gave patients greater access to information flow from their PCP.

Barriers and Facilitators

Coordination of Care

At two of the study sites (see Table 2, sites 1 and 2), patients predominantly perceived their care to be coordinated. They perceived that both the staff member calling them and their PCP were in accord. Patients at these two sites who received outreach calls or mailings were confident that their physician was directing their care and were comfortable with panel management staff communicating on behalf of their physician. At the two other sites, some focus group participants perceived lack of care coordination, with three or more patients at each site reporting experiences of disconnected communication between panel management, primary care, specialty care, and/or pharmacy staff (see Table 3, quotations from patients: “Some coordination-of-care issues”).

Table 2. Variation in implementation and site-specific characteristics across studies

<table>
<thead>
<tr>
<th></th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
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</thead>
<tbody>
<tr>
<td>Type of model</td>
<td>PCP/MA</td>
<td>PCP/Team</td>
<td>PCP/RN</td>
<td>PCP/Team</td>
</tr>
<tr>
<td>Primary outreach staff</td>
<td>MA</td>
<td>Team</td>
<td>RN</td>
<td>Team</td>
</tr>
<tr>
<td>Previous experience of</td>
<td>Clinic</td>
<td>Clinic</td>
<td>Care management</td>
<td>Combination</td>
</tr>
<tr>
<td>outreach staff</td>
<td></td>
<td></td>
<td>(mostly)</td>
<td></td>
</tr>
<tr>
<td>Staffing ratio</td>
<td>5 PCPs:1 MA</td>
<td>No fully dedicated staff, but modular staff had some protected time</td>
<td>5 PCPs:1 RN</td>
<td>10 PCPs:1 team member (mix of licensed and nonlicensed)</td>
</tr>
<tr>
<td>(PCPs to dedicated panel</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>management staff)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical location of</td>
<td>Outside module</td>
<td>Inside module</td>
<td>Outside module</td>
<td>Combination</td>
</tr>
<tr>
<td>staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time in place</td>
<td>3 years</td>
<td>3 years</td>
<td>1 year</td>
<td>1 year</td>
</tr>
<tr>
<td>Implementation</td>
<td>Incremental</td>
<td>Incremental</td>
<td>Rapid</td>
<td>Rapid</td>
</tr>
<tr>
<td>Study site</td>
<td>1 medical center</td>
<td>1 clinic</td>
<td>7 facilities</td>
<td>12 facilities</td>
</tr>
<tr>
<td>Number of PCPs at study</td>
<td>28</td>
<td>8</td>
<td>156</td>
<td>160</td>
</tr>
<tr>
<td>site (all using panel</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>management)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Reserved panel</td>
<td>60–180</td>
<td>&gt;60</td>
<td>45</td>
<td>80</td>
</tr>
<tr>
<td>management time for PCP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>per month (minutes)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focus group—overall</td>
<td>Coordinated</td>
<td>Coordinated</td>
<td>Less coordinated</td>
<td>Less coordinated</td>
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<tr>
<td>patient perception of</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>coordination of care</td>
<td></td>
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MA = medical assistant; PCP = primary care physician; RN = registered nurse.
provide the necessary self-management support for patients over the phone and greater support to PCPs by making recommendations for treatment. However, observation suggested that use of more-skilled licensed staff may shift the direction of clinical decision-making responsibilities. When PCPs delegated more to staff, they potentially had less control over decision making and a weaker relationship with their patients. The relationship between staffing and role structure is further explored in the Discussion section of this report.

Findings from physician interviews, direct observation, and patient focus groups all suggested that a key factor contributing to effective coordination of care—regardless of scope of practice—is the skill of the outreach staff in communicating with patients and physicians. As one program implementer explained, “A key is getting the right staff for the program—those who can communicate effectively with PCPs and patients, ideally someone with a primary care background, and someone who is comfortable with computers and databases.” Patients expressed less concern about the scope of practice or title of staff contacting them but great concern that those staff members be directly tied to their PCP and be carrying out their physician’s orders.

Culture Change

Interviews and observation revealed that as with many other changes to core organizational processes, introduction of panel management presented a culture change that needed to be managed. Some physicians explained that when the program began at their facility, they felt that control of their patients was being taken away from them. Other physicians felt that panel management added extra work with not enough time designated for that work. Some physicians felt pressured to practice in ways that were not comfortable for them, such as being asked to make clinical decisions (e.g., the addition of new medications) without having a conversation first with their patient. Some physicians who expressed these concerns explained that over time they came to accept and support the program, whereas others said that they found ways to modify the program to meet their needs and practice style.

Many sites found that a key strategy for supporting implementation was demonstration of performance improvement to staff and physicians. Sites used feedback, ongoing reporting mechanisms for PCPs and staff, and education sessions led by physician champions to support acceptance of panel management as an effective quality improvement tool.

Program Oversight

Panel management implementers explained that close program oversight of outreach staff practices and program processes were essential to their program’s success. One implementation team explained that “having standard operating procedures for staff has been critical, especially because our staff work across 12 facilities. We needed to develop these early on and adapt them as necessary. We also needed to educate physicians and patients about how this program works.” Implementers also reported that it is important to closely monitor phone outreach to make sure scripts for staff are clear and that staff are effectively communicating with patients. Some programs have instituted ongoing training or coaching (including peer feedback) for both phone outreach staff and PCPs.

All program implementers believed that process and efficiency measures (number and type of patient contacts for panel management outreach staff and/or PCP review; and changes in patients’ health status) should be monitored, evaluated, and reported. Some of the observed programs monitored

<table>
<thead>
<tr>
<th>Table 3: Patient experiences—in their own words</th>
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<tbody>
<tr>
<td><strong>Satisfaction with PCP</strong></td>
</tr>
<tr>
<td>• “I am very happy with my care because my doctor looks at the total health picture.”</td>
</tr>
<tr>
<td>• “A nurse is now on my doctor’s team—she is very helpful in getting through to the doctor … Interacting by telephone, we can get to the nurse in half an hour. And she goes to the doctor for me.”</td>
</tr>
<tr>
<td><strong>Satisfaction with panel management outreach</strong></td>
</tr>
<tr>
<td>• “I’m fine receiving a call as long as everything comes in the name of my physician. The person calling me needs to be on the same page as my physician.”</td>
</tr>
<tr>
<td>• “I feel absolutely great about the call. Patients get drowned in their own personal problems. You have kids and you forget about yourself. When someone reminds you of your health, it’s really important. And I appreciate it very much.”</td>
</tr>
<tr>
<td><strong>Some coordination-of-care challenges</strong></td>
</tr>
<tr>
<td>• “A nurse called me and said they are recommending I take a cholesterol medication. I should go to the pharmacy to get it. So I went … but they had no knowledge of it. It all sounded a little disconnected. It sounded like they are not talking to each other. And I don’t want to be the go-between for different sets of people.”</td>
</tr>
<tr>
<td>• “Does the nurse coordinate with the doctor, or do they do this stuff on their own? I’m fine [receiving a call] as long as everything comes in the name of my physician. The person calling needs to be on the same page as my physician.”</td>
</tr>
</tbody>
</table>

PCP = primary care physician.

The Permanente Journal/Summer 2007/Volume 11 No. 3 17
Panel management outreach staff (and PCPs) specifically for volume of patient outreach and follow-up work to gauge the appropriateness of workload. The literature on phone outreach for managing chronic disease notes that if programs are not appropriately designed, telephone care providers or PCPs can become frustrated, burned out, or less aggressive in addressing care gaps. One KP program implementer explained, “You need to support the PCPs. Don’t make them feel guilty about not getting to the work. Understand their challenges and find ways to support them to get [them] on board.”

Discussion
The project reported here was designed as an early, rapid assessment of the potential and transferability of panel management and is subject to several limitations. The number of sites studied (four) is small. The site selection and interviewee selection processes were nonrandom, which could have introduced bias. Also, although there was some indication that two of the four study sites were able to provide better coordination of care from the patient’s perspective, the data are not sufficient to attribute this advantage to any specific practice, because multiple confounding factors complicate interpretation of the findings. The two sites that appeared to have stronger coordination of care had been in place much longer than the other two sites, giving the former time to fine-tune the programs and processes. In addition, these two sites implemented panel management in a sequential manner over time, rather than implementing in many modules at once. Although causal- ity cannot be established, this study provides value by identifying potential strengths and limitations that can accompany panel management implementation, so that potential adopters have an opportunity to put in place measures that benefit from the experiences of other sites.

A related limitation of these findings is the lack of quantitative measures to more fully evaluate models. Panel management is spreading across KP in the absence of comprehensive quantitative data on its impact. The changing nature of all components—information technology, people, and process—across KP challenge our ability to develop compelling data on impact. There remains great variation among adopter sites. Issues such as optimal staffing, amount of dedicated physician time, workflow, and communication are still the subjects of experimentation. Currently, programs are not fixed and continue to develop and change. These factors make it challenging to identify superior models or to evaluate models more rigorously at this stage. As a result, the findings summarized here should be regarded as hypothesis-generating. The remaining discussion focuses on hypotheses regarding two specific issues: care coordination and self-management support.

Panel Management and Coordination of Care
A key element in high-quality primary care is care coordination, with all caregivers having detailed knowledge of care the patient is receiving from other sources. Numerous studies have shown that coordination of care is associated with greater levels of population health and patient satisfaction.7–11 In light of patient experiences documented in this study, coordination of care within the panel management process seemed to represent an important area for greater inquiry and attention. For example, in one focus group a patient reported that she was told by panel management staff that medications were ordered, but when she went to the pharmacy there were no medications there. A few examples of this type of experience surfaced in each of the two sites where some patients experienced challenges related to coordination-of-care.

The two relatively more coordinated sites (most patients experiencing their care as coordinated) shared certain features, but as noted, we cannot determine whether these factors directly contribute to the observed differences across sites. Possible contributors to coordination include limited roles for nonphysician staff in clinical decision making; tightly coupled physician–staff relationships with clearly defined and transparent roles for support staff; and program size, maturity, and evolution (see Table 2).

Research on using telephone support to manage chronic disease suggests that using clinic-based staff and tightly linking these types of programs to clinic-based care can contribute to greater program effectiveness. The most effective programs, research suggests, are those that link phone outreach to outpatient care and clinician follow-up.7 However, the evidence of the impact of staffing decisions on program effectiveness is not conclusive.

We hypothesize that one contributor to patient perceptions of coordinated care may be team preparation—more specifically, staff preparedness for the role that they take on in panel management. Patients overwhelmingly expressed tremendous satisfaction with their
PCPs and a strong desire to have their PCPs involved in directing their care, but their satisfaction with outreach staff was mixed. It is possible that staff who are accustomed to having a directive role and semiautonomous relationship working with patients may implicitly convey a sense of authority that is inconsistent with the explicit message that the physician is directing the care; this ambiguity of authority may confuse patients. In contrast, nonlicensed staff may give a stronger impression that their role is to support communication between patient and physician, thus preventing any misunderstandings.

We also hypothesize that a second pathway by which use of licensed staff (eg, registered nurses or pharmacists) in the PMA role may affect coordination is the reduction of physician engagement in panel management. At sites where medical assistants conduct outreach, it is possible that physicians are delegating fewer panel management activities and retaining greater personal ownership and responsibility for clinical decisions. By contrast, at sites where PMAs are licensed staff, PMAs—under protocol—have the authority to draft treatment orders for physician review. Physicians with licensed PMA staff may spend less time generating their own orders, thus decreasing their role in directing care and decreasing their role in assuring coordination. Choice of PMA staffing—licensed or unlicensed—is influenced by a tension between the greater efficiency of having orders drafted by nonphysician staff and the potential for decreasing coordination and/or weakening patients’ confidence that their physicians are fully overseeing their care.

Other possible factors that might improve the patient experience and contribute to a more coordinated patient experience include “warm handoffs,” with physicians explaining to patients the new roles of panel management staff or activities; strong communication skills for outreach staff, coupled with training programs and education and skills development; and ongoing program oversight. Other factors may also contribute to differences in patient experiences, and these should be factored into further evaluation of panel management activities. Some additional factors might be panel size, collocation of panel management staff and physicians, staffing ratios, and the amount of physician and nonphysician designated time.

Panel Management and Self-Management Support

A second issue, also related to choice of staffing, is the role of self-management support in panel management. Some study sites are coupling proactive outreach with self-management support. Other sites are not doing so, and at these sites, the transition from traditional care management to panel management—with its emphasis on brief patient contacts—may be decreasing capacity for self-management support. Because self-management support has been identified as an integral aspect of chronic disease care and one that favorably affects health status and health care utilization,12–14 this issue is an important area for additional attention and inquiry.

Conclusion

This new approach to population care has potential for improving quality and enhancing patient relationships with PCPs and teams. Our studies of early adopters point to next steps as this innovation continues to spread: the need for clarification of role definition and scope of practice; development of standardized work flows, training, and scripts that support safe and reliable communication and coordination of care; ongoing attention to management of staffing and expectations so that panel management does not unduly burden PCPs; and maintenance or development of adequate support for self-management.

Additional research of several types is needed before panel management’s impact can be fully understood. Ongoing measurement of patient perspectives regarding their care is required to monitor care quality and patient satisfaction with these new practices. Longer-term studies are needed to identify factors associated with high performance and to evaluate the impact of these programs on quality, cost, and physician and staff satisfaction. Ongoing work at KP will continue to explore and study the impact and promise of this emerging approach.
individuals for their support at critical moments in the research, analysis, and/or write-up: Lisa Arellanes, Beth Branthaver, Suzanne Furuya, Lucy MacPhail, Sabine Nicoleau, Helen Pettay, Estrella Shoka, Laura Skabowski, and four anonymous reviewers.

Katharine O’Moore-Klopf of KOK Ed provided editorial assistance.

References

Organization Transformation

Culture does not change because we desire to change it. Culture changes when the organization is transformed; the culture reflects the realities of people working together every day.

— Hesselbein F. The Key to Cultural Transformation. Leader to Leader 1999 Spring;12.
Church-Based Heart Health Project: Health Status of Urban African Americans

Abstract

One of the major health disparities in the African-American population is the high incidence of underdiagnosed cardiovascular disease prior to onset of symptoms. Cardiovascular diseases are one of the chief causes of decreased longevity, reduced quality of life, and poor treatment outcomes among African Americans. The Church-Based Heart Health Project, a pilot initiative of Kaiser Permanente (KP) Ohio’s Center of Excellence for Health Disparities and Cultural Competency for African American Health, was implemented in 2004 as an innovative and proactive response to confront this cardiovascular health disparity in greater Cleveland’s African-American population. The goal of this program was to reduce individual participants’ risks for cardiac events (that is, heart attack, heart disease, or cardiac death) by 1) providing individual risk assessment and interpretation and 2) cataloging the generalized health status of urban churchgoing African Americans in greater Cleveland. We describe the cardiovascular risk factors present in a random population of urban churchgoing African Americans participating in sponsored health screenings at their church. A convenience sample of 144 African-American adults participated in this study. Twenty-five percent (37) were men and 75% (107) were women, and participants’ mean age was 54.2 years. Ninety percent were not members of KP Ohio. Cardiovascular risk factors measured included body mass index, lipid levels (cholesterol, high-density lipoprotein, low-density lipoprotein, triglycerides), blood pressure, brief health history, Framingham Coronary Heart Disease Prediction Score, and National Heart, Lung, and Blood Institute prediction score for ten-year risk. A large portion of the population was found to have at least one risk factor for coronary heart disease (CHD).

Background

The poor state of health of urban African Americans has been attributed to disproportionately large incidences of heart disease, diabetes, and stroke, the leading causes of death in the United States. These diseases are the major causes of decreased longevity, decreased quality of life, and poor treatment outcomes among African Americans. The elimination of health disparities in the United States is a high-priority need because research indicates that African Americans (and other people of color) live with more comorbid conditions that negatively affect the quality of their lives and die at a younger age than their Caucasian counterparts. Heart disease is about 40% higher among African Americans than among Caucasians, and strokes are more likely in African Americans than in Caucasians. Cardiovascular disease mortality in African Americans aged 20-74 years is at least 35% higher than in Caucasians. Certain modifiable risk factors, including hypertension, high cholesterol, tobacco use, obesity, and lack of exercise are the main targets for primary and secondary prevention of cardiovascular diseases. Undergirding health disparities are factors that directly affect the health of African Americans and other people of color, such as education level, socioeconomic status, communication barriers between health care provider and patient, and overt discrimination. Research indicates that individuals and families with more education and higher income are more likely to take a larger role in managing their health care. They have higher levels of health literacy and a support structure that values lifestyle changes to promote good health. Lack of higher education and adequate income have been cited as the reasons many members of minority groups
lack health knowledge and skills and do not have effective health-seeking behaviors. However, even among middle-class African Americans, health disparities exist; there is a direct correlation between discrimination and cardiovascular risk. Increasing socioeconomic status and education levels do not directly correlate to better health outcomes in African Americans nor to high adherence rates to healthy lifestyle interventions. In addition, the lack of successful communication between patients and health care providers negatively affects health outcomes.

Because of the long historical precedent for provision of health-promotion programs aimed at hard-to-reach populations by partnering with African-American churches and community centers, there is significant research illustrating that both neighborhood-linked and faith-based health promotion and education results in improved health status and better medical outcomes such as better disease control, earlier diagnoses, and fewer comorbidities for the entire African-American community. Holt et al. reported that church helps African Americans to use their spiritual health to improve their physical health, ability to cope with stress, and ability to make healthy lifestyle choices. However, interventions targeted at the African-American community seem to fall short of the desired outcome of eliminating the population’s disproportionate burden of disease morbidity and mortality.

Methods
The Church-Based Heart Health Project, a pilot initiative of Kaiser Permanente (KP) Ohio’s Center of Excellence for Health Disparities and Cultural Competency for African American Health, was offered in 2004-05 on-site at African American churches in the service areas of the Kaiser Permanente Cleveland medical facilities. By bringing this program to the people it was meant to help, we eliminated access barriers and were able to reach people who would not otherwise be reached by our in-house programs.

Between 2004 and 2005, a descriptive study design was used to catalog the health status of urban churchgoing African Americans in the greater Cleveland area. Anonymous, free health screening for glucose levels, lipid levels, blood pressure, and body weight to determine cardiovascular risk was offered on-site directly after worship services at African-American churches in our service areas. A total of 144 parishioners (90% were not members of KP Ohio) from six churches participated. Screening included customized result interpretation, brief counseling and education by KP clinicians, and targeted provision of risk-reduction interventions at the churches. The American Heart Association’s Search Your Heart curriculum, a culturally adapted program, was used for the risk-reduction portion of the program.

Weight was measured on a portable scale, and participants were asked to self-report their height. Blood pressure was measured using a manual sphygmomanometer. Blood samples were collected, and blood glucose (random), total cholesterol, low-density lipoprotein, high-density lipoprotein, and triglyceride levels were immediately analyzed on a handheld meter (CardioCheck PA Whole Blood Test System, Polymer Technology Systems, Indianapolis, Indiana; OneTouch Ultra LifeScan, Milpitas, California) by a registered nurse, supervised by a physician. Any screening participants whose tests had abnormal results were referred either to their usual primary care physician or to the Free Clinic in the Greater Cleveland Metropolitan Area. The project also included follow-up phone calls by the registered nurse to those participants; the calls showed that 71% of those referred for immediate follow-up care did seek it and...
that 14% of those counseled to stop smoking did. Framingham Coronary Heart Disease Risk Prediction Scores were determined for 40 participants. Participants’ ten-year risk of developing CHD was determined by using the National Heart, Lung, and Blood Institute prediction score for women and for men.

Results
Not all study participants had all variables evaluated; number and percentage are described individually here for each variable. Twenty-five percent (37) were men and 75% (107) were women. The mean age of participants was 54.2 ± 16 years, with only 26 participants being younger than 40 years; the rest of the sample ranged in age from 40 to 92 years (Figure 1).

The mean body mass index (BMI) was 29.8 m/kg² (SD = 6.8 m/kg²) with a very broad BMI range from 17.7 to 62.4 m/kg². Of 146 participants (132 subjects had complete data sets for BMI calculation), 28 (19%) had BMIs in the normal range; <25 m/kg². The rest of the participants had BMIs above the normal range >25 m/kg² categorizing them as overweight or obese; 49 (33.6%) had BMIs between 25 and 30 m/kg², categorizing them as overweight; 41 (28.1%) had BMIs between 30 and 38 m/kg², categorizing them as obese; and 14 (9.6%) had BMIs >38 m/kg², categorizing them as morbidly obese (Figure 2).

Blood pressure, blood glucose (random), total cholesterol, low-density lipoprotein, high-density lipoprotein, and triglyceride levels were measured for all participants (Table 1).

Many of the participants had clinical values for these measures outside the normal range: 65% had a systolic blood pressure higher than normal (normal range, 120–130 mm Hg), 51% had high total cholesterol levels (range, 200–240 mg/dL), and 48% had high triglyceride levels (range, 150–200 mg/dL).

The Ten-year Framingham Coronary Heart Disease Prediction Score was determined for 40 participants (Table 2). For the men tested, the ten-year risk was 13% ± 1% (range, 4%–31%; n = 5); for the women tested, it was 7.7% ± 4% (range, 1%–20%; n = 35).

Discussion
Little work has been done since Thomas et al (1994) determined the predictors of effective church-based health outreach programs for African Americans.22 Our study also cataloged the health status of attendees of churches with active health ministries and found that a large portion of the population in question had at least one risk factor for cardiovascular disease; this is consistent with findings of other studies of African Americans.23 Almost 80% of participants in this study had a BMI above normal and approximately 50% had at least one elevated lipid value ...

Table 1. Clinical characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Normal</th>
<th>High normal</th>
<th>High</th>
<th>Danger zone</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Range</td>
<td>N (%)</td>
<td>Range</td>
<td>N (%)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>≥25</td>
<td>28 (19)</td>
<td>25–30</td>
<td>49 (34)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure (mm Hg)</td>
<td>120–130</td>
<td>42 (35)</td>
<td>130–139</td>
<td>20 (16)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diastolic blood pressure (mm Hg)</td>
<td>&lt;80</td>
<td>95 (79)</td>
<td>80–89</td>
<td>6 (5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Random blood glucose (mg/dL)</td>
<td>&lt;120</td>
<td>101 (76)</td>
<td>120–140</td>
<td>15 (11)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cholesterol (mg/dL)</td>
<td>&lt;200</td>
<td>64 (49)</td>
<td>— —</td>
<td>200–240</td>
</tr>
<tr>
<td>Low-density lipoprotein (mg/dL)</td>
<td>&lt;140</td>
<td>47 (64)</td>
<td>— —</td>
<td>140–170</td>
</tr>
<tr>
<td>High-density lipoprotein (mg/dL)</td>
<td>&gt;60</td>
<td>61 (46)</td>
<td>— —</td>
<td>40–60</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>&lt;150</td>
<td>65 (52)</td>
<td>— —</td>
<td>150–200</td>
</tr>
</tbody>
</table>
this combination of obesity and high lipid levels significantly influences heart health and associated cardiovascular disease risk. Increased cardiovascular risk was present when compared with the general population using the Framingham Coronary Heart Disease Prediction Score.

**Limitations**

Our study had several limitations. First, the sample was recruited in six churches in one Midwestern city over the period of one year, limiting our ability to generalize to other urban settings. However, several reports document similar health problems facing urban African-American populations in other large cities, suggesting some commonality of issues. Second, because all participants were churchgoers and the screenings were done at their churches, the participants might not be representative of the target population as a whole. Third, all data in this study were either self-reported (height), with the potential for social desirability effects, or were measured by handheld monitoring devices, which have the potential for introducing significant measurement error.

**Conclusions**

We have described here a reality for urban African-American churchgoers that indicates a high preponderance of cardiovascular risk factors and associated morbidity. Although African-American churches promote healthy lifestyles as part of their ministry efforts, our findings indicate that our population’s cardiovascular health needs improvement. Our study participants had more CHD risk factors than the general population, which might mean that the church health ministry programs are not efficacious as they could be. These programs might be more effective if they partnered with other community health resources rather than relying solely on internal church resources. A majority of the participants had one or more cardiovascular risk factors that could be significantly reduced by lifestyle changes; therefore, a concerted effort by church health ministries to implement lifestyle behavior change programs is necessary.

**Future Research**

New modalities of health education outreach need to be developed to address easily modifiable lifestyle changes to decrease disease risk factors. Future studies also need to encompass both the churchgoing population and the population at large in African-American urban communities to determine whether these groups have the same levels of risk. Access flexibility in the health care system for urban African Americans is necessary to respond to persons with screening results that indicate cardiovascular risk; different care delivery mechanisms must be explored. Additionally, we must determine the underlying reason that health care disparities still occur in the African-American population.

The research reported in this article was funded by a grant from the Kaiser Permanente Institute for Culturally Competent Care.

**Table 2. Framingham Coronary Heart Disease Prediction Scores**

<table>
<thead>
<tr>
<th>Sex</th>
<th>Ten-year coronary heart disease risk (with standard deviation)</th>
<th>Range (%)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>13% ± 1%</td>
<td>4–31</td>
<td>5 (12.5)</td>
</tr>
<tr>
<td>Female</td>
<td>7.7% ± 4%</td>
<td>1–20</td>
<td>35 (87.5)</td>
</tr>
</tbody>
</table>

**Acknowledgment**

Katharine O’Moor-Klopf of KOK Edit provided editorial assistance.

**References**

11. Pappas G, Queen S, Hadden W,
Implementation

Guidelines alone have little benefit without effective implementation.

Promoting Patient Safety:
The Rapid Medical Response Team

By Dawn Gould, RN, MSN, CNS

Abstract

Context: Adverse events are estimated to affect up to 17% of hospitalized patients and to cause up to 98,000 patient deaths per year in the United States. Unexpected codes in hospitalized patients are one of the most significant adverse events, carrying a risk of death that is reported to range from 50% to 80%.

Objective: The Rapid Medical Response Team (RMRT) was an initiative designed to reduce adverse events, specifically failure to rescue, leading to nonintensive care unit (nonICU) codes. This initiative was funded, as part of the Transforming Care at the Bedside (TCAB) program, by a grant from the Robert Wood Johnson Foundation.

Design: To determine whether the RMRT had a significant impact on our nonICU code rate, we did a retrospective, noncohort comparison of 2004 (preRMRT) data with 2005 (postRMRT) data.

Main Outcome Measures: Our main outcome measures were nonICU codes, mortality rate, and unplanned patient transfers to the intensive care unit (ICU).

Results: There was a decrease in the nonICU code rate per 1000 discharges from 1.90 in 2004 to 1.01 in 2005. Implementation of the RMRT correlates to a statistically significant decrease in the nonICU code rate (p = .018; relative risk, 0.53 [95% confidence interval, 0.31–0.91]). The nonICU mortality rate remained unchanged at 2.01%. The unplanned ICU transfer rate for 2005 was 47%.

Conclusions: Implementation of RMRTs can decrease nonICU code rates and the rate of unplanned ICU transfers. RMRTs can empower staff, enhance expertise and communication skills, and support a culture of safety.

Clinical Vignette

Mr X, a 72-year-old man, was hospitalized with an infection of his dialysis graft. Within the preceding two days, Mr X had complained of abdominal pain. His abdomen remained soft and nontender. Today, during hemodialysis, Mr X complained of nausea and midepi-gastric pain. His blood pressure dropped to 70 mmHg systolic and his oxygen saturation fell to the mid-70s. The patient was diaphoretic, tachycardic, and pale.

Introduction

Safety is freedom from accidental injury.1 This definition from the Institute of Medicine (IOM) Quality Committee is the foundation on which the health care community strives to provide quality patient care. Since the publication of the IOM’s landmark books, To Err Is Human: Building a Safer Health System (1999)2 and Crossing the Quality Chasm: A New Health System for the 21st Century (2001),3 the health care community has focused increasingly on ensuring patient safety through the development of processes to avoid adverse events and improve the quality of care. This unwavering goal for Kaiser Permanente (KP) began in the early 1990s with the establishment of a relationship with the Institute for Healthcare Improvement (IHI). KP’s National Patient Safety Program, a product of this collaboration, which is a basic tenet for the provision of care in all Kaiser Foundation Health Plans and Hospitals, and independent Permanente Medical Groups, has embraced safety as its core component and includes strategic goals such as safe culture, safe support systems, and safe patients.

Delivering safe care on a daily basis is multifaceted and complex. It requires solid participation from leadership and all labor partners within the facility and a broad collaborative partnership with organizations such as the IHI. The commitment to quality within KP has been forged on the principle that all medical and nursing staff work routinely with KP leaders in program testing, implementation, and redesign. After the publication of the IOM books, the IHI launched major change initiatives intended to improve communication, prevent adverse events and avoidable deaths, and improve the overall quality of hospital care.
The Permanente Journal/ Summer 2007/ Volume 11 No. 3

Promoting Patient Safety: The Rapid Medical Response Team

Research has shown that adverse events, defined as any harm that occurs to patients from medical care, whether or not as the result of error, are associated with higher rates of poor outcomes and death and that many adverse events are preceded by physiologic signs that are clearly abnormal. A review of the literature identifies three main systemic issues contributing to adverse events:

1. Failure to plan
2. Failure to communicate
3. Failure to recognize a patient’s deteriorating condition (failure to rescue).

A fundamental goal for the Roseville Medical Center staff was to reduce adverse events. Adverse events are estimated to affect up to 17% of hospitalized patients and cause up to 98,000 patient deaths per year in the US.\(^4,5\) Research has shown that adverse events, defined as any harm that occurs to patients from medical care, whether or not as the result of error, are associated with higher rates of poor outcomes and death and that many adverse events are preceded by physiologic signs that are clearly abnormal.\(^6,7\) A review of the literature identifies three main systemic issues contributing to adverse events:

<table>
<thead>
<tr>
<th>Table 1. Roseville Medical Center Rapid Medical Response Team executive sponsors</th>
</tr>
</thead>
</table>
| **Barbara Crawford, RN, MS**  
Vice President, Quality and Regulatory Services,  
Kaiser Permanente Northern California Region |
| **Sandy Sharon, RN, MBA**  
Assistant Administrator, Patient Care Services,  
Roseville Medical Center, CA |
| **Charles B Meek, RN, BSN**  
Department Manager, Medical-Surgical, Roseville Medical Center, CA |

The Joint Commission, formerly known as the Joint Commission on Accreditation of Healthcare Organizations, states that two of three primary causes of sentinel adverse events are lack of communication among hospital staff and inadequate patient assessments.\(^8\)

Through evaluation of incident and code reports, the Roseville Medical Center focused on identifying and developing methods to reduce the number of adverse events, specifically failure to rescue, leading to unexpected codes within our facility. Unexpected codes in hospitalized patients constitute one of the most significant adverse events; the death rate for unexpected codes has not changed since 1997. The risk of death from unexpected codes in hospitalized patients is reported to range from 50% to 80%.\(^9\)

With the commitment and full support of our executive sponsors (Table 1), our TCAB committee opted to pilot a Rapid Medical Response Team (RMRT) in an effort to decrease the number of failure-to-rescue events. The RMRT, one of the IHI-recommended change initiatives, provides a systematic mechanism for medical-surgical staff to obtain immediate critical care expertise in evaluating patients and providing early interventions to minimize or prevent deterioration of patients’ conditions. Unlike a code team, an RMRT has the objective of early intervention before the patient’s condition deteriorates to the point that s/he requires resuscitation. RMRTs have been shown to reduce the incidence of cardiac arrests outside the intensive care unit (ICU) by 50%, reduce the rate of medical-surgical patient transfers to the ICU by 25% to 30%, and decrease hospital mortality by up to 26%.\(^6\) In addition to improving safety, quality, and care for patients, RMRTs benefit staff through the development of a service and educational partnership between hospital units and through enhanced communication and clinical skills. The ultimate result is a reduction in adverse events and improved clinical practice.

**Developing the Rapid Medical Response Team**

The TCAB committee comprises licensed and unlicensed staff, who collaborated with representatives from our Labor-Management Partnership (labor partners), including respiratory therapy staff, executive leadership, and the representatives of the disciplines involved in our code process, to begin developing the initiative. Although RMRTs are a relatively new concept in the US, they have been successfully used in Australia since 1990.\(^10\) Since that time, several US health care organizations have developed initiatives. The TCAB committee reviewed the information on RMRTs implemented by other facilities and chose a design model based on one implemented at Baptist Hospital in Memphis, Tennessee, that had been profiled by IHI. The target population was the nonICU (medical, surgical, and telemetry) hospitalized population, which, for Roseville Medical Center, is typically older (with a representative age of >70 years) with multiple comorbidities.
The initial RMRT discussions began in June 2004. A timeline was established for development that included the first trial targeted for September 4, 2004, and an evaluation of current resources, development of protocols, development of effectiveness metrics, and evaluation of staff educational needs. The TCAB committee outlined the concept, identified the activities essential to the initiative development, detailed how the components would work, and, later, supported implementation.

Integral to all Roseville Medical Center initiatives is the basic KP National Patient Safety Program quality strategic focus, which is to partner with our patients to maintain and improve their health through effective prevention, early diagnosis, appropriate treatment, and follow-up. To ensure that this focus is the core of all initiatives, the overarching TCAB structure encompasses, as collaborative partners, our administrative leaders and Quality Assessment and Improvement Program staff, including leadership from all major committees such as the Patient Quality Committee, Risk Management Committee, the Professional Practice Committee, and the Code Blue Committee. Incident reports, unplanned ICU transfers, and code reports are evaluated by leaders in these committees to identify trends, performance improvement concepts, professional performance needs, and systems issues, as well as to formulate recommendations and to initiate change. Executive leadership reviews all recommendations from these groups.

Collaboration and continuing staff support from these major stakeholders, along with direct involvement and support of our administrative and executive leadership was fundamental to the development of this initiative and is essential to its ongoing success. The culture of the Roseville facility, as well as that of KP overall, begins with our leaders and their steadfast commitment to programs built on the foundation of safety and the use of outcomes as proactive opportunities for system improvements.

During the development process, the overarching objectives were defined as:

- Maximizing the climate of safety for medical-surgical patients
- Promoting a more cohesive clinical approach hospitalwide
- Augmenting the expertise and communication skills of our nurses throughout the facility.

Because the focus population of RMRTs is nonICU patients, specifically medical-surgical and telemetry inpatients, we anticipated a cultural change. Through development of a more collaborative mind-set supporting enhanced nursing skills, we anticipated that staff would recognize changes early and minimize barriers that could compromise patients’ safety. To evaluate the effectiveness of the initiative, the following specific outcome measures were proposed:

- Decreased adverse events, including nonICU cardiopulmonary arrests (codes)
- Decreased mortality
- Decreased unplanned ICU transfers
- Increased staff awareness of physiologic indicators of deterioration
- Increased staff communication.

As the concept developed, the TCAB committee concluded that it was vital for the team to be accessible to anyone in the facility who felt a need for it, and the initiative was structured in such a way that anyone in the facility could initiate an RMRT call by contacting our facility operators. As call criteria were developed, they were made sufficiently broad to encourage calls for subjective concerns, such as the “intuition” nurses frequently describe or because they were worried about the patient, as well as more quantifiable physiologic changes that are premonitory signs of physical deterioration (Figure 1).5,7,13,14 The Roseville RMRT was designed to be composed of an ICU charge nurse, chosen for excellence in clinical nursing judgment, and a respiratory therapist (RT) for expertise essential for enhanced assessments and support of patients’ pulmonary needs. Together, they provided the resources to establish an ICU level of care.

With a focus on promoting a safe culture, a critical prerequisite was to improve staff recognition of at-risk patients before their condition deteriorates to provide a safety net to prevent further deterioration.

Figure 1. Rapid Medical Response Team Call Criteria.
Consequently, a benchmark for the initiative would be the staff’s ability to recognize the need to rescue. Therefore, education would be essential for success. The educational elements developed included components focused on eliminating barriers to contacting and using the RMRT. All staff, including physicians, nurses, and ancillary staff were included in the RMRT educational process. The education began initially with the RMRT introduction: the composition of the team, the objectives for the team, when and how to contact the team, how the data would be collected, and how staff and patients would receive feedback. All staff received copies of the call criteria, which were also prominently displayed in the two trial units, and the data collection tool (Figure 2). The key ongoing educational program components, implemented simultaneously with the introduction, consist of Human Factors and Critical Event Team Training (CETT) to enhance the skills of staff in detecting deterioration. Additionally, because our staff communicate and document using Situation, Background, Assessment, and Recommendation (SBAR), concurrent training in SBAR, underscoring the critical role of communication in quality patient care, is routinely provided. Current thinking postulates that “failure to communicate” leading to adverse events may be indicative of a nurse’s hesitancy to call because of difficulty in communicating findings, because subtle changes may be difficult to articulate, or because of failure to appreciate the urgency of the situation, a lack of knowledge, or failure to seek advice. The commitment to ongoing staff education in communication and assessment skills remains crucial.

The data collection tool supports a direct measure of adverse events, specifically nonICU codes, mortality, and unplanned ICU transfers. The data collection process includes a debriefing mechanism that provides insight into staff awareness of the physiologic indicators of patient deterioration and of communication effectiveness and whether staff have embraced the collaborative cultural change approach that the RMRT provides. After an RMRT call, the completed data collection tool is reviewed by the department manager. All data are validated by chart reviews, staff interviews, and patient and family meetings. The manager then enters the data into a database, where it can be analyzed for trending and tracking as well as shared with other facilities and organizations. If an RMRT call results in calling a code, both RMRT data and code data are collected. The code data are reviewed and validated for process by management and forwarded to our Quality Department, where it is validated for meeting code criteria. It is then entered into the National Registry of CardioPulmonary Resuscitation (using software version 5.0/5.01; Digital Innovation, Inc, Forest Hill, Maryland), to be shared with the national registry as part of an international database of inhospital resuscitation events.

The RMRT data, after review and completion by the department manager, are entered into spreadsheets and charts compiled in Microsoft Office Excel 2003 (version 11; Microsoft, Redmond, Washington). Reports are shared monthly with the TCAB and Patient Quality Committees for analysis and trending.

The RMRT process begins when a call is placed to the facility operators, requesting the RMRT. Once contacted, the operators use text-messaging and overhead paging to send the RMRT to the unit and room number. The overhead page allows workers in other disciplines, including physicians, nursing supervisors, and department managers, to participate in the call.

![Figure 2. Rapid Medical Response Team Record.](image-url)
The patient’s primary nurse remains with the patient throughout the call. The ICU nurse, designated the team leader, completes an initial physiologic assessment with the primary nurse, while the respiratory therapist assesses respiratory needs, provides respiratory support, and makes respiratory recommendations. The ICU nurse collaborates with the physician on the assessment findings and subsequent recommendations. Either the primary nurse, a nursing supervisor, or the department manager records all events on the RMRT data collection tool. Another nurse from the unit remains available to the team throughout the call. When the outcome includes transfer to a unit with a higher level of care, the RMRT accompanies the patient. The department manager who chairs our TCAB committee is notified each time the RMRT is called. This manager is responsible for collecting the data tools from each event, validating all information entered on the tool, and, within 24 hours of the call, reviewing the patient chart for antecedent events. The department manager or designee also meets with the primary nurse who was caring for the patient at the time of the call to discuss the circumstances leading to the call, then contacts the patient or the patient’s family members to assess outcomes, augment our personal approach to care, and further define the root cause of the call. If system problems are identified, executive leadership, quality, and other affected departments are alerted as an initial step in generating system analyses and changes.

Executive leadership has been involved with the initiative since inception and has supported staff through the change process with regular feedback about the activities and outcomes, planned educational opportunities, and successes. Executives, along with the quality program committees, use the information received from the individual call data to evaluate and modify existing processes to enhance clinical and operational results for quality of care and patient safety.

Beginning September 4, 2004, the initiative was piloted on two medical-surgical units on the evening shift. Results were evaluated at the one- and two-month marks, with changes in process made on the basis of outcomes, and the initiative was expanded to the night shift on the two units in November. Training continued for all staff. On January 1, 2005, the initiative was expanded hospital-wide and outcome data collection began in earnest.

Data Analysis

Code data from 2004 (preRMRT) were compared with 2005 (postRMRT) data, code and RMRT calls, to determine whether the RMRT had a significant impact on our nonICU code rate. This data excluded all “do not resuscitate” patient data and data from codes occurring in the Emergency Department or in other nonmedical-surgical areas. Prior to analysis, the data from both years were reviewed and validated by the department manager and the clinical nurse specialist to ensure accuracy. Incomplete information was eliminated from analysis; accordingly, the analysis is unadjusted for age, sex, or comorbidity.

To determine whether the RMRT had a significant impact on our nonICU code rate, data from January 1 through December 31, 2004, were compared with data from January 1 through December 31, 2005, using \( \chi^2 \)-square analysis. Statistical Analysis Software (version 9.1, SAS Institute, Cary, North Carolina) was used to perform the analysis. The first full year of hospitalwide RMRT implementation was 2005. Four nonICU codes, which had occurred during the staff training period in

<table>
<thead>
<tr>
<th>Table 2. NonICU codes and deaths in 2004 and 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codes January 1 through December 31, 2004 [preRMRT]</td>
</tr>
<tr>
<td>------------------------------------------------</td>
</tr>
<tr>
<td>Facility</td>
</tr>
<tr>
<td>Facility code rate per 1000 discharges</td>
</tr>
<tr>
<td>NonICU (medical-surgical)</td>
</tr>
<tr>
<td>NonICU (medical-surgical) code rate per 1000 discharges</td>
</tr>
<tr>
<td>95% CI</td>
</tr>
<tr>
<td>Total discharges</td>
</tr>
<tr>
<td>Facility deaths*</td>
</tr>
<tr>
<td>NonICU deaths*</td>
</tr>
<tr>
<td>NonICU death rate*</td>
</tr>
<tr>
<td>Facility raw mortality rate</td>
</tr>
</tbody>
</table>

*Death rates are nonadjusted.

CI = confidence interval; ICU = intensive care unit; RMRT = Rapid Medical Response Team; RR = relative risk.
2004, were included with the 2004 data.

Data analysis reflected a decrease in nonICU code rate per 1000 discharges, from 1.90 in 2004 to 1.01 in 2005, dropping from 39 codes to 21 (46% decrease). The implementation of the RMRT correlates to a statistically significant decrease in the nonICU code rate (p = .018; relative risk, 0.53 [95% confidence interval, 0.31–0.91]; Table 2). Additionally, our facilitywide code rate decreased from 4.38/1000 discharges in 2004 to 3.72/1000 discharges in 2005. Considering that the average age of the Roseville Medical Center patient has historically been older than in other institutions and that older patients are more likely than other patients to have comorbidities, an adjusted analysis might have resulted in even greater statistical significance.

A second analysis method, Control Chart methodology, also indicates that a trend is beginning to emerge from the data to suggest more than a common cause. With this methodology, further data points will be necessary to confirm that the RMRT is the “special cause” (Figure 3).

The overall unadjusted mortality rate in our facility rose slightly from 2.7% per 1000 discharges in 2004 to 2.8% in 2005; however, the nonICU mortality rate remained unchanged at 2.01%. During the same time frame, our total discharges from the facility increased from 20,990 (2004) to 21,224 (2005). Our unplanned ICU transfer rate for 2005 was 47%. Seventy-two transfers occurred as a result of 152 RMRT calls. This suggests that, over the course of the year, the staff activated the RMRT sufficiently early to avoid transfers in 53% of the patients. Over time, training will be modified on the basis of the type of physiologic changes most likely to require transfer.

Although other changes had been implemented in 2004 that were making a positive impact on our nonICU code rate, the effect of the RMRT implementation is readily apparent. As has been the case in other studies, there was an inverse relationship between the number of calls and the number of codes, with the exception of the first quarter of 2005, when there were 44 calls and eight codes (18%). Nurses’ hesitancy to call may be one explanation. Theoretically, because the initiative was

![Figure 3. Control Chart methodology for codes outside the intensive care unit (ICU).](image)

*Training and Implementation to all Med-Surg units (09/04/04–12/31/04)*
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ORiGiNAl ARTiClE

gains of expert collaboration and support from the team.

frequently, the staff began to recognize the secondary gains of expert collaboration and support from the team.

Results

The implementation of the RMRT has signaled a complete cultural change for Roseville Medical Center. Prior to RMRT, contacting the physician was the only option available to nurses when they identified an adverse physiologic change in a patient. RMRT provides a second option that is immediately available and for which the only criterion is a “feeling of concern.” Anticipating a barrier to placing the call, we ensured that much of our preparatory and continuing education has focused on the perceived benefits of the initiative—for patients, nurses, and physicians. Consequently, nurses feel empowered to request assistance. RMRT provides that assistance immediately, shares critical care expertise and knowledge, and is supportive and nonjudgmental while sensitively fostering new working relationships. The trust that has developed between the RMRT and the medical-surgical staff endorses their mentoring relationship. The physicians have found that the interventions of the RMRT have frequently averted potential crises and augmented their ability to intervene by receiving, through the refined use of SBAR and enhanced critical-thinking skills, more succinct, comprehensive patient information. Since all staff have been encouraged to educate patients and their families about the availability of the RMRT, making our patient partners in ensuring safety, two family-initiated RMRT calls have been responded to, and the RMRT quickly resolved all concerns.

Evaluations of RMRT calls and outcomes have precipitated changes in the educational programs presented. CETT is routinely provided to support staff in augmenting their expertise in identifying patients with physiologic indicators of deterioration. The monthly trainings have been expanded to provide six-hour programs encompassing SBAR, Human Factors, and CETT for Roseville Medical Center staff as well as other KP facilities in a collaborative effort to support the expansion of RMRTs. Recently, a virtual patient simulator has been incorporated to further enhance teamwork, assessment skills, and patient care. This type of training has been shown to improve team performance, assessments, and patient outcomes. The ongoing education emphasizes specific patient-centered events, with identification of early deterioration being paramount. The global approach has centered on developing and supporting a collaborative mind-set.

Regular review of antecedent events has led to proactive systems changes. For example, instances in which patients were allowed to remove their oxygen sources during ambulation were identified. This occasionally led to hypoxic responses, patient distress, and, sometimes, RMRT calls. Once this problem was identified, a multidisciplinary Oxygen Task Force was created to evaluate and update our current standards; to implement team-centered, educationally based competencies focusing on respiratory issues; and, to provide a “reliable standard of excellent care.”

The direct participation and collaboration of all staff and our labor partners during initiative development and implementation has strengthened the commitment felt toward the RMRT. A clear sense of mission and shared vision of enhancing patient safety and improving patient outcomes has stimulated the enthusiasm that staff have consistently displayed. As the team was called more frequently, the staff began to recognize the secondary gains of expert collaboration and support from the team. They also received acknowledgment and support for their own skills through event analyses and feedback. The advantages of better communication skills, with more concise information sharing and more expedient results, became apparent as well. Collectively, these have resulted in improved clinical proficiency and accentuated patient safety. Theoretically, these benefits, in addition to the decrease in nonICU codes, are a direct reflection of a broad, successful culture change.

With solid support from executive leadership throughout the implementation of the RMRT, the KP Patient Safety Program vision has been shared in ways that empower both our staff and our patients. A strong partnership has been built on mutual goals, resulting in both short-term and long-term quality gains emphasizing patient-centeredness. Continuous feedback, ongoing education, and information sharing have sustained the initial culture change and continue to ensure improve-

As the team was called more frequently, the staff began to recognize the secondary gains of expert collaboration and support from the team.
ment. Additionally, patients at the Roseville Medical Center have demonstrated their satisfaction with the RMRT and the comprehensive cultural change by moving us from the top one-third in patient satisfaction surveys to the number-one ranking of KP facilities in Northern California for seven of eight months.

Presentations on our initiative have been given to the TCAB Learning & Innovation Community Meeting in Tampa, Florida (March 2005), and the Joint Commission Conference on Critical Linkages: Nurse Staffing, Patient Safety and Transforming Care at the Bedside, in Seattle, Washington (May 2006). In 2005, a regional committee, California Region RRT (Rapid Response Team) Collaborative, was formed to coordinate and evaluate all aspects of the teams and to support the development of RMRT teams, discuss emerging trends, and share ideas with other facilities (See Sidebar: “Northern California Regional Spread of Rapid Response Teams”). This committee has developed a standardized data collection tool that all KP Northern California facilities will use. The new tool will promote the collection of consistent, comparative data from all facilities. Our department manager has chaired this collaborative, which includes representatives from Sunnyside (Oregon), Hawaii, West Los Angeles, and Fontana (Los Angeles area), in addition to many non-KP facilities, such as Cedars-Sinai (Los Angeles), Queens in Honolulu, and the Department of Health Services Los Angeles County Hospitals.

In an effort to further partner with other health care organizations, the initiative has been presented to the Sacramento–Sierra–Stanislaus–San Joaquin Area Patient Safety Collaborative. Additionally, the Roseville Medical Center RMRT has been the subject of articles published in the TPMG Forum (July–August 2005) and Advance for Nurses (July 2006).

With the success of the Roseville Medical Center RMRT, all of the Northern California and several of the KP Southern California Medical Centers have embarked on initiatives to implement RMRTs.

No additional costs have been incurred with the implementation of the RMRT. Conversely, significant cost savings may have been generated through hospital days...
saved. However, these savings are likely far superseded by avoidance of the nonquantifiable psychological and physical toll that adverse events exact on patients and their families.

Conclusion

The achievements of the RMRT at the Roseville Medical Center are clearly evident, with a decreased code rate and a decreased relative risk of nonICU codes being called for nonICU patients. As Donald Berwick, MD, MPP, FRCP, President and CEO, IHI, so succinctly stated during the launching of the 100,000 Lives Campaign, “Some is not a number, soon is not a time.”

With the incorporation of RMRTs throughout all KP Northern California facilities all medical-surgical patients can feel safer in their facilities and all the facilities can achieve a higher quality of patient care and better patient outcomes. The focus on patient safety has provided an opportunity to develop an initiative of excellence that dovetails with the mantra of KP’s Patient Safety Program: “Patient safety is every patient’s right and everyone’s responsibility.”

In the case vignette presented earlier, when Mr X showed symptoms of deterioration, the RMRT was called. An assessment led to immediate transfer to the ICU where he was stabilized, evaluated further and, within a very short time, successfully operated on for a perforated duodenal ulcer. Our team had averted a potential code and provided immediate ICU-level of expertise in care. Mrs X summarized the sentiments of many of the Roseville Medical Center’s patients when she told the department manager, “Your team saved my husband’s life.”

Acknowledgment

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

References


Disclosure

Parts of this article have been submitted to the Joint Commission as an initiative summary supporting the use of process and outcome measures to improve organization performance and quality and safety of care.
Introduction

Depressive syndromes are commonly seen in the primary care setting. The National Institute of Mental Health estimates that 9.5% of adult Americans (about 19 million people) suffer from Major Depressive Disorder (MDD). Within Kaiser Permanente (KP), the overall prevalence of depression is about 8.4%, and direct medical costs to care for members with depression exceeds $2 billion annually.

In the primary care setting, treatment of depression usually includes evaluation by a physician, brief patient education, and either antidepressant therapy, referral to a behavioral health specialist or, in severe, resistant, or chronic cases, both a prescription and a referral. Although most depressed patients can be successfully treated by primary care clinicians, depression remains unrecognized or undertreated in many patients.

The first Major Depression Clinical Vignette, based on the 2002 CMI guideline, was published in the Winter 2002 issue of The Permanente Journal. This article discusses updated MDD diagnostic and treatment recommendations, based on the 2006 CMI Guideline for the Treatment of Major Depression in Adult Primary Care patients, and new evidence from the Sequenced Treatment Alternatives for Resistant Depression (STAR*D) trial.

Case Example

A 28-year-old married, employed female computer programmer with two young children is seen for a four-week history of fatigue, insomnia, headache, abdominal discomfort, and difficulty concentrating at work. She denies signs and symptoms of an acute infectious process and did not have headache or abdominal pain before the previous month. She has obtained intermittent relief from headache by using acetaminophen, and she takes a multivitamin regularly. She is appropriately and professionally dressed, and her children accompany her in the examination room. She appears tired but in no acute distress. Results of physical examination, including neurologic screening, are normal.

How should you proceed toward making a diagnosis? What treatment options are available? How should you follow this patient over time?

Definition of Major Depressive Disorder

MDD is characterized by at least two weeks of either depressed mood or loss of interest in previously pleasurable activities along with four or more additional symptoms, including:
- guilt
- sleep disturbance
- psychomotor retardation or agitation
- appetite disturbance
- difficulty concentrating
- decreased energy
- suicidal ideation, intention, or plan.

The mnemonic device DIGSPACES (Depression, loss of Interest, Guilt, Sleep disturbance, Psychomotor agitation/retardation, Appetite changes, loss of Energy, Suicidal thoughts) is a helpful way to remember these key symptoms of MDD. Diagnosis and treatment of other types of depression (eg, adjustment disorder with depressed mood; dysthymia; minor depressive disorders; depression with psychotic features; and bipolar disorder) are beyond the scope of this article.

Who Should be Screened for Depression?

Patients with cancer, chronic pain, heart failure, diabetes, recent stroke, or a recent acute cardiac event have higher rates of depression than the general population. Elderly patients with multiple medical comorbidity may also be at increased risk for depression. Patients with a prior history of MDD are at risk for recurrence. Other patients—those with multiple somatic complaints without known cause, women in the antenatal and postpartum periods, victims of domestic abuse, and HIV-positive patients—may also be candidates for screening.

Some evidence indicates that one-time screening of adults 40 years of age...
Patients with current suicidal ideation should be asked about their intentions ("Do you think you will commit suicide?")

Diagnosis of MDD

Several screening tools are available to assist clinicians in screening for depression (Table 1).22-31 Many of these tools can be completed by the patient and easily scored by the clinician or by an assistant. These tools have similar sensitivity and specificity.28,30,32-40 One instrument, the PHQ929 is available as a questionnaire in KP HealthConnect.

A “yes” answer to one of the following two questions (see Table 1: Two-question Screening) is as sensitive a screen for MDD as most of these screening tools, but has a high false-positive rate.22 Therefore, a positive two-question screen needs to be confirmed with additional clinical history or a validated diagnostic instrument to determine if the patient meets criteria for major depression; a “no” answer to both questions will miss very few cases of major depression.

All positive screening results should be confirmed with careful attention to possible substance abuse, medical, and other psychological causes or comorbidity (Table 2). The patient in the above example denied using alcohol or drugs and denied current or past physical, sexual, or emotional abuse; in addition, the complete blood cell count (CBC) and thyroid-stimulating hormone (TSH) level were normal. (TSH is measured to rule out hypothyroidism, a common postpartum condition.)

Assessing Severity of Depressive Symptoms

Symptom severity is an important guide to selecting proper treatment for MDD. Many depression-screening instruments provide a range of scores corresponding to mild, moderate, and severe depression.22-40 Patients with five or six symptoms of MDD who have slightly impaired daily functioning are mildly depressed. Patients with six or seven MDD symptoms and moderately impaired daily functioning are moderately depressed. Patients with eight or nine MDD symptoms with profoundly impaired functioning in daily activities or suicidal intention or plans are severely depressed.

Assessing Suicidal Ideation

All depressed patients, regardless of illness severity, should be screened for suicidal ideation. Many patients with depression have thoughts of suicide; asking “Have you thought about taking your life?” does not make patients more prone to attempt suicide. Patients with current suicidal ideation should be asked about their intentions (“Do you think you will commit suicide?”) and if they have a plan (“Have you thought about how you would kill yourself? “Do you plan to kill yourself? If so, when?”). Clinicians should elicit a promise from actively suicidal patients not to harm themselves and should assess adequacy and availability of patient support systems (family, friends, and clergy). A behavioral health specialist should be contacted immediately in these cases. Risk factors for suicide include: recent loss; medical hospitalization within the past year; history of psychiatric hospitalization or suicide attempts; living alone; severe vegetative symptoms; severe hopelessness; comorbid substance abuse; and other comorbid psychiatric conditions. Patients with these risk factors should be closely monitored.11-14 For every suicide death there are up to 25 nonfatal suicide attempts. Men and the elderly are more likely to have fatal suicide attempts than women and adolescents.45

Table 1. Instruments reviewed by the CMI Depression Guideline Group to screen for major depressive disorder (MDD) in adults

<table>
<thead>
<tr>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two-question screening:22</td>
</tr>
<tr>
<td>&quot;During the past month, have you often been bothered by feeling down, depressed, or hopeless?&quot;</td>
</tr>
<tr>
<td>&quot;During the past month, have you often been bothered by little interest or pleasure in doing things?&quot;</td>
</tr>
<tr>
<td>Beck Depression Inventory (BDI)23</td>
</tr>
<tr>
<td>Center for Epidemiologic Studies in Depression scale (CES-D)24</td>
</tr>
<tr>
<td>Depression Arkansas Scale (D-ARK)25</td>
</tr>
<tr>
<td>Geriatric Depression Scale (GDS)26</td>
</tr>
<tr>
<td>Outcomes Questionnaire 45 (OQ-45)27</td>
</tr>
<tr>
<td>Primary Care Evaluation of Mental Disorders (PrimeMD)28</td>
</tr>
<tr>
<td>Patient Health Questionnaire (PHQ-9)29</td>
</tr>
<tr>
<td>Quick Diagnostics Panel (QDP)30</td>
</tr>
<tr>
<td>Zung Self-Rating Depression (SDS)31</td>
</tr>
</tbody>
</table>

Treatment of MDD

Medication vs Psychotherapy

For most mildly or moderately depressed adult primary care outpatients, medication and psychotherapy are equally effective, although psychotherapy might be slower to take effect.47 A shared decision-making approach describing the pros and cons of each option should be used with these patients to help them select initial treatment options consistent with their values and concerns. One study48 found that patients who select psychotherapy achieve better outcomes than patients who are “assigned” to it. A shared decision-
making approach in patients with other conditions has been shown to improve patient knowledge and to decrease patient uncertainty about type of treatment.931 This approach can also help instill a sense of control in depressed patients, who often feel “lost” as a result of their depression.

Treatment recommendations should also be based on cultural considerations. One study52 found that patients of different cultural backgrounds often prefer psychotherapy to medication, while another study53 specific to low-income Latinos found that this population prefers combination therapy over medication or counseling alone.

Severely depressed patients may respond better to medication than psychotherapy54 and may respond better to the combination of medication and psychotherapy.5155 Consultation with a psychiatrist or other behavioral health specialist is recommended for severely depressed patients seen in the primary care setting.

Types of Antidepressant Medication

All antidepressant classes appear to be equally effective in depressed patients regardless of their age, the severity of depression,77 or the presence of another severe medical illness.84 The CMI Depression Guideline Development Team did not find high-quality studies comparing the effectiveness of different antidepressants in patients of different ethnic groups.

In the first 6 to 12 weeks of therapy, selective serotonin reuptake inhibitors (SSRIs) are somewhat better tolerated than tricyclic agents (TCAs) (number needed to treat, 20-33).58-59 Risk of death by overdose is greater with TCAs than with SSRIs, although rate of suicide from all causes does not differ on the basis of type of antidepressant.60-65 However, given the lethality of TCAs when overdosed, the CMI Depression Guideline Development team strongly recommends that TCAs be avoided by patients who are suicidal.5 Antidepressant agents have different side effect profiles that clinicians should consider when prescribing for patients with other comorbidities; patients may express a preference for a type of medication on the basis of discussing class-specific side effects with the clinician. Given the generally equal effectiveness of antidepressants, cost is also a consideration, especially for patients with tiered or no prescription coverage. Patients successfully treated for depression with a particular antidepressant in the past should be offered that agent again.

Research examining the effectiveness of hypericum (St John’s wort) is equivocal. While some studies showed a benefit over placebos66 or an effect equal to SSRIs67, others68,69 have suggested that the data on hypericum are “inconsistent and confusing” primarily because of the lack of standardized preparations across trials, variations in patient populations studied, and overall study design quality. The CMI Depression Guideline Development Team shares these concerns about the data regarding St John’s wort. The US Food and Drug Administration (FDA) does not regulate St John’s wort, and the amount of active ingredient may vary widely between and within brands. For these reasons, the CMI Depression Guideline Development Team recommends caution in prescribing St John’s wort for treatment of depression. Clinicians should consider discussing these concerns with patients who wish to use St John’s wort. This substance should not be used in combination with other antidepressant agents.

**Table 2. Selected differential diagnosis of MDD**

<table>
<thead>
<tr>
<th>Concurrent psychiatric conditions</th>
<th>Concurrent medical conditions</th>
<th>Medication-related</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjustment disorder</td>
<td>Endocrine: hypothyroidism</td>
<td>Antihypertensive/ cardiovascular agents: reserpine</td>
</tr>
<tr>
<td>Bipolar disorder</td>
<td>Cushing’s disease</td>
<td>clonidine</td>
</tr>
<tr>
<td>Dysthymia</td>
<td>Central nervous system: Parkinson’s disease</td>
<td>methyl dopa</td>
</tr>
<tr>
<td>Personality disorder</td>
<td>Alzheimer’s disease multiple sclerosis</td>
<td>digitalis</td>
</tr>
<tr>
<td>Psychotic depression</td>
<td>brain tumors</td>
<td>hydralazine</td>
</tr>
<tr>
<td>Posttraumatic stress</td>
<td>Cardiovascular system: stroke</td>
<td>prazosin</td>
</tr>
<tr>
<td>disorder/abuse</td>
<td>myocardial infarction</td>
<td>procainamide</td>
</tr>
<tr>
<td>Seasonal affective disorder</td>
<td>congestive heart failure</td>
<td>Sedative hypnotic agents: barbiturates</td>
</tr>
<tr>
<td>Somatization</td>
<td>Miscellaneous: rheumatoid arthritis</td>
<td>chloral hydrate</td>
</tr>
<tr>
<td>Substance abuse</td>
<td>AIDS</td>
<td>benzodiazepines</td>
</tr>
<tr>
<td></td>
<td>pernicious anemia</td>
<td>Anti-inflammatory agents: indomethacin</td>
</tr>
<tr>
<td></td>
<td>carcinoma</td>
<td>pentazocine</td>
</tr>
</tbody>
</table>

**Treatment Phases and Follow-up**

**Acute Phase**

The acute phase of treatment for MDD is defined as the period extending from the start of treatment that achieves symptom remission for a period of three months. The risk of patients discontinuing treatment is highest in the first months of treatment.59
Because of higher risk of lifetime recurrence, the Depression Guideline Development Team recommends longer term treatment for patients with two or more lifetime episodes of major depression.5

Therefore, follow-up is needed to assess patient adherence to therapy, symptom remission, and, if medication is chosen, presence of worrisome or unacceptable side effects. No scientific evidence suggests an optimal frequency of follow-up during the acute phase, but Health Plan Employer Data Information Set (HEDIS) criteria require three follow-up contacts (including one face-to-face contact with a prescribing provider) in the first 12 weeks of treatment.76 On the basis of consensus and clinical judgment, the CMI Depression Guideline Development team believes that a minimum of two follow-up contacts should occur in the acute phase: one within the first month, and the other four to eight weeks after the first contact. On the basis of the experience of the team members other successful models of care for depressed patients,71,72 contacts may be in person, by phone or via e-mail.5

Several options are available for patients who do not achieve symptom remission within 6 to 12 weeks. The diagnosis should be reevaluated, and possible presence of other untreated comorbid conditions should be considered. Adherence to treatment regimen should be assessed and reinforced. Dosage of medication may be increased; the medication can be changed to a different antidepressant in the same or different class,5,7,9 or psychotherapy and medication can be combined. Augmentation with bupropion or buspirone or adding low dose desipramine to an SSRI may also be attempted. Adding lithium5,10 or T310 may also be attempted in refractory cases. Referral to a behavioral health specialist is also an available option for patients who do not respond to prescribed medication.

Continuation Phase

After the acute phase has ended, patients should continue treatment for at least an additional 6 to 12 months.5,7-9 Terminating treatment sooner is associated with early recurrence of symptoms.77 No available data exist to suggest an optimal frequency of patient follow-up during the continuation phase. The CMI Depression Guideline Development Team consensus opinion recommends at least one follow-up during the fifth or sixth month of treatment to assure continued remission of symptoms and patient adherence to treatment as well as to determine necessity of adjusting treatment.5 More frequent follow-up can be scheduled on the basis of clinical judgment and patient preference.

Discontinuation or Maintenance?

A single episode of MDD is associated with a 50% lifetime risk of recurrence; two episodes are associated with a 70% lifetime recurrence risk, and three or more episodes are associated with a 90% lifetime recurrence risk.78 After successfully completing acute and continuation phase treatment for a first episode of major depression, patients should be offered a trial of medication discontinuation.19 Fluoxetine at doses less than 20 mg daily can be discontinued without tapering with a relatively low risk of adverse effects;79 higher fluoxetine doses and other medications should be tapered over a two- to four-week period.79,81 Patients with MDD should be educated about this risk and instructed to call their clinician at the first signs or symptoms of recurrent MDD. Data suggest that risk of recurrence is highest during the first year after medication is discontinued.21 The CMI Depression Guideline Development Team suggests that patients be reassessed three months after discontinuing medication and again at 12 months.

Because of higher risk of lifetime recurrence, the Depression Guideline Development Team recommends longer term treatment for patients with two or more lifetime episodes of major depression.5 Available data10,82 and consensus of the CMI Depression Guideline Development Team suggest that a treatment duration of 15 months to 5 years or longer after the acute phase response demonstrates benefit. No available data exist to suggest an optimal frequency of patient follow-up during maintenance treatment. The CMI guideline recommends at least one annual contact with the patient to detect symptom relapse and to determine need for treatment adjustment.5 These patients should also receive patient education on the signs of depression relapse.

Patient Education

Despite a trend toward increasing acceptance, many patients still feel stigmatized by the diagnosis of MDD. Therefore, clinicians should explain to these patients that MDD is a real illness and is not “all in their head.” Comparison with diabetes may be helpful (Table 3). Patients choosing medication should be informed about side effects and given instructions designed to enhance compliance with prescribed medication regimens (Table 4).85 Patients should also be educated about the signs and symptoms of relapsing or worsening depression.

Table 3. Script for explaining the diagnosis of depression to patients

"Depression isn’t all in your head, and it’s not a personal failing. It’s a real illness caused by imbalance of chemicals in your body—just like diabetes. In diabetes, your body chemicals get out of balance and can’t control your blood sugar. In depression, chemicals in your brain get out of balance, and it affects the way you think, act, and feel."

Table 4. Medication discontinuation guidelines

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxetine</td>
<td>&lt;20 mg daily</td>
<td>2-4 weeks</td>
</tr>
<tr>
<td>Lithium</td>
<td></td>
<td>3 months</td>
</tr>
<tr>
<td>T3</td>
<td></td>
<td>3 months</td>
</tr>
</tbody>
</table>

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**Patient Self-Management**

Several self-management strategies may be helpful as adjunct treatments for MDD (Table 5). They help patients regain a sense of control. Studies have not compared self-management strategies to “traditional” first-line treatment for major depression; most studies have focused on patients with depressive symptoms, few of whom have a diagnosis of MDD. Due to these and other limitations, the CMI Depression Guideline Development Team could not recommend for or against these strategies as sole treatment for MDD; however, the consensus of the Guideline Team is to consider these self-management strategies as an *adjunct* to other evidence-based MDD treatments.

**Specialty Referral**

The CMI Depression Guideline workgroup recommends referral or consultation with a behavioral health specialist for the situations listed in Table 6.2

**Case Example Diagnostic and Treatment Approach**

In addition to sleep disturbance, decreased energy, and difficulty concentrating, the patient in the above example admitted being sad and tearful as well as feeling guilty and worrying about her parenting skills, and she had lost interest in socializing. She also admitted to worrying about work performance and being somewhat irritable with her husband. She was not suicidal and had no prior history of depression or other psychiatric illness, but she thought her mother may have been depressed. Other medical comorbidity was excluded, and she was diagnosed with MDD, first episode, with secondary anxiety (not meeting criteria for generalized anxiety disorder). After participating in a shared decision-making approach, she selected pharmacotherapy with an SSRI and started fluoxetine, 10 mg daily, the next morning. At two-week follow-up, her depressed mood and energy were “50% better,” but she was still having trouble concentrating and sleeping and was still irritable. The dose of fluoxetine was increased to 20 mg in the morning, and 50 mg of trazodone was added at bedtime to help with sleep. At six-week follow-up, she was sleeping better, and her depressed mood and guilt about parenting were “almost gone.” Her energy was “returning to normal,” but she still worried about her work performance and reported having continued irritability with her husband. She elected not to change her medication regimen or to add psychotherapy and, at 12-week follow-up, reported total symptom resolution. She remained on medication, without further symptoms, for one year (three months of acute-phase treatment plus nine months of continuation-phase treatment). She was then offered and elected a trial of medication discontinuation. She remained asymptomatic at three weeks and at three month follow-up calls. During a health maintenance visit one year after medication discontinuation, she reported slight decrease in appetite as well as increase in worry and irritability, which she attributed to job stress. Repeat screening was not diagnostic for recurrent MDD or anxiety. The patient was re-educated on the symptoms of MDD and elected to monitor symptoms without resuming medication. At follow-up 3 months, 6 months, and 12 months later, the symptoms had resolved, and the patient remained in remission.

**Conclusion**

This vignette illustrates how clinicians can apply current evidence,

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**Table 4. Patient instructions for taking medication**

<table>
<thead>
<tr>
<th>Instructions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antidepressants only work if taken every day (specific time/daily routine).</td>
<td></td>
</tr>
<tr>
<td>Antidepressants are not addicting or habit forming. Benefits appear slowly and may take two to six weeks.</td>
<td></td>
</tr>
<tr>
<td>Mild side effects are common and usually improve after a couple of weeks.</td>
<td></td>
</tr>
<tr>
<td>It’s important to continue the medication even after you feel better.</td>
<td></td>
</tr>
<tr>
<td>Antidepressants must be continued for a minimum of 7-12 weeks.</td>
<td></td>
</tr>
<tr>
<td>Call with any questions. If you feel you need to stop medication, please let us know.</td>
<td></td>
</tr>
</tbody>
</table>


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**Table 5. Depression self-management strategy recommendations from the 2006 CMI Depression Guideline**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise is recommended as an adjunctive strategy (in addition to antidepressants or psychotherapy) for treating the symptoms of Major Depressive Disorder (MDD)</td>
<td></td>
</tr>
<tr>
<td>Bibliotherapy is an optional adjunct strategy (in addition to antidepressants or psychotherapy) for treating the symptoms of MDD. Patients may be advised to read written material based on cognitive-behavioral approaches to depression, <em>Feeling Good: The New Mood Therapy</em></td>
<td></td>
</tr>
<tr>
<td>Befriending (which consists of designated befriender meeting the depressed person to talk and socialize for at least one hour per week) is an optional adjunct to antidepressants or psychotherapy for treating the symptoms of MDD</td>
<td></td>
</tr>
<tr>
<td>Patient self-help materials on the following Internet sites are an optional adjunct strategy (in addition to antidepressants or psychotherapy) for treating the symptoms of MDD: Blue Pages (<a href="http://bluepages.anu.edu.au">http://bluepages.anu.edu.au</a>)</td>
<td></td>
</tr>
<tr>
<td>Mood Gym (<a href="http://moodgym.anu.edu.au">http://moodgym.anu.edu.au</a>), and Overcoming Depression on the Internet (<a href="http://www.believebetter.org">www.believebetter.org</a>)</td>
<td></td>
</tr>
<tr>
<td>Self-management strategies should be used as an adjunct to and not in lieu of other evidence-based treatments for MDD</td>
<td></td>
</tr>
</tbody>
</table>
Table 5. Consensus criteria for referral to a behavioral health specialist

<table>
<thead>
<tr>
<th>Criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two months of treatment without desired clinical improvement</td>
</tr>
<tr>
<td>Active homicidal ideation</td>
</tr>
<tr>
<td>Active suicidal ideation</td>
</tr>
<tr>
<td>Bipolar or manic behavior</td>
</tr>
<tr>
<td>Counseling with or without medication</td>
</tr>
<tr>
<td>Difficulty adhering to treatment plans</td>
</tr>
<tr>
<td>Domestic violence</td>
</tr>
<tr>
<td>Failure to respond to second antidepressant</td>
</tr>
<tr>
<td>Lifelong/recurrent depressions</td>
</tr>
<tr>
<td>Partial response to medication</td>
</tr>
<tr>
<td>Psychotic symptoms</td>
</tr>
<tr>
<td>Significant alcohol/other substance abuse</td>
</tr>
<tr>
<td>Unclear diagnosis</td>
</tr>
</tbody>
</table>

including the 2006 CMI Guideline for Treatment of Major Depression in Primary Care Adult Patients, to patient care scenarios. The full guideline document is available on the Permanente Knowledge Connection Web site: http://cl.kp.org/pkc/national/cmi/programs/depression/guideline/files/CMI_Depression_Guidelines_2006.pdf. The adult depression guideline is updated every two years; the next revision is scheduled for early 2008. CMI has achieved depression disease management recognition from the National Center for Quality Assurance (NCQA).

Acknowledgments

The authors would like to thank Elizabeth HB Lin, MD, MPH, for sharing her more recent research and for her help in revising Table 4. The authors would also like to thank the members of the guideline development team for their hard work during the guideline development process. A complete list of guideline work group members can be found in the Depression Guideline, available online at: http://cl.kp.org/pkc/national/cmi/programs/depression/guideline/bkgr_ackn.html (password protected).

References

2. KP Care Management Institute Clinical Outcomes of Evaluation (CORE) System; Adult Depression Prevalence, 2Q 2006.
24. Irwin M, Artin KH, Oxman MN. Screen-


Sri Lanka Poison Control: Toxicology Case Studies in Narrative

Sri Lanka. A tear-shaped island in the Indian Ocean, this is an ancient land with a long, incredible, and sometimes unfortunate history. Several decades of civil war have left the social infrastructure feeble and the general populace vulnerable to both physical and mental illness. Rebuilding efforts of the last few years were set back even further when the devastating 2004 tsunami struck and clashes between the military and rebels—the Liberation Tigers of Tamil Eelam (LTTE) or Tamil Tigers—intensified.

During completion of a fellowship in medical toxicology in San Diego, I traveled to Sri Lanka for a rotation in that country’s only poison center. The burden of disease from poisoning in Sri Lanka, and throughout South Asia, is staggering—the number of severe poisonings and fatalities many times greater than in industrialized countries. I met many doctors who are involved almost daily in managing difficult poisoning and snakebite cases without access to many basic medical resources. The following passages are from my journal and e-mail notes.

Arrival
(April, 2006)
I landed in Sri Lanka about an hour north of Colombo, the capital city—one airport serves the whole country. I stepped out of the airport and, before I knew it, I was in a taxi, speeding toward the town. My cab driver, unregistered in an unmarked car, darted into and out of the taxi lane, furtively looking for police. All officially registered taxis here are white minivans, so he was certainly nervous about picking up passengers.

We made small talk while he drove. I recalled some last-minute advice: distribute money in many places—and slipped a few bills into each sock and pocket. The driver is a Buddhist and speaks English quite well. He told me that as a “tsunami patient,” he had spent three days in a hospital at the time of the disaster. A shoulder injury—possibly a dislocation, not a fracture—occurred when his car rolled into the water. I asked, “Why were you in the hospital so long?” He said, “There were too many people and not enough doctors.” I let him know how shocking and heartbreaking it was to see the news about the tsunami. He seemed like a decent man—at the end of the hour-long trip he wrote down his cell phone number in case I needed another ride. He even invited me to go see his family’s rural home on the south coast. In the early morning hours we finally found my guesthouse in the Cinnamon Gardens district of Colombo. After nearly two days in flight I was ready for a real bed.

Later that morning, I awoke with no idea of the time. The birds there are LOUD. It was cloudy and the air was thick with moisture and the smells of incense and petrol. From the balcony, I spotted four large crows with mischievous eyes. A squirrel-like animal was making a high-pitched chik-chik noise. Deep,

Rais Vohra, MD, is an Assistant Professor of Emergency Medicine at the David Geffen School of Medicine at UCLA and Director of Medical Toxicology at the Olive View-UCLA Medical Center. E-mail: raisvohra@hotmail.com.
lush green trees and vines were everywhere outside of my bedroom window.

A local newspaper stated that the LTTE had set off a claymore mine on the northeast coast of the island, injuring soldiers and a British tourist couple. Tensions escalated, though the government was “committed” to continuing peace talks.

History
Sri Lanka (previously Ceylon), blessed with incredibly diverse natural beauty and year-round moderate climate, has welcomed visitors for many centuries. The Buddha visited three times; Sinbad the Sailor of the Arabian Nights visited twice, as chronicled in his 6th and 7th voyages; and Sir Arthur C Clarke, noted author and inventor, moved to “the Emerald Island” in 1956 and still lives there.

Environment
Colombo was still hot in April and the summer monsoon had officially begun; consequently the climate was both hot and humid, but I was having a wonderful time. The capital city is a coastal metropolis, which lives, works, and plays according to the rhythms of the sea, and breathes a daily sigh of relief at dusk. Life is hard for almost everyone, but they tried to be helpful despite language barriers. Although I had been warned about hustlers and thieves, everyone acted civil and followed the rules, except the rickshaw operators, who drove as if they were immortal. It was actually fun to haggle with them—I was forced to slowly learn the language that way—and I always offered to pay double if they would let me drive but no one accepted.

Hospital and Medical System
The overall medical system is as ambitious as it is under-resourced. The National Poisons Information Centre (NPIC) is based at the National Hospital of Sri Lanka (NHSL), the municipal hospital for the city and surrounding towns. It is the tertiary referral hospital for government-run hospitals on the island. Like the rest of the city, NHSL is overcrowded and disorganized, run almost entirely by interns and house officers. Somehow things get done with a logic and pace that I never totally decoded. The charts remain at the bedside; progress notes are handwritten on thin crepe paper; labs are recorded on slips the size of sticky notes tied onto the chart with yarn. All care and inpatient medications are free in the municipal (government-run) hospitals; patients pay for outpatient prescriptions, labs, and x-rays.

Because I arrived just after a holiday for Buddhists (New Year) and Christians (Easter) the poison center was not fully staffed: one doctor and one research officer on duty with an incredibly polite assistant who made really good chai tea.

Medical Practice
CT and MRI scanning is only done at private hospitals and is exceedingly uncommon. For ICU infection control measures, a sterile gown and “clean” flip-flops are required. The general medical and surgical floors are almost always full and crowded—in several wards I saw two patients sharing single beds. In a rural hospital, rubber gloves are
washed and dried for reuse. Patients are given their records, compressed into a single laminated page, to take with them at the time of discharge.

At the NPIC, we received five calls over two consecutive days. Many poisoned patients reside on the wards, unknown to the NPIC. The ward interns call only when they have a question, not to report a case. There is no central registry in the emergency room or triage room to track all admitted patients. To track poison patients, I had to inquire from ward to ward. The doctors and staff were usually cooperative, though unsure as to my reason for inquiring. Most poisoning incidents admitted to the National Hospital are from ingestion; snake bites are more common in rural-area hospitals.

Case Studies

The following eight cases are studies of common poisonings at the National Hospital, though unique experiences for me.

Case 1: Dapsone

In my first week, the NPIC received a call about a woman age 19 years. Three months earlier she had been diagnosed with the dermal variety of leprosy; she now had a few scars that looked like freckles. After an argument with her husband (women are shy about disclosing domestic problems) she ingested an overdose of her medications (exact dosage unknown). Relatives gave her a glass of coconut milk—a common home remedy—to induce emesis; it worked well. In the “Accident and Casualty Ward” (Emergency Department), she was given oral sodium bicarbonate to induce further emesis and finally activated charcoal, a common protocol.

The NPIC was called on the patient’s arrival to the floor, for advice about a medication called “MDT,” evidently an “antiepilepsy” drug. The poison center director explained that this was a congener for dapsone. We advised observing for delayed methemoglobinemia and hemolysis, but without a blood gas machine in that hospital, they couldn’t get cooximetry. Instead, they tested her for “methemoglobinuria” and for the telltale chocolate-colored blood when drawn. By the next morning the patient was asymptomatic, the CBC was within normal parameters, and the plan was for psychiatric review before discharge.

Case 2: Acetaminophen

After “fighting with her mother,” a woman age 19 years ingested 50 tablets of “Paracetol” three days before being admitted for dehydration. She presented with vomiting and drowsiness, and admitted to the overdose the next morning. Because drug levels are unavailable, acetaminophen overdose, which is becoming very common in Sri Lanka, is routinely managed symptomatically. Most patients can’t afford expensive liver function tests. Ironically, they are eligible to receive free IV n-acetylcysteine, although not all wards stock it. Treatment is started solely on the basis of history of ingesting greater than 150mg/kg. Physicians use a 24-hour continuous IV infusion protocol. This patient’s prothrombin time rose to 33 and transaminases to the 600s, and then normalized. Although abandoned decades ago in the west, many smaller hospitals still use methionine because NAC is considered too expensive. Methionine (2.5 grams q 4 hours x 4 doses) is an alternative sulfur-donating compound to help regenerate the glutathione molecules in hepatocytes.

Case 3: Paraquat

In an emotional fit, a bulldozer operator and part-time farmer, age 36 years, ingested 50 cc of the green-colored herbicide Gramoxone.
(paraquat)—or so he related to the admitting team along with relating a recent history of green vomiting. He was given 300 cc of 30% fuller’s earth, gastric lavage, and then activated charcoal. (Both fuller’s earth and bentonite are talc-like binding powders that can inactivate paraquat in the stomach). He was being observed for respiratory failure.

He looked fine; he was actually walking around. The house staff doubted the history of ingestion—he had no oropharyngeal lesions, a telltale sign of the corrosive paraquat. The only finding in his mouth was orange-stained teeth from his chronic betel nut habit. Paraquat can cause sudden collapse and respiratory failure during the first ten days, so without objective measures, the staff felt compelled to observe him. They didn’t obtain a chest radiograph given the absence of symptoms, and had no reagents for a urine test for paraquat. Oxygen saturation monitoring is available only in the ER and ICU, so he was treated with several doses of intravenous fluids and kept on a vegetarian diet “for renal protection.” Eventually he was discharged, asymptomatic. Our conclusion was that he was scaring his family with the threat of paraquat ingestion, or else he took far less than he said he did.

A true paraquat ingestion is tragic—patients develop oral burns and within days progress to Adult Respiratory Distress Syndrome (ARDS) and respiratory fibrosis. The manufacturer of paraquat has developed a testing kit to help doctors make a rapid diagnosis. Adding sodium bicarbonate and sodium dithionite powder to urine can establish the diagnosis. In the presence of paraquat, urine turns purple. I demonstrated this kit to myself by adding paraquat to “clean” urine and watched the color change to a deep turquoise. With diquat, a renal toxin used in herbicides in the US, the urine turns yellow-green with this test.

**Case 4: Phosphoric Acid**

A woman age 31 years with a past history of ingesting organophosphates ingested an unknown amount of phosphoric acid after an abusive attack by her alcoholic husband. Upon arrival at the hospital, she was treated with gastric lavage. Her initial labs showed: arterial blood gas: 7.23/pCO2 22/pO2 44/bicarb 9, sodium 157, K 4.2, BUN 23, creatinine 0.5. No calcium or phosphate levels were sent. Urinalysis showed only 1-2 pus cells. An x-ray showed bilateral interstitial markings, and she was diagnosed with ARDS. However, I was not convinced she didn’t vomit and aspirate acid, reflecting aspiration pneumonia. When I saw her five days later she was recovering and tolerating soft solids. Her medications included cefotaxime, ranitidine, metoclopramide, and steroids. Although she complained of throat pain, I saw no lesions. The plan was to endoscopy her as an outpatient in a few weeks. Phosphoric acid is an interesting ingestion because, in addition to the corrosive local injuries, it can also cause systemic hypocalcemia, hyperphosphatemia, and acidosis.

**Case 5: Cardiac Glycosides**

A young woman ate a part of a fruit from her garden and then (ruefully minimizing her intent) said she mistakenly ate two seeds of a fruit from one of her trees. Her family made her swallow coconut milk at home and she vomited. She also developed headache and fainting later that night. In the hospital she was treated with omeprazole, domperidone (an antiemetic) and fluids. Her heart rate drifted down over the first 12 hours of admission from the 70s into the 50s. Her electrolytes were normal per the house staff and no further treatment was rendered. NPIC was called because her pulse was still in the 60 to 70 range on day three and the house officer wanted to know the half life of this toxin.

I examined her partially consumed fruit, called Dia-Keneru or sea mango (*Cerebra manghas*). It contains cardiac glycosides similar to digoxin. She may have eaten parts of the peel although she insisted she picked out a couple of seeds and ate them. By the next afternoon, her heart rate was in the 100s and she was discharged. Patients in Sri Lanka must be monitored much longer than in a Western setting, where digibind can be given quickly to mitigate symptoms of toxicity.

In Sri Lanka, ingestion of yellow oleander (*Thevetia peruviana*) seeds is a very common method of self-poisoning, with fatalities reported with only four seeds, called “lucky nuts.” Poisoning is due to digoxin-like compounds, and characterized by vomiting, then bradycardia and other cardiac rhythm disturbances.

Much of the basic pharmacokinetic data for herbal and plant toxins has not been established. Because of the different varieties of plants, as well as unavailability of digibind due to cost, many physicians have extensive experience with the course and severity of cardiac glycoside poisonings. This is ironic, as many of the initial studies showing safety and efficacy of digibind were done in Sri Lanka with patients poisoned by yellow oleander. Researchers from the United Kingdom and Australia have continued to seek other, less costly treatments of yellow oleander poisoning here.
Case 6: Snakebite
A house officer told me that a man with a cobra bite died the day before I arrived. He was bitten on the hand, went into renal failure, and transferred from the ward to the ICU, but expired anyway. He was a “snake catcher.”

Snakebites are a major cause of morbidity and mortality in Sri Lanka, particularly in rural and agricultural regions. After a bite, patients bring in the killed snakes to help physicians choose the type of antivenom to administer. The most common type of snakebite is from the hump-nosed viper (Hyphnale hyphnale), for which there is no antivenom. Symptoms of bite initially include mild local edema, necrosis, and blister formation; eventually, a quarter of patients develops renal insufficiency. Sometimes a Russell’s viper or a cobra is brought in as evidence of a recent encounter.

Case 7: Arecholine
The areca nut (Areca catechu), usually called betel nut because it is wrapped in leaves of the Piper betel, is found on street-corner carts all over South Asia. It is mixed with spices, fennel, candy pieces, wrapped, and painted with a chalky paste of calcium carbonate; the slightly basic chalk accelerates the release of plant alkaloids. The most potent compound in betel nut is arecoline, which resembles acetylcholine and works on nicotinic and muscarinic receptors.

One night I ate several betel nuts and got mydriatic, flushed and slightly buzzed. Unfortunately, it was drizzling and after dark and I got a little lost, wandering into a Buddhist shrine/temple—there is one on almost every other street corner—which was empty except for a few stray cats. I met a man performing his nightly prayers who warned about the drug addicts that haunt these temples at night. I fearfully walked back to my guesthouse.

Case 8: Cyanide
As they were trying to plant a claymore mine in the northeast part of the country, two Tamil Tigers, members of the LTTE, were caught by the military. Each of them immediately tried to swallow a capsule of cyanide. One of them was prevented from swallowing the capsule and he survived. The other became ill and was taken to a peripheral hospital where they specifically treated him for cyanide poisoning with hydroxy-cobalamin without much effect. Twenty-four hours later, he was transferred to the NHSL in Colombo. I was out of town, chasing snakebite cases in the small hospitals of the beautiful hilly countryside in the center of the island.

Meanwhile, a female suicide bomber, also a member of the LTTE, targeted a military hospital and base in the capitol. The woman detonated herself near an army jeep. She was standing at a speed bump to ensure that the vehicle would be moving slowly. Her target was an officer in the army, but she was successful in only sending him to the OR for a hemicolectomy, not to the morgue. He was a top-ranking army commander in Sri Lanka. The bomber had claimed to be pregnant, bypassing security by making an obstetric appointment at the army hospital.

I didn’t even know about these developments until the next morning when I returned to the hospital. With both the army commander and one of the Tigers there, the hospital was a very tense place, and the city even more so. The terrorist who ingested cyanide was admitted to the intensive care unit, then intubated after losing consciousness, although he never had acidosis on blood gas. They didn’t check a lactate level, which can be used as a surrogate marker for severe cyanide toxicity. He was given thiosulfate (one dose of 25 mL from the antidote kit) but he remained hypotensive. He was even given a dose of cobalt EDTA at the recommendation of the toxicology attending physician. In the
1970s, studies conducted on sheep suggested that, like hydroxocobalamin, this compound can bind and inactivate cyanide, but the side effects are poorly tolerated and thus should only be used as a last resort. The thiosulfate was never redosed. He was arrested and died early the morning after I returned.

After these attacks, much of the city hastily converted into a military-occupied police state. To be honest, at this point I was truly scared. The government had positioned armed police and soldiers everywhere but they weren’t much solace standing there, because anyone with a grim determination could still plow through their barricades with a car bomb. It was astonishing that hundreds of people still milled about in front of the hospital every morning, which I suppose is a testament to the average Sri Lankan’s humanity and pacifism. Everyone was apprehensive, especially because they knew how much worse it can get when half the city is road-blocked and there are curfews, and people are picked up for interrogation every day. The military was starting to launch air strikes against some LTTE camps in the northeast part of the island, but as with all air strikes, there would be collateral damage, which could provide further motivations for the rebels to continue their aggression.

Before I left Sri Lanka two fretful weeks later, I noted many aphorisms posted in public places in reference to civil war, signs that, in retrospect, have an added poignancy as the prospects for a significant ceasefire have grown even more dim.

Reflection

In his essay The Myth of Sisyphus, the Algerian-French author Albert Camus said, “There is but one truly serious philosophical problem, and that is suicide.” In the course of my rotation, I often wondered why there was such a high rate of suicide in Sri Lanka. When I asked people I met, they cited many factors: poverty, civil war, and easy accessibility of toxic substances in a poorly regulated agricultural economy. There also seems to be a cultural tendency towards self-harm that defies ethnic or class barriers. Other countries have these issues, and yet in Sri Lanka overdose is much more common.

I was riding a bus to the hospital one day and saw graffiti on a fenced school courtyard along a sidewalk—“Life Sucks!” In the US, I wouldn’t have given it a second thought, but here it unnerved me, particularly since it seemed to shout out the answer to the “philosophical problem” that Camus defined. The graffiti writer’s despair, eagerly vented in an absurd and loud scrawl along a noisy street, is touching. It bespeaks the despair of a whole segment of society.

Perhaps I have been asking the wrong question. Perhaps instead of asking why there is such a relatively high rate of overdose in Sri Lanka, I should ask its converse: What is it that makes people under the same immensely stressful circumstances NOT resort to self-destructive behaviors? What can we as caregivers learn from their resilience, and how can that strength of resolve be shared with others in the community? What is the antidote to despair?

Acknowledgments

I would like to express my sincere gratitude to Dr. Ravindra Fernando and the staff of the National Poisons Information Centre in Colombo, Sri Lanka, for their kindness and hospitality; to the many doctors and patients I was able to meet in Sri Lanka; and to Dr. Richard Clark of the California Poison Control System, San Diego.

Reference

Sharon Higgins, MD, is the Executive Medical Director for Northwest Permanente. Dr Higgins enjoys travel and documents her experiences through photography and journals. This photo was taken while on safari in the Serengeti using digital equipment.

Another of Dr Higgins’s photographs may be seen on page 70.
Tachycardia-Induced Heart Failure

By Jitenbhai J Patel, MD
Charles T Whittaker, MD

Abstract
Heart failure associated with tachyarrhythmias can very often be reversed by dealing with the underlying tachyarrhythmia. Typically characterized by left ventricular dilation and subsequent systolic dysfunction, this disorder can be caused by both atrial and ventricular arrhythmias, most commonly chronic atrial fibrillation. Whereas for most cardiomyopathies there is little that can be done to reverse the progression of the disease, in tachycardia-induced heart failure the patient’s often debilitating symptoms can be ameliorated. This is particularly important in the primary care setting because tachyarrhythmias, particularly atrial fibrillation, are commonly encountered. The alert physician will be able to diagnose and treat tachyarrhythmias, which can result in improvement of systolic function within weeks and often normalization within several months.

Introduction
Congestive heart failure (HF) affects close to five million patients in the United States, with coronary artery disease being the leading etiology, accounting for 70% of HF cases. This often debilitating disease is typically progressive unless a reversible etiology can be identified. Among the reversible causes, tachycardia-induced heart failure (TIHF) provides a unique opportunity in the primary care setting for intervention to halt and possibly reverse HF in affected patients. The incidence of TIHF is largely unknown; however, studies involving patients with atrial fibrillation (AF) show that up to 50% of patients with AF and left ventricular dysfunction have some degree of TIHF. This disorder can occur at any age, from the fetal period to old age. From innovative techniques such as intrauterine cardioversion to simply controlling a patient’s heart rate with traditional medications, reversal of this form of HF can provide a gratifying experience for both the patient and practitioner in an otherwise progressive condition. The following case report illustrates the importance of recognizing TIHF and reviews the pathophysiologic, diagnostic, and treatment considerations of this disorder.

Case Example
A man, age 53 years, with a medical history of morbid obesity presented to the Emergency Department complaining of shortness of breath. This symptom was new and had started approximately one week before presentation. The shortness of breath was worsened by walking and decreased with rest. He noted that he had had two-pillow orthopnea for the past week. On examination, the patient had an irregular pulse of 120 beats per minute with no murmur. Lung examination findings were normal, and there was no peripheral edema. Troponin I levels were elevated but indeterminate, both initially and when serially repeated. An electrocardiogram was obtained and revealed AF with a ventricular rate of 150 beats per minute. The patient’s chest radiograph showed slight cardiomegaly. His heart rate was controlled with carvedilol (Coreg).

An echocardiogram showed four-chamber enlargement, global hypokinesis, and an estimated ejection fraction of 15%. Cardiac catheterization showed a 90% stenosis in the first obtuse marginal coronary artery, which was dilated with stent deployment. Severe hypokinesis was again observed during catheterization, with an ejection fraction of 20%. A cardiology consultant suggested that the patient’s cardiomyopathy was out of proportion to his degree of coronary artery disease and that his tachyarrhythmia was a likely major contributor.

After six months of controlled heart rate anticoagulation, an echocardiogram showed an improvement in ejection fraction from 20% to 60%. The patient subsequently had successful radiofrequency ablation treatment for his AF and his improvement continued until this report.

Discussion
Pathophysiology
Several tachyarrhythmias have been associated with the deve-
Tachycardia-Induced Heart Failure

opment of HF, including AF, atrial flutter, automatic atrial tachycardia, atrioventricular nodal reentry tachycardia, automatic atrioventricular junctional tachycardia, and ventricular tachycardias. Although ventricular tachyarrhythmias cause a more severe depression in left ventricular function, more common are the supraventricular variety, specifically AF. The hemodynamic changes that occur include ventricular systolic dysfunction, decreased cardiac output, increased ventricular filling pressures, and increased vascular resistance. Perhaps the most convincing evidence relating tachyarrhythmias to HF comes from animal studies in which HF was induced secondary to rapid pacing. After one day, a decrease in cardiac output was observed and the decrease continued to decline for up to five weeks. Prompt cessation of pacing then resulted in improvement of left ventricular function as soon as 24 hours after termination and a subsequent return to normal within weeks.

The pathophysiologic changes that lead to the development of HF in patients who have a tachyarrhythmia are not clearly understood. Furthermore, it is not clear whether the structural cardiac changes observed in cardiomyopathy are the result of the tachyarrhythmia or if the tachycardia is due to the changes seen in cardiomyopathy. Nonetheless, a number of mechanisms have been proposed that seek to explain why tachycardia leads to left ventricular dysfunction: myocardial energy depletion, abnormal calcium handling, myocardial ischemia, and extracellular matrix remodeling.

The means by which myocardial energy stores were exhausted, leading to decreased levels of high-energy phosphates, including adenosine triphosphate and creatine. Mitochondrial structural and functional defects were also observed.

Additionally, it has been postulated that abnormal calcium handling may be an underlying mechanism by which tachycardia induces cardiomyopathy. Calcium channel activity as well as calcium transport in the sarcoplasmic reticulum have been found to be considerably abnormal in myocytes after pacing. These changes occur soon after tachycardia is induced and may remain for up to four weeks after cessation of pacing. Exactly how calcium abnormalities lead to left ventricular dysfunction, however, is not clear.

It has also been proposed that chronic rapid heart rates may result in ischemia, which can lead to some form of reversible ventricular dysfunction. This claim is supported by observations that there are abnormal subendocardial and subepicardial blood flow ratios in addition to impaired coronary flow reserve. This damage likely leads not to cell death but rather to myocardial shock or stunning, which is reversible.

The final mechanism often related to the development of THF is that of extracellular matrix remodeling. In paced animals, cellular changes are noted, including loss of myocytes, contractile dysfunction, myofibril misalignment, and abnormalities in the attachment of myocytes to the basement membrane. The changes can affect overall contractility, leading to the observed cardiomyopathy.

Diagnosis

Perhaps the most important factor in regard to the diagnosis of TIHF is a high index of suspicion. Because evidence of gradually worsening ventricular function in the setting of chronic tachycardia is not often apparent clinically, awareness of this reversible condition is vital. Evaluation may be done noninvasively using imaging modalities such as echocardiography or multiple gated acquisition scan, which demonstrate systolic dysfunction and left and right ventricular dilation.

Prognosis

Although actual recovery of ventricular function can vary, it is clear that control of tachycardia can produce some, if not complete, reversal of cardiomyopathy in most patients. Reports on the recovery time of ventricular function differ, but the most improvement can be seen within the first several weeks, with continued slow improvement for up to six months. This will vary depending on the duration of the tachycardia and if other forms of heart disease are present.

Management

It is clear that controlling tachyarrhythmia can reverse TIHF, at least partially. However, case management will vary according to the particular tachyarrhythmia and so is outside the scope of this case report. Of interest, however, is AF as the underlying cause of TIHF, because it both has been well studied and is the most common cause. It has been shown that patients with HF whose AF is controlled experience an overall lower mortality, but whether this is because of rate control or rhythm control is not as clear. Several studies attempting to discern which is superior, rate control or rhythm control, have shown that either one is acceptable.
If initial attempts at drug therapy fail, atrioventricular node ablation with pacemaker implantation is an effective alternative.14

**Summary**

Perhaps the most relevant aspect of TIHF to primary care practice is that control of tachycardia can improve or completely resolve a patient’s cardiomyopathy. For a disease in which most only have hopes of delaying progression and limiting symptoms, the idea that a cure, or even a modest improvement in quality of life is available, makes early detection a critical task for primary care providers because they are in a setting where early detection is more likely. With a high index of suspicion, diagnosis followed by heart rate control can provide marked improvement in systolic function in as little as one month. 

**Acknowledgment**

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

**References**


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**An Occasional Heart Attack**

As for me, except for an occasional heart attack, I feel as young as I ever did.

— Robert Benchley, 1889-1945, American humorist and actor
Prevalence

The prevalence of signs and symptoms in patients presenting to Emergency Departments is in large part related to the relative distribution of mast cells in the body: skin > respiratory tract > gut. In one representative report, >90% of patients had flushing and/or hives but 5% to 10% did not. Respiratory symptoms occurred in 40%, gastrointestinal symptoms in 30%, and shock occurred in about 10% of those patients presenting to Emergency Departments with anaphylactic reactions. Generally, the more rapid the onset of symptoms after exposure to the offending agent, the more severe the reaction.

Scope

Data on the prevalence of the risk of anaphylaxis are limited. Calculations based on reported reactions in the United States range from approximately 3 million to 41 million individuals who have had a serious allergic reaction in their lifetime. Eleven million have experienced a life-threatening reaction. Each year in the United States, 800 people have fatal anaphylactic reactions. This number may be an underestimate, because some cases of unexplained death or shock may in fact be due to anaphylaxis. Some patients do not present with the more obvious signs such as hives or respiratory distress, so their condition may go unrecognized and treatment may be delayed.

This review presents a working definition of anaphylaxis (See sidebar: A Working Definition of Anaphylaxis) and summarizes leading causes, emergency treatment, and prevention. Resources for clinicians and patients are listed at the end of the review.

Calculations based on reported reactions in the United States range from approximately 3 million to 41 million individuals who have had a serious allergic reaction in their lifetime.

Report of a Case

A nurse, age 32 years, with a history of hives, angioedema of the lips and eyelids, and stridor after eating an avocado, eats a plum and within minutes experiences similar symptoms. Her condition partially responds to initial treatment with a fast-acting antihistamine and an injection of epinephrine, yet she experiences a second wave of symptoms as well as hypotension while being transported to the Emergency Department by paramedics.

This nurse has latex sensitivity that developed after several years of repeated exposure to latex gloves. She had subsequently developed a cross-sensitivity to foods associated with latex allergy, namely avocados and stone fruits (pitted) such as plums. Her anaphylaxis was compounded by the use of latex gloves and equipment during the paramedic transport. (Note: Currently the chances of this happening are low because the use of natural-rubber latex has been significantly reduced in the medical environment. However, previously sensitized health care workers need to be cautious.)

Table 1. Nonimmunoglobulin E causes of anaphylaxis (anaphylactoid reactions)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Mechanism</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonimmunoglobulin E immunologic</td>
<td>Complement activation</td>
<td>Cobra venom reaction, dextran, intravenous immunoglobulin</td>
</tr>
<tr>
<td></td>
<td>Anaphylatoxin, intravenous aggregates</td>
<td></td>
</tr>
<tr>
<td>Nonimmunologic</td>
<td>Direct activation of mast cells (secretagogues)</td>
<td>Opiates</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ionic contrast media: It is a misconception that this reaction is due to iodine allergy</td>
</tr>
<tr>
<td>Sensitivity to nonsteroidal anti-inflammatory drugs</td>
<td>Pharmacologic inhibition of cyclooxygenase, leading to increased generation of lipoxygenase products</td>
<td>ASA, ibuprofen, Toradol</td>
</tr>
</tbody>
</table>

Michael S Kaplan, MD, is the Chief of Allergy Service and Allergy Program Director at the Los Angeles Medical Center; and Clinical Professor of Pediatrics and Allergy at UCLA in California. E-mail: michael.s.kaplan@kp.org.
Mechanisms and the Most Common Causes of Anaphylaxis in the US

- IgE-mediated:
  - Foods
  - Medications
  - Insect venoms
- Non-IgE-mediated (Table 1):
  - Acetylsalicylic acid/nonsteroidal anti-inflammatory drugs
  - Ionic contrast media.

Management of Anaphylactic Reactions
Office Management
Rapid initiation of treatment can be critical. Follow these steps to treat anaphylactic reactions in the office (Table 2):

1. Assess the ABCs (airway patency, breathing effort, and circulation) and mentation.
2. Administer epinephrine intramuscularly by auto-injector (eg, EpiPen, Twinject) for serious or potentially serious reactions.
3. Administer a fast-acting antihistamine. Add an H2-blocker, pending the reaction's course. Antihistamines relieve the acute effects of itch, flushing, and perhaps some angioedema. They are not effective for hypotension. H2-blockers may help ameliorate the cardiovascular effects of histamine release from mast cells surrounding the coronary arteries.
4. Administer albuterol for bronchospasm.
5. Administer oxygen at 6 to 8 L/minute.

A Working Definition of Anaphylaxis

Anaphylaxis can be defined as follows:

1. An acute, severe, or life-threatening systemic reaction caused by the release of mediators from mast cells or basophils
2. Most commonly—but not exclusively—mediated by immunoglobulin E (IgE)
3. Possibly mediated by non-IgE immune reactions or nonimmunologic direct release of mediators (anaphylactoid reaction)
4. Most often occurs within minutes of exposure to an allergy-causing agent
5. A condition that should be suspected in patients presenting with any of the following signs and symptoms; a patient may have some, all, or none in any particular category:
   - Skin: Flushing, urticaria with itching. In severe reactions, skin manifestations may be delayed while cardiovascular collapse is occurring. Angioedema may be present. Increased vascular permeability can allow the transfer of up to 50% of the intravascular volume into the extravascular space within ten minutes in extreme cases.
   - Gastrointestinal: Unexplained nausea, vomiting, diarrhea, abdominal cramps
   - Respiratory: Stridor, dyspnea, asphyxiation, or asthma symptoms; reduced peak expiratory flow rate
   - Circulatory: Unexplained hypotension or collapse. Rarely, this can occur without skin manifestations.
   - Systemic: A sense of impending doom. This is a valuable sign for impending shock. If asked how they feel, these patients think that they are going to die and often say, “I don’t feel right.”
6. Highly likely when the first of the three following criteria plus at least one of the other criteria are filled:
   - Acute-onset illness (minutes to several hours) with involvement of the skin, mucosal tissue, or both, as noted above, plus at least one of the following:
     - Respiratory compromise
     - Reduced blood pressure or weakness or syncope
   - Two or more of the following after exposure to a likely allergen for the patient:
     - Skin and/or mucosal tissue involvement
     - Respiratory compromise
     - Reduced blood pressure or weakness or syncope
     - Persistent gastrointestinal symptoms
   - Reduced blood pressure after exposure to a known allergen for the patient:
     - Infants and children: Systolic blood pressure <70 mm Hg if one month to one year old; <70 mm Hg + (2 × age) or >30% decrease in systolic blood pressure if one to ten years old
     - Adolescents and adults: Systolic blood pressure <90 mm Hg or >30% decrease from usual baseline
7. Can be confirmed by an elevated serum tryptase level:
   - Specific for mast cell–mediator release
   - Can remain elevated for three to six hours after the onset of symptoms, unlike plasma histamine, which is evanescent
   - May not be elevated in many cases of food-related anaphylaxis
Patients with a history of anaphylaxis who are undergoing procedures that carry a high risk for an anaphylactic reaction should be pretreated. The suggestions that follow are based on the severity of the acute reaction and the patient’s past history.

These are definite indications:
- Rapidly evolving hives and angioedema even in the absence of hypotension or respiratory distress
- Hypotension
- Expression by the patient of a sense of impending doom. In this circumstance, most patients tend to say the same thing, as if they were reading from a script: “Something isn’t right” or “I don’t feel right.”
- Angioedema in the throat manifested by altered speech quality, drooling, or difficulty swallowing
- Respiratory distress

These are probable indications:
- Generalized hives
- Any signs or symptoms of anaphylaxis in a patient with a prior history of severe allergic reaction or anaphylactic shock
- Multiple bites or stings from an insect known to have caused an allergic reaction in the past.

**Precautions**

Patients should be observed for an appropriate period of time before discharge from medical observation. These are some of the reasons to observe patients for an extended period:
- Prolonged severe reaction or signs and symptoms refractory to initial treatment
- Rapid recurrence of signs and symptoms after initial response to treatment
- Presentation with uncontrolled asthma
- Inadequate supervision or monitoring of patient at home, as with an elderly person living alone
- Patient who lives too far from access to emergency services
- Significant comorbidities.

### Table 2. Equipment and medications for office management of anaphylaxis

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure monitor</td>
<td>Epinephrine (Adrenalin)</td>
</tr>
<tr>
<td>Intravenous supplies for fluid support</td>
<td>Fast-acting H&lt;sub&gt;1&lt;/sub&gt; and H&lt;sub&gt;2&lt;/sub&gt; antihistamine (oral and parenteral)</td>
</tr>
<tr>
<td>Oral airway and endotracheal tubes</td>
<td>Vasopressor agents</td>
</tr>
<tr>
<td>Oxygen, tubing, and mask</td>
<td>Solu-Medrol</td>
</tr>
<tr>
<td></td>
<td>Colloid or crystalloid intravenous fluids</td>
</tr>
<tr>
<td></td>
<td>Glucagon</td>
</tr>
<tr>
<td></td>
<td>Albuterol</td>
</tr>
</tbody>
</table>

### When to Administer Epinephrine

There are no universally accepted guidelines as to the minimal reaction that requires epinephrine administration. The suggestions that follow are based on the severity of the acute reaction and the patient’s past history.

#### When to Administer Epinephrine

1. For hypotension, place the patient in the recumbent position and elevate his or her legs.
2. Infuse normal saline or colloid volume expanders for shock or hypotension.
3. Use glucagon or dopamine for refractory hypotension.
4. Be aware that although systemic corticosteroids may decrease the intensity of late-phase or biphasic reactions and asthma symptoms, there is no evidence that they are effective for anaphylactic shock in humans.

#### Pretreatment in High-Risk Procedures

Patients with a history of anaphylaxis who are undergoing procedures that carry a high risk for an anaphylactic reaction should be pretreated. Asthma should be stabilized with systemic corticosteroids and bronchodilators. The following represents recommended pretreatment of older children and adults before the use of ionic contrast media. (See Table 3 for pediatric doses.)

- Prednisone, 20 to 50 mg orally, 13 hours, 7 hours, and 1 hour prior to the procedure
- Diphenhydramine, 50 mg, 1 hour prior
- Orally: cimetidine, 300 mg, or ranitidine, 150 mg, 13 hours and 1 hour prior.

#### Follow-Up Care

Patients with a history of anaphylaxis who are undergoing procedures that carry a high risk for an anaphylactic reaction should be pretreated.

Patients should continue treatment at home with antihistamine until the reaction has subsided. Oral corticosteroids may prevent or decrease the effects of an ongoing or recurrent reaction. Patients should be discharged with enough injectable epinephrine for two emergency doses and should be able to demonstrate knowledge of how and when to use the auto-injector.

In a review of 676 Emergency Department charts of patients treated for anaphylaxis, only 16% of patients were discharged with epinephrine injectors and only 12% were referred to an allergy specialist.

Patients should be referred to an allergy specialist if they have had a severe reaction without an obvious or previously defined trigger; have a reaction that is thought to be due to a food, drug, insect sting, or exercise; or have a reaction that is food-dependent and exercise-induced.

The patient, the patient’s family, and the primary care clinicians referring the patient should expect the allergy specialist to determine whether an anaphylactic event
Patients should be discharged with enough injectable epinephrine for two emergency doses and should be able to demonstrate knowledge of how and when to use the auto-injector.

Table 3. Medication doses

<table>
<thead>
<tr>
<th>Drug</th>
<th>Adults</th>
<th>Children</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine</td>
<td>25–50 mg</td>
<td>1 mg/kg, ≤50 mg</td>
</tr>
<tr>
<td>Oral, IM, or IV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ranitidine</td>
<td>1 mg/kg</td>
<td>12.5–50 mg, ≤150 mg</td>
</tr>
<tr>
<td>IV over 10–15 minutes</td>
<td>150–300 mg</td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cimetidine</td>
<td>4 mg/kg</td>
<td>No established dose</td>
</tr>
<tr>
<td>IV slow drip</td>
<td>300–400 mg</td>
<td>No established dose</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epinephrine 1:1000</td>
<td>0.2–0.5 mL</td>
<td>May be repeated in 5–10 minutes if needed</td>
</tr>
<tr>
<td>IM or subcutaneous*</td>
<td>May be administered via EpiPen</td>
<td></td>
</tr>
<tr>
<td>Refractory hypotension IV dopamine</td>
<td>2–20 μg/kg/min or 0.025–0.25 mL/kg/min</td>
<td></td>
</tr>
<tr>
<td>400 mg in 500 mL of NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucagon</td>
<td>1–5 mg IV over 5 minutes by continuous IV, 5–15 μg/min</td>
<td>20–30 μg/kg; maximum 1 mg</td>
</tr>
</tbody>
</table>

*In a study of healthy children who were not experiencing shock, IM epinephrine given in the upper, outer thigh achieved higher and more rapid peak blood levels than did the same dose given subcutaneously or at other peripheral sites.

IM = intramuscular; IV = intravenous; NS = normal saline.

Anaphylaxis occurred; determine rule out causes of the reaction; determine whether other medications in the patient’s regimen might be aggravating or interfering with treatment of the episodes, and suggest alternatives; educate the patient about how to avoid triggers; educate the patient and the patient’s family about how to recognize the symptoms of an allergic reaction; create a written emergency plan for the patient and for other caretakers; and reinforce how and when to use epinephrine for emergency purposes.

Happy Ending

Fortunately for the nurse who had prolonged and recurrent anaphylaxis after eating a plum, the outcome wasn’t the pits. An astute emergency medicine specialist recognized the association of latex sensitivity to stone-fruit anaphylaxis and promptly ordered the use of nonlatex materials for the care of this patient in the emergency department. Her condition responded to volume expansion, additional epinephrine, H₁ and H₂ antihistamines, and corticosteroids. Her condition stabilized after an hour in the Emergency Department, and she was discharged after overnight observation. Before discharge, she was instructed in the use of an EpiPen. A consult with an allergist confirmed her sensitivities. The allergist reinforced her knowledge of EpiPen use and provided information on avoidance of latex products and potential cross-reacting foods. ✤

Acknowledgment

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

References


Resources

www.foodallergy.org
www.aaaai.org
www.acaai.org
www.medicalert.org (1-800-432-537)
“You Gotta Be Crazy!”
Tales of My Practice in Rural Maine

By Ronald Blum, MD

I was raised in an eastern Pennsylvania city of 100,000, in a nuclear family, my parents honoring their marriage vows 'til death did them part. I had a typical conventional education—public school, liberal arts college, then medical school in "the big city"—Philadelphia. In the days before family medicine had declared itself a specialty, I emulated my family doctor—who also graduated from my alma mater, Jefferson Medical College—and strove to prepare myself for general practice and community service. I chose pediatrics for my internship, with plans for a year of internal medicine and perhaps surgery, as well. I soon learned that kids weren't just little adults, but adults were really just big kids, at least for the most part, and stayed in pediatrics for the full three years. My residency in the Bronx (an even bigger city) enabled me to take two months of electives each year in adult medicine disciplines, so I felt reasonably prepared for independent primary care practice when the time came. But I couldn't have predicted the location.

Northern Maine

“What do you mean you want to practice in northern Maine?” was my father's reaction to the plan. “You gotta be crazy!”—he had hoped I would open an office in our Pennsylvania city. In the days before family medicine had declared itself a specialty, I emulated my family doctor—who also graduated from my alma mater, Jefferson Medical College—and strove to prepare myself for general practice and community service. I chose pediatrics for my internship, with plans for a year of internal medicine and perhaps surgery, as well. I soon learned that kids weren't just little adults, but adults were really just big kids, at least for the most part, and stayed in pediatrics for the full three years. My residency in the Bronx (an even bigger city) enabled me to take two months of electives each year in adult medicine disciplines, so I felt reasonably prepared for independent primary care practice when the time came. But I couldn't have predicted the location.

Several months ago, back in “moose country,” I met Ronald Blum, MD, a big city doctor practicing in a tiny and obscure town in rural Maine. His professional life was so different from the typical large US city practice that I thought he had a tale worth telling and even suspect that some of us might be a bit envious.

— Vincent J Felitti, MD, Senior Editor

Medicine Around The World

It is easy to believe that what we do and believe medically in the US must generally be the way medicine is viewed and practiced all over the world. In our efforts to understand the diversity of the practice of medicine around the world, we continue to explore the experiences of physicians around the world as they describe their medical practices, that we all may better understand the wide range of what we do.

Several months ago, back in “moose country,” I met Ronald Blum, MD, a big city doctor practicing in a tiny and obscure town in rural Maine. His professional life was so different from the typical large US city practice that I thought he had a tale worth telling and even suspect that some of us might be a bit envious.

— Vincent J Felitti, MD, Senior Editor
wound with saline and Betadine and applied a sterile dressing to hold him until he could get to a real surgeon. Thus began my first "woods lesson." There was no way he was about to drive the 35 miles to the nearest hospital for surgical treatment. "You can treat it best you can doc, or I'll get by on my own." And he clearly meant it. Well, medicine had not yet become so liability conscious, and I was, after all, in a small village in northern Maine, where legal consequences were a distant concern. With renewed determination, I re-examined the wound. Tendons, though exposed, were intact. No significant injury to vessels or nerves was apparent, and all finger functions were preserved. So after generous local infiltration anesthesia, I carefully debrided devitalized tissue and wood chips, and scrubbed out soil and oil, and flushed, and flushed again. I then carefully sutured what viable fragments of epidermis I could capture, generously covered the wound with nonadherent dressing and hoped for the best. Needless to say, none of my New York City experience had specifically trained me for this. When he was too busy in his store to come in for my required daily wound checks and dressing changes, I called on him. The wound healed. It never got infected. The absence of nearby specialists approached in an urban practice. "You can treat it best you can doc, or I'll get by on my own." The Permanente Journal/Summer 2007/Volume 11 No. 3

"You Gotta Be Crazy!" Tales of My Practice in Rural Maine

My Own Private Practice

My practice has been busy, stimulating, and gratifying. For most of my years here the only other providers serving the area’s 5000-6000 residents were staff at the still-operating Rural Health Center, which sits on the opposite corner of the block from my office. Although they get cost-based reimbursement from Medicare—currently about $108 per visit—I get less than $30 for the same code. Being a rural provider has allowed me to practice an incredible breadth of medicine, an experience not even approached in an urban practice. The absence of nearby specialists (the nearest tertiary care hospital is 100 miles away) has allowed me to be involved in all aspects of my patient’s care. This location has afforded me the opportunity to forge close relationships with the other physicians and provided unending learning opportunities. I have administered IV chemotherapy protocols weekly, every two weeks, or as needed, in my office, to patients who visited the oncologist only quarterly. I have performed a wide range of outpatient surgeries in my office, including trauma repairs, biopsies, vasectomies, and even an inguinal herniorrhaphy under local anesthesia. I’ve ridden ambulances, resuscitated newborns, attended the local Amish community at their farms, set fractures, and grieved with family members when resuscitation failed. I’ve completed surgery by flashlight when we lost electric power (a more frequent occurrence earlier in my career); I’ve fabricated custom splints so farmers can continue their harvest in spite of an injury. I attended patients in the local nursing home and mentally and physically handicapped adults in the group home. I serve as a Medical Examiner (coroner) for the area, school doctor, and as a public health officer. In all these roles, I never have hesitated to seek advice from colleagues, and only rarely have been refused assistance.

Professional and Family

My opportunity for professional advancement has not been limited. I’ve served as preceptor at the Family Medicine Residency Program, as well as to students in my office. I’ve been involved with a variety of specialty organizations, serving in local, state and national positions. I became a Fellow in the American Medical Association at the age of 30, and have held other leadership positions in local, state and national organizations. I’ve been involved with a variety of specialty organizations, serving in local, state and national positions.

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Academy of Family Physicians (AAFP). I have had opportunities to teach in those venues and interact with some of our nation’s leading physicians. I served as president of our hospital medical staff and of the Maine Academy of Family Physicians, as advisor to the American Hospital Association, and on the Board of the New England College of Occupational and Environmental Medicine. I am one of Maine’s two delegates to the AAFP and Vice-Chair of the Work Fitness and Disability Section of the American College of Occupational and Environmental Medicine (ACOEM).

Meanwhile, back at the homestead, my wife and I raised four great kids—children, that is—along with some kids, chickens, turkeys, rabbits, and an occasional sheep. Although it was a concern at first, I can say assuredly their education did not suffer for being raised in the country and attending a small school. If anything the advantages outweighed the compromises. The eldest have attended prestigious colleges and university and are well set to succeed in life. Our youngest are still at home, so we continue to watch soccer and basketball games and help prepare for proms and parties. I’ve pursued my interests in gardening, camping, fishing, canoeing, sailing, and photography, served as a scoutmaster, and been active in our congregation’s religious life.

**The Business Side**

No, I don’t think I was crazy for settling here, although separation from our families in Pennsylvania over the years has presented some hardship. If there is a negative, I’ve alluded to it above—the business side. When I went into practice with “Ol’ Doc Daniels” in 1978, we decided to raise his standard office call fee (we now call it a 99213) to $7, more than double what he charged when he started practice. Office care was busy, and we supplemented that income with service at the hospital, nursing home, school, and local industry.

Over the years rates (and expenses) have increased exponentially, but the payor shift and practice climate has changed dramatically. As economic changes have brought closures in area farms and pulp, paper, and lumber mills (our major local industries), there are fewer working-age families with indemnity insurance or Worker’s Compensation coverage. Many of my current patients are enrolled in Medicare and Medicaid, which in the current political structure are no longer profitable, usually representing a financial loss. Another shift in care delivery is the employment by the hospital of almost all the nearby physicians. Their hours and responsibilities no longer dictated by practice demands, they are not particularly interested in sharing patient care or covering my patients in my absence. However, those practicing hospitalist care are perfectly willing to accept my patients for admission. Thus I reluctantly relinquished inpatient care, sacrificing the patient’s continuity of care and satisfaction for the political reality of modern medicine, and sacrificing an income source, as well.

My financial stability has been the result of alternative practice pursuits. While others of my colleagues (no, I am not alone in this lifestyle choice) have supplemented their practices working in the Emergency Room or teaching, my niche has been Occupational Medicine. Working part-time over the years with several local employers, in some cases on site, I have developed expertise and a reputation in this relatively unpopulated specialty, providing an unusual service for a rural area. Income is not filtered through third parties, and as an independent contractor I can maintain professional and ethical independence. Supplemental education has allowed me to become a Fellow in ACOEM, an independent examiner for insurers and lawyers seeking objective assessments, and part-time Medical Director for a large area employer with multiple plant sites.

**Sincere Service**

My varied interests and flexibility have served me well in this unique and welcoming setting. I get a lot of satisfaction (and occasional garden products or moose meat) from my patients, some of whom I’ve cared for their entire lives and are now returning with their new families. Most local folks carry on multiple tasks to survive—one or two jobs, cut firewood, garden and hunt to supplement the larder, yard sale, perhaps sell some arts or crafts, all in order to continue this clean lifestyle in a beautiful environment. Well, my practice is not much different. My life is full, my service sincere, my main regret is that the government rural health programs should be complementary and cooperative, rather than competitive and adversarial. But I have maintained a medical practice with honesty and integrity, without depending disproportionately on taxpayers, and demonstrate by example the plausibility of rural private practice. Nah, I’m not crazy.
“Laukahi Street”

oil on canvas, 21”x17”

By Douglas Davenport, MD

“Laukahi Street” was painted from a field where Dr Davenport’s children played soccer. He was inspired by the colors and patterns of the neighborhood that looked out over the field.

Dr Davenport is an emergency medicine physician at the Moanalua Medical Center in Hawaii.

Another of Dr Davenport’s paintings may be seen on the cover.
Sidney Garfield, MD, the physician co-founder of Kaiser Permanente (KP) and father of Permanente Medicine, is often hailed as a great visionary and innovator in American medicine. He was the man who joined prepayment to multispecialty group practice and articulated the principles of a new and revolutionary model of health care financing and delivery. But as revealed in his remarks to a group of Permanente physicians (see: Advice to Permanente Physicians from Dr Sidney Garfield, page 60), Dr Garfield’s genius was not limited to grand-scale ideas. He also understood a great deal about the everyday, real-world workings of organizations, partnerships, and power—lessons that are as relevant today as they were 33 years ago and lessons that strongly informed the creation of The Permanente Federation, which observes its tenth anniversary this year.

The unique organization that Dr Garfield and Henry Kaiser created some 60 years ago was based on an uncommon partnership of sometimes-adversarial interests—an independent physician organization and an independent health plan with its own hospitals. Dr Garfield (and probably Mr Kaiser, too) understood clearly that a vital key to making this unlikely partnership into an organization capable of the transformation of medical care that Dr Garfield had envisioned was power—more specifically, a balance of power in the form of financial strength and solidarity of purpose and action. With the security and confidence that flows from such balance, the partners at the heart of the organization could take on Dr Garfield’s “most important” third lesson—the imperative to constantly innovate and open themselves and their organization, KP, to the risks and rewards of change.

Dr Garfield articulated his lessons to the Permanente leadership some 20 years after he and many of his colleagues had had the first two of those lessons branded into their consciousness by the near-death experience that precipitated the Tahoe Agreement of 1955. In that landmark accord (which would become a kind of unofficial “constitution” of KP), the physicians reasserted their challenged roles in the joint management of the overall organization vis-à-vis Mr Kaiser and the Health Plan, which had taken a unilateralist direction. Perhaps by 1974, the year he made his remarks to The Permanente Medical Group leaders, Dr Garfield feared that the memory of those hard-won lessons had lost their edge, or that the great majority of physicians who had joined the Medical Groups since Tahoe had never learned them.

Certainly, as KP neared its 50th anniversary in the mid-1990s, the time was ripe to reassert the lessons of a balanced partnership once again, this time through the creation of a physician federation, as Dr Garfield had urged back in 1974.

It is not necessary to get into the particulars of the problems that beset KP on its 50th anniversary; suffice it to say that the basic partnership of the Medical Groups and Health Plan had once again become unbalanced. The Health Plan management structure, on the basis of large geographic divisions, was seriously out of alignment with the regional structure of the Permanente Medical Groups. At the national level, the Medical Groups lacked a unified voice to negotiate with the more centralized Health Plan management. Fundamental differences of philosophy emerged over the pace and nature of program expansion. In addition, uncertainties arose over the commitment to the core KP delivery model and confidence in the long-term viability of the partnership itself was challenged. To top it off, there were growing indications that a financial crisis loomed over the horizon (which would ultimately bring on another near-death experience). It was not a pretty picture.

Fortunately, as in the early 1950s, leaders on both sides of the organization resolved to work for the partnership rather than against one another. The effort took the form of a yearlong negotiation toward completion, in June 1997, of a new National Partnership Agreement (NPA), which many at the time naturally dubbed “Tahoe II.” At the heart of that agreement was a rebalancing of the power relationship through the formation in early 1997 of The Permanente Federation. Creation of the Federation gave the separate and autonomous Medical Groups a unified and therefore stronger voice with which to negotiate and participate in the management of the program with national Health Plan leadership.

The joint management structure took the form of a new high-level entity, the KP Partnership Group (now KP Program Group [KPPG]), consisting of equal representation of Health Plan leaders and Federation/PMG medical directors.

Looking back from the distance of ten fulfilling years, I suspect that all those who were involved in the NPA development and the formation of the Federation must feel, as I do, a great deal of pride and satisfaction in what was achieved—and what was averted. Out of the NPA came not only The Permanente Federation, but the Care Management Institute — a jointly managed entity with a mandate to pursue the kind of programwide quality improvements that Dr Garfield envisioned in his third lesson. Also, the Federation’s venture development process, another product of the NPA, has contributed to the financial strengthening of the overall organization. In the areas of quality and service improvement, IT development, external

Jay Crosson, MD, is the Executive Director for the The Permanente Federation.
relations, and other endeavors, the renewed partnership between the Federation, Health Plan, and organized labor (through the Labor Management Partnership) has been a historic contribution to maintaining KP’s reputation for excellence and superior value.

With the Medical Groups speaking in a cohesive voice, the new KPPG moved decisively toward development of a national strategy in 1997 that would ensure alignment on the organization’s direction over the next decade. That strategy included development of KP’s first explicit brand strategy as a key to future success in an increasingly competitive marketplace. While the brand process has evolved over the years to the current, highly successful Thrive campaign, it has remained rooted in the original commitment to position KP as a unique and uniquely capable delivery system, built around the core principles of Permanente Medicine as defined by the Medical Group leaders and the Federation.

With alignment on the brand strategy, the new KPPG proceeded to develop and implement new processes for national decision making regarding long-term financial planning; performance metrics; national regulatory, legal and governmental policies; membership growth and geographic expansion; and capital investments in essential capabilities, including new facilities and technologies. Perhaps one of the greatest achievements of the newly strengthened partnership was the KPPG’s ability to commit to, and ultimately to implement, a programwide, cutting-edge clinical and administrative information system—a commitment that is now being fulfilled with KP HealthConnect.

As the Federation, which I have had the honor of leading for these last ten years, observes this anniversary, it goes without saying that I am proud of its role, as well as the individual contributions of the Permanente Medical Group Medical Directors and the Federation staff, in reaffirming the important lessons that Dr Garfield urged upon us 33 years ago. The Permanente Federation, at its best, is the very manifestation of the potential of physician solidarity that Dr Garfield described.

Most important, the rebalancing of the partnership’s power relationship through the National Partnership Agreement of 1996 has enabled both sides to work together more effectively in pursuing that invaluable third lesson, the pursuit of innovation and an openness to the winds of change. It is the safest of all bets that over the next decade, as in the last, we will confront both threats and opportunities that are unimaginable today and that will challenge our long-held and surest beliefs. KP will succeed, as it has in the past, by maintaining, above all else, its commitment to its original mission of “affordable, quality health care for our members and our communities” by whatever means, and in the words of our founder, by “keeping (our) arms on each other’s shoulders and (our) eyes on the stars for innovation and change for the future.”

From Advice to Permanente Physicians from Dr Sidney Garfield.

* From Advice to Permanente Physicians from Dr Sidney Garfield.
New Approaches to Confronting an Imminent Influenza Pandemic

By David S Fedson, MD

The February 2007 decision of the Indonesian minister of health to suspend shipments of H5N1 influenza virus isolates to World Health Organization Collaborating Centers indicated that international cooperation is likely to be inadequate in any upcoming influenza pandemic. Access to pandemic-relevant influenza vaccines will be difficult for people in all countries, not just those in developing nations. Three affordable alternatives are proposed here that could be made available to people worldwide. The potential role of statins, in spite of important epidemiologic and experimental support, has not yet been discussed in the general medical literature, much less in the public press. The authors believe that all three approaches must be considered if we are to think and act seriously about responding to the possibility of an imminent pandemic.

—Vincent J Felitti, MD, Senior Editor

Abstract

Scientists and health officials are concerned that an H5N1 influenza pandemic could be both imminent and catastrophic. Managing it will be difficult. Supplies of antiviral agents will be limited and expensive. Clinical development of adjuvant-combined, antigen-sparing, inactivated vaccines has been slow; the vaccines will take several months to produce and the global capacity to produce them will remain limited for several years. People who live in countries without vaccine companies—more than 85% of human-kind—will have little prospect for being immunized. Thus, new approaches are needed to confront an imminent pandemic. The interventions must be scientifically promising and already licensed or near licensure. Moreover, the global industrial capacity to produce them must be large and already in place. Three interventions meet these criteria. Within a few months, several billion doses of live-attenuated H5N1 vaccines could be produced in existing egg-based or cell culture production facilities and several billion doses of an H5 recombinant hemagglutinin (rHA) vaccine could be produced in existing pharmaceutical bioreactors. In addition, generic medications such as statins might be able to moderate the aberrant innate immune response that characterizes human cases of H5N1 influenza. Statins would be affordable and available worldwide on the first day of the pandemic. Given the limitations of current efforts to develop and produce antivirals and conventional vaccines, urgent attention must be given these promising new approaches to pandemic control.

Introduction

Health officials throughout the world are concerned that the H5N1 avian influenza virus could be the cause of the next human influenza pandemic. It is estimated that if the 1918 pandemic were to recur today, it would kill between 51 million and 82 million people worldwide.1–3 However, the case fatality rate for H5N1 influenza is approximately 60%, and thus a pandemic caused by this virus could kill hundreds of millions and conceivably lead to a partial global population die-off. No one can estimate the probability that a pandemic of this magnitude will occur, but it is certainly possible.

Many influenza scientists have said that the next pandemic could be imminent and the molecular evolution of the H5N1 virus looks increasingly threatening. Yet scientists are also concerned that “pandemic fatigue” will lead governments to reduce their commitments to develop and produce the vaccines, antivirals, and other agents that will be needed. What can be done to focus government attention on practical approaches to confronting an imminent pandemic?

Yet scientists are also concerned that “pandemic fatigue” will lead governments to reduce their commitments to develop and produce the vaccines, antivirals, and other agents that will be needed.
The Inadequacy of Current Antivirals and Inactivated Vaccines for Pandemic Control

For control of the next influenza pandemic, only limited supplies of antiviral agents will be produced. In addition, they will be expensive and available only in countries that can afford to stockpile them. Moreover, experience with the neuraminidase inhibitors (Tamiflu, etc) used to treat patients with H5N1 infection indicates that at current dose levels, they fail to improve survival rates. Studies of larger doses, longer treatment periods and newer agents are planned, yet even if these studies are successful, the difficult problems of inadequate supply and high cost will remain.

Inactivated (killed-virus) vaccines are the mainstay for controlling seasonal influenza and are regarded as the primary intervention for controlling the next pandemic. A pandemic vaccine, however, will take many months to produce, and producing an H5N1 vaccine will be especially difficult. The reverse genetics-engineered seed strain used for producing an H5N1 vaccine gives poor yields in vaccine production facilities (less than one third of those normally expected). Moreover, the vaccine by itself is poorly immunogenic and requires an adjuvant to improve immunogenicity. Consequently, if confronted today with an imminent H5N1 pandemic, the world’s vaccine companies could produce in six months enough doses of the most promising vaccine formulation (an adjuvanted vaccine containing 3.75 µg hemagglutinin [HAI]) to immunize with two doses approximately 700 million people. This is fewer than the number of people who live in the nine major vaccine-producing countries: Australia, Canada, France, Germany, Italy, Japan, the Netherlands, the United Kingdom, and the United States. In the US, the sole domestic vaccine producer could produce in six months enough doses to immunize only 130 million people.

Recently, the United States licensed a nonadjuvanted H5N1 vaccine containing 90 µg HA per dose, but this vaccine will never be used. In Europe, several adjuvanted H5N1 vaccines containing 3.75 to 30 µg HA per dose have been registered, yet none of these developments improve the prospects for global vaccine supply. More people might be immunized if vaccines considered to be potentially cross-protective were stockpiled in advance, but this approach will be adopted in a limited way by very few countries.

Currently, almost all doses of inactivated influenza vaccine are produced in embryonated eggs. To increase production capacity, the US government has invested $1 billion to accelerate the construction of cell culture vaccine production facilities. In other countries, vaccine companies are making similar, though smaller, investments, usually without any government assistance. Despite these initiatives, four to five years are required to construct and obtain regulatory approval for new production facilities. Consequently, there is little chance that the potential global supply of conventional pandemic vaccines will increase substantially within this period.

Given these facts and the possibility that the next pandemic could be imminent, it is clear that antiviral agents will be available to only some of the people who live in few developed countries. Moreover, people who live in countries that do not have vaccine companies (>85% of humankind) will have virtually no chance of receiving pandemic vaccines. For those who do live in countries with vaccine companies, vaccination will still be difficult.

Three New Approaches to Confronting an Imminent Pandemic

The fundamental reason why most of the world’s people will remain vulnerable to an imminent pandemic is the lack of global industrial capacity that will allow us to quickly produce adequate supplies of affordable inactivated vaccines and antiviral agents. None of the current efforts to develop vaccines and antivirals addresses this fundamental need. Thus, it is not surprising that initiatives for pandemic preparedness concentrate on community mitigation and nonpharmaceutical interventions.

Three new approaches could help us better confront an imminent pandemic. Two involve vaccines, one that is already licensed for seasonal use and another that could be licensed within one year. The third approach involves a generic medication that is widely available and inexpensive. It is not clear whether time will show these three approaches to be the best ways to confront a pandemic; other promising interventions in early stages of development may eventually prove to be better. Nonetheless, all three of these interventions share one unique and fundamental advantage: the industrial capacity already exists to produce them quickly in sufficient supply to meet global demand. What is lacking is the social imagination and political will to demonstrate that they are efficacious and ensure they can be produced.
A Live-Attenuated Pandemic Vaccine

A safe and effective live-attenuated, cold-adapted, intranasal, trivalent influenza vaccine has been available for seasonal use in the US for several years, and it is now licensed in a refrigerator-stable formulation. Investigators are working to develop a similar vaccine for pandemic use. One such vaccine has been shown to protect against challenge infection with various H5N1 viruses in experimental animals.

A live-attenuated H5N1 pandemic vaccine could have several practical advantages—one-dose, needle-free, intranasal administration; enhanced local immunity in the respiratory tract; and perhaps reliable cross-protection against different clades of H5N1 virus. A small clinical trial has shown that a live-attenuated vaccine incorporating the HA of a current human H5N1 isolate is poorly immunogenic, but there are good reasons to believe that this would not be seen with a vaccine incorporating the HA from a highly transmissible pandemic virus. If an acceptably immunogenic, live-attenuated H5N1 vaccine could be developed, it could not be used for prepandemic immunization because it might reassort with a circulating seasonal influenza virus and thereby gain increased transmissibility. However, it could be stockpiled for use once a new pandemic virus had emerged.

The company that produces the seasonal live-attenuated influenza vaccine currently has a limited capacity to produce a pandemic vaccine (45 million doses per month), although production capacity will increase significantly by 2011. However, its production technology is highly efficient and this is an enormous advantage; compared with trivalent vaccine production in cell culture or eggs, the number of doses of monovalent pandemic vaccine that could be produced could increase by either 100- or 180-fold, respectively. The vaccine virus itself could be produced in any compatible facility; for example, the licensed facility of a company that would ordinarily produce virus for an inactivated H5N1 vaccine. Once the bulk vaccine virus had been produced, the other steps in the vaccine production process could, if necessary, be transferred to other facilities. It is also possible that animal influenza vaccine production facilities could be used if they meet regulatory specifications. This would not disrupt production of conventional pandemic vaccines in human vaccine production facilities and would take advantage of the very large existing global capacity for producing animal influenza vaccines, 80% of which is located in Asia. Given focused attention to clinical, regulatory, and industrial development, it is conceivable that several billion doses of a live-attenuated, pandemic vaccine could be produced within a few months of the emergence of a new pandemic virus.

A Recombinant Hemagglutinin Pandemic Vaccine

Recently, a randomized controlled trial of a trivalent, seasonal, recombinant HA (rHA) vaccine showed it to be safe, immunogenic and probably clinically efficacious and an application for registration will be filed in the US in 2007. Given the similar immunogenicity of nonadjuvanted rHA H512 and split-virus H5N113 vaccines and the demonstrated antigen-sparing effects of adjuvanted H5N1 vaccines, an efficacious low-dose adjuvanted rHA H5 pandemic vaccine is a very real possibility.

Producing a pandemic vaccine involving rHA would first require cloning the gene for the pandemic virus HA in a baculovirus vector.

Table 1. Number of people who could be immunized against an H5N1 pandemic with conventional egg-based or rHA vaccines (hypothetical)

<table>
<thead>
<tr>
<th>Number of months of production</th>
<th>Amount of HA antigen (µg HA)</th>
<th>Egg-based vaccine</th>
<th>rHA vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>10</td>
<td>44 M</td>
<td>425 M</td>
</tr>
<tr>
<td></td>
<td>3.75</td>
<td>117 M</td>
<td>1.1 B</td>
</tr>
<tr>
<td>Six</td>
<td>10</td>
<td>263 M</td>
<td>2.5 B</td>
</tr>
<tr>
<td></td>
<td>3.75</td>
<td>700 M</td>
<td>6.8 B</td>
</tr>
</tbody>
</table>

B = billion; HA = hemagglutinin; M = million; rHA = recombinant hemagglutinin.

The estimates for both vaccines assume that two doses of adjuvanted vaccine would be required for each person.

The estimate for egg-based production assumes that yields of reverse genetics-engineered H5N1 vaccine viruses would be 33% of the yields for seasonal vaccine viruses and that the global capacity to produce egg-based seasonal vaccines is 350 million doses per year.

The estimate for rHA production uses yields that are reduced to 25% of those estimated from the company’s pilot studies and assumes that 25% (500,000 L) of the global pharmaceutical bioreactor capacity (2 million L) could be harnessed for rHA vaccine production.

In 2005 the world population was estimated to be 6.45 billion people.
This vector would be used to transfect insect cells that are then grown in a pharmaceutical bioreactor. A similar system is already being used to produce a new human papillomavirus vaccine. Thus, rHA antigen for pandemic vaccines could be manufactured in any existing pharmaceutical bioreactor facility.

Pilot studies show that a 10,000 L bioreactor could produce one million doses of a 135 µg rHA vaccine every five days. This information has been used to estimate the number of doses of pandemic rHA vaccine that might be produced worldwide (Dunnill P, Fedson DS, unpublished observations). Our estimate assumes that

- Five 5-day production cycles could be accommodated each month
- An effective adjuvanted rHA would need to contain only 10 µg or 3.75 µg rHA per dose
- Twenty-five percent of the existing global pharmaceutical bioreactor capacity of two million L (approximately 60% of which is located in the US) could be diverted for several months to produce rHA antigen
- Large-scale production yields in existing bioreactor facilities might be only 25% of those projected from pilot study experience.

Given these assumptions, the estimate of the number of doses of rHA vaccine that could be produced can be used to compare hypothetically the number of people who could be immunized worldwide with conventional egg-based inactivated H5N1 and rHA H5 vaccines (Table 1). Three months' global production of the conventional vaccine (3.75 µg HA, adjuvanted) would be enough to immunize with two doses 350 million people. In contrast, three months' production of an adjuvanted 3.75 µg rHA pandemic vaccine would be enough to immunize almost 3.4 billion people. This number is probably greater than the number of people who could be effectively immunized by all of the world's health care systems.

The contrasting scenarios shown in Table 1 are hypothetical. Nonetheless, they give a good indication of the potential scale and speed of rHA H5 vaccine production when compared with that of conventional egg-based H5N1 vaccines; the increase per month might be ten-fold, if not greater. Producing an rHA vaccine would improve dramatically the global prospects for pandemic vaccination.

### Statins: A Possible Alternative for Treatment and Prophylaxis of Pandemic Influenza

Because of the inadequacies of the current antiviral and vaccine approach to control an influenza pandemic, an effective alternative is needed. One possibility is to use medications that are already produced as generics and are available and affordable worldwide. Statins, the drugs used to treat high cholesterol levels and prevent heart disease, are one such group that should be considered.14

The scientific rationale for the potential role of statins in pandemic influenza prophylaxis and treatment is based on their known anti-inflammatory and immunomodulatory effects.15 Statins might help control the aberrant innate immune response (cytokine storm) that characterizes human H5N1 infection, a response that could accompany infection with a virulent pandemic virus.14,16,17

Several observational studies have shown that recent prescriptions for statins are associated with 30% to 50% reductions in hospitalizations for chronic obstructive pulmonary disease and pneumonia and 40% to 60% reductions in pneumonia and all-cause mortality18–21 (Table 2). One observational study22 showed that statins had no effect on outcomes in patients with pneumonia, although there were several problems with its methods, including the definition of statin users and the way propensity scores were used in risk adjustment (Table 2). None of these studies was able to address directly the question of whether it is necessary to continue or to initiate statin treatment after hospital admission. However, early inhospital statin treatment benefits patients with other conditions associated with cytokine dysregulation, such as acute myocardial infarction,23 major noncardiac surgery,24 and bacteremia.25 Moreover, withdrawing statin treatment after hospital admission can be harmful.25,26 These findings strongly suggest that in patients with pneumonia, the full benefits of statins will require continued treatment after the onset of illness.

The observational studies of statins and pneumonia have provided an “epidemiological signal of protection” and clearly indicate the urgent need for additional research. Studies in animal models (especially ferrets and nonhuman primates) of acute H5N1 and 1918 influenza16,17 could help determine whether statin treatment, with or without concomitant antiviral treatment, could help control the aberrant immune response that accompanies these infections. In addition, observational studies of inpatient statin treatment of pneumonia patients in and out of influenza seasons would provide a strong indication of whether statins could benefit patients with seasonal as well as pandemic influenza.

The scientific argument for pandemic treatment and prophylaxis...
with statins is persuasive, but it must be confirmed in experimental and clinical studies. If, however, statins are shown to be of benefit, the public health argument for their use in a pandemic would be hugely compelling. Currently, a five-day course of treatment with a neuraminidase inhibitor costs $60 to $90 in the US, and the global availability of these agents is limited. By contrast, generic statins are available worldwide and are inexpensive. In the US, a five-day course of treatment would cost approximately $1.75, whereas in a developing country such as India, it would probably cost less than $1.00. Moreover, unlike vaccines and antivirals, statins would be available in almost all countries on the first day of the pandemic.

Requirements for Developing and Implementing These New Approaches

Any effort to quickly produce very large numbers of doses of live-attenuated and/or rHA pandemic vaccines would first require demonstrating their immunogenicity and safety, a process that, if tightly organized, should take no more than a few months. Far more important and more difficult would be the planning and development needed to identify production facilities, validate scale-up and bioprocessing procedures, sort out intellectual property and liability issues, ascertain overall demand for the vaccines, and arrange guaranteed financing for vaccine production and distribution. This could best be done by a top-down management system. Ideally, it would be coordinated by an international agency such as the World Health Organization. If this were not politically feasible, it would have to be undertaken by the governments of one or two countries. Government management could be especially important for brokering and funding the collaborative arrangements between companies that otherwise might not have commercial reasons to work together. Although this enterprise would be unprecedented in scale and complexity, the governments of vaccine-producing countries must be mindful of the economic and political consequences of not undertaking it.

A strong argument can be made for simultaneously pursuing a bottom-up approach that seeks to demonstrate the rationale for treatment and prophylaxis using existing generic medications that modify the host response to serious influenza virus infections. Whether agents such as statins would be more effective when used alone or with concomitant administration of an antiviral agent will have to be determined. If they were found to be effective, their global availability and affordability could be critically important, especially for developing countries.

Conclusion

Influenza scientists have repeatedly warned that the next pandemic could be imminent and might be catastrophic. Yet the collective ef-

Table 2. Improved outcomes from recent treatment with statins in patients with COPD and pneumonia

<table>
<thead>
<tr>
<th>Principle investigator (reference)</th>
<th>Study design; number of study subjects</th>
<th>Outcome</th>
<th>Adjusted odds ratio (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mancini18</td>
<td>Case control; 2907/98,917</td>
<td>COPD, hospitalization</td>
<td>0.71 (0.64–0.77)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All-cause mortality</td>
<td>0.49 (0.41–0.58)</td>
</tr>
<tr>
<td>Mortensen19</td>
<td>Retrospective cohort; 110/677</td>
<td>30-day pneumonia mortality</td>
<td>0.36 (0.14–0.92)</td>
</tr>
<tr>
<td>van de Garde20</td>
<td>Case control; 4719/15,322</td>
<td>Pneumonia, diabetes, hospitalization</td>
<td>0.50 (0.28–0.89)</td>
</tr>
<tr>
<td>Schlienger21</td>
<td>Case control; 1227/4734</td>
<td>Pneumonia, hospitalization</td>
<td>0.63 (0.46–0.88)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30-day pneumonia mortality</td>
<td>0.47 (0.25–0.88)</td>
</tr>
<tr>
<td>Mortensen*</td>
<td>Retrospective cohort; 1567/7085</td>
<td>30-day flu season pneumonia mortality</td>
<td>0.56 (0.40–0.79)</td>
</tr>
<tr>
<td>Hak*</td>
<td>Retrospective cohort; 22,638</td>
<td>Pneumonia</td>
<td>0.62 (not stated)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All-cause mortality</td>
<td>0.49 (not stated)</td>
</tr>
<tr>
<td>Majumdar22</td>
<td>Prospective cohort; 325/3090</td>
<td>Hospital mortality/ICU admission (adjusted for administrative data only)</td>
<td>0.88 (0.63–1.22)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Age (adjusted for administrative data) pneumonia severity index and propensity score</td>
<td>1.10 (0.76–1.60)</td>
</tr>
</tbody>
</table>

COPD = chronic obstructive pulmonary disease; ICU = intensive care unit.

*Unpublished observations.
New Approaches to Confronting an Imminent Influenza Pandemic

Tourts of governments, companies, and international organizations such as the World Health Organization have failed to match the magnitude of the pandemic threat. In an analysis of another disaster that scientists had foreseen—the Challenger launch explosion—an American sociologist concluded that the failure to prepare “... was a mistake embedded in the banality of organizational life and facilitated by an environment of scarcity and competition, elite bargaining, uncertain technology, incrementalism, patterns of information ... (and) ... organizational structures ... that normalized signals of potential danger and re-aligned action with organizational goals.” Stripped of its academic jargon, this statement is a stinging indictment of “business as usual.” In an analysis of cultural challenges to envisioning worst case scenarios, another author concluded, “A less than perfect trajectory cannot deter us. ... We can do significantly better in fighting calamity and catastrophe than current efforts allow. Given the stakes, ... we would be truly remiss if we simply failed to try.”

The continuing occurrence of human H5N1 infections represents a very real and possibly imminent pandemic threat, one that in a worst case scenario could have unimaginable consequences for humankind. Current evidence indicates that we cannot count on having adequate supplies of antivirals and inactivated vaccines to respond to this threat. Failure to understand our current predicament could be costly to people everywhere.

Live-attenuated and rHA vaccines offer realistic near-term possibilities for global immunization. Statins represent another potentially promising approach to pandemic treatment and prophylaxis. Developing the scientific basis for the clinical use of these three interventions will require the efforts of investigators from many disciplines. At the same time, governments must begin to harness the resources and facilities that will be needed for their production and distribution to all countries that will want to use them. The costs of not doing so could be incalculable.

Acknowledgment
Katherine O’Moore-Klopf of KOK Edit provided editorial assistance.

References
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8. MedImmune presentation. 2006 analyst and investor day, Gaithersburg MD, December 6, 2006.
No Warning

Mr Barry relates stories of people who went to work feeling well and dropped dead on the job with no warning.

Sharon Higgins, MD, is the Executive Medical Director for Northwest Permanente. Dr Higgins enjoys travel and documents her experiences through photography and journals. This photo was taken while on safari in the Serengeti using digital equipment.

Another of Dr Higgins’s photographs may be seen on page 49.
Why Now Is the Time to Enact Health Care Reform

By George Halvorson


We spend more money on health care by far than any other country and yet nearly 50,000,000 Americans are uninsured at least part of the time each year.¹ To make matters worse, well-documented studies show us that nearly 50% of the time American patients are receiving less than adequate, inconsistent, and, too often, unsafe care.²

We have reached the point where both health care delivery and health care financing in America need new directions. The old approach isn’t technically broken—because it continues to function—but it performs at unacceptable and unaffordable levels in far too many ways for far too many people. Our current approaches to care delivery and health care financing are sadly inadequate for what we need health care to do in this country today.

We don’t really have a health care delivery system in this country. We have an expensive plethora of uncoordinated, unlinked, economically segregated, operationally limited micro systems, each interacting in ways that too often create suboptimal performance both for the overall health care infrastructure and for individual patients. Our current approach to financing both care and health care coverage too often leaves us with major operational problems as well as serious ethical issues relative to resource allocation. Our current approach to health care resource consumption can lead to unconscionably inadequate access to quality care for far too many Americans. Those problems are exacerbated for minority Americans. When it comes to racial and ethnic disparities in care and coverage, we very sadly have grown to accept as the status quo in America what should be seen as completely unacceptable differences in care delivery and care outcomes for our various minority populations. Our current nonsystem is expensive, frequently ineffective, and the distribution of care resources are often dangerously and shamefully inequitable.

This is clearly the wrong place to be.

What we need to do at this point is bring everyone—labor, management, consumers, carriers, the uninsured, the underinsured, caregivers, government agencies, patients, and the community—together to form a consensus on an approach that can truly get the job done. Then we need to turn that consensus into practical, functional operational reality as soon as we can get that whole agenda in place.

Eight Developments That Finally Make Health Care Reform Possible

Major health care reform is achievable right now in this country to a degree that literally was not possible until now.

Why do I say that? Because there are eight recent developments in American health care that have combined to give us, for the first time ever, a very real opportunity to systematically improve both care delivery and reduce the costs of care on a large scale in a relatively short time frame. I have touched on several of these issues in the prior chapters already. But I think we need to look at them in terms of a package of events, opportunities, and issues that, taken together, give us a chance to make a real difference in American health care.

Those eight developments are creating what might be a “perfect storm” in favor of health care reform.

Without those specific developments, care delivery improvement and real market reform would be extremely difficult, if not impossible. With them, if we do the right things in the most effective ways, health care reform can actually happen. Soon.

So what are the magical eight recent developments that make health care reform much more possible right now?

George Halvorson is the CEO and Chairman of the Board of Kaiser Foundation Health Plan, Inc, and Kaiser Foundation Hospitals.
1. Common Provider Number

The first key new health care reform ingredient is the common provider number. All health care providers in America will soon have, by law, a single identification number that clearly identifies each individual provider for all payers and for all care. That new single ID requirement is a huge step forward for health care data use.

The national single provider code requirement is a recent development, created by an extension of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This particular HIPAA provision requires use of the common provider number by May of 2007. The common provider number is an extremely important new tool. It changes access to care data in a critically important way. Until now, it has been functionally impossible to track individual provider performance using available electronic databases about care. The only electronic databases that exist have been created and held by the various payers of claims—the health plans, insurers, third-party administrators, and public program payment shops. Each of these private and public payers has used their own unique, proprietary provider-coding system, so there has been no way to link data from the various payers’ claims payment databases in ways that could create either overall provider accountability or performance measurement. A single provider could and did have multiple identification codes, each code limited to a single payer’s database, so the various payer databases could not be coordinated or aggregated in any effective way.

Tracking how well a given provider did in taking care of a chronic disease like asthma was made extremely difficult—if not impossible—by the fact that no two existing electronic records of his or her care could be linked together.

If we really believe that data is the essential first step for any continuous improvement process or model, then the importance of having a single, unique longitudinal numerical code for each provider becomes glaringly obvious.

If we really believe that data is the essential first step for any continuous improvement process or model, then the importance of having a single, unique longitudinal numerical code for each provider becomes glaringly obvious.

2. Computerized Databases

The second major development that makes systematic health care reform finally possible is the emergence of computerized databases for all payers. Until very recently, a minority of health care claims were submitted electronically from care providers to insurers, health plans, and government payers. The resultant nonelectronic data flows were inconsistent and undependable in ways that significantly undermined the potential effectiveness of the final data sets for use in tracking health care delivery.

Today, with HIPAA regulations making the electronic data flow from providers to payers a standardized, more efficient, confidentially protected process, the databases for the payers are pretty much all electronic. The new HIPAA and industry standards for electronic data transmission also are set up to create a more uniform data flow. As a result, the old, relatively inaccurate and inefficient paper claim is being replaced very rapidly by far more accurate electronic claims submissions.

To make the process even more useful, the time frames between actual care delivery for a given patient and the electronic filing of a claim about that patient’s incident of care have recently shrunk precipitously, to the point where the new electronic database for payers now has increasing value as a relatively current care management and provider support tool as well as a history-based performance tracking tool.

3. Electronic Claims Data Portability

The value of that claims-payment based electronic data reporting tool is being further enhanced by the new willingness of the entire health care payer industry to commit as an entire industry to both data portability and data interoperability. The industry set itself a major new and almost revolutionary goal in 2006 to achieve a functional ability on the part of all insurers and payers to electronically move data between payers in ways that closely resemble comparable data flows in the banking industry. That ability is being piloted even as you are reading this book. So a significant supply of health care data is now becoming electronic, timely, standardized, and portable.

That is a data bonanza for health care. We are going from all data being held exclusively in separate paper medical records—inert and inaccessible—or in a myriad of fragmented electronic claims payment files with different data standards and unusable provider ID codes to a new world of interchangeable electronic data and consistent, national provider ID codes. From a data perspective, that is revolutionary. It’s a huge change.

There are, as I noted earlier, two major potential users for that new data. That new data flow can create longitudinal databases for each individual patient in the form of a Personal Health Record (PHR) and it can also create communitywide databases that can be used to
People have begun to appreciate how little data people have to make important care decisions. 

Pulling electronic claims payment data out of paper-based insurance company files and making it available for measurable process improvement is a huge step forward for health care reform. We are at the first stages of that process, but I expect it to unfold very quickly once the database is available.

Again, the very best, most complete, and most useful database about patient care is the electronic health record. The number of providers putting those complete automated medical record systems in place is growing rapidly. But many smaller provider sites are still several years away from having those full electronic health record systems operational. In the meantime, however, as I described in earlier chapters, a lot of heavy lifting on health care accountability and reform can be done using the new electronic database created by the claims payment process and facilitated by HIPAA, the single provider ID number, and the new industry accords on data portability.

4. Governmental Transparency About Payment Data

A fourth major new element that enables and encourages reform is the unprecedented recent willingness of the government to create much greater levels of transparency about provider performance data using information from the current Medicare and Medicaid databases. The government has historically been both relatively secretive and extremely selective in its use of that data. The current administration is calling for a broad and sweeping transparency—a new level of data sharing from the government that could quickly prime the pump for important comparisons of provider performance.

In an Executive Order of August 22, 2006, the White House stated the following:

It is the purpose of this order to ensure that health care programs administered or sponsored by the Federal Government promote quality and efficient delivery of health care through the use of health information technology, transparency regarding health care quality and price, and better incentives for program beneficiaries, enrollees, and providers. It is the further purpose of this order to make relevant information available to these beneficiaries, enrollees, and providers in a readily usable manner and in collaboration with similar initiatives in the private sector and non-Federal public sector.3

That is another revolutionary development. Medicare is the largest single purchaser of care in America.4 To make that massive Medicare database about provider performance transparent is a huge step toward real market reform. That work isn’t done yet, but it is now underway—and the enlightened intentions of the senior policy makers are pretty clear.

5. Universal Awareness of the Quality Issues

The fifth major development that is making health care reform possible now is the emergence, finally, of a widespread awareness across policy makers, politicians, buyers, care providers, and patients that our current health care infrastructure is badly flawed, perversely incented, inadequately coordinated, incredibly inconsistent, strategically unfocused, and too often dangerously dysfunctional. The powerful and persuasive Institute of Medicine studies7 combined with John Wennberg’s work at Dartmouth8 and Beth McGlynn’s work at RAND2 have shown beyond any doubt that our health care delivery infrastructure nonsystem leaves a lot to be desired.

Until recently, quite a few health care policy makers wanted somehow to restructure health care to get back to some level of entirely mythical “good old days”—the days when Marcus Welby-like physicians knew everything about care and made great, science-based decisions for each patient with no interference from any outside influences like health plans, government regulations, or scientific, performance-tracking databases.

Now, everyone knows that the world of unstructured care has given us a real quality chasm to cross—and a lot of people are ready for someone to design and build a bridge across that chasm. People are ready for some level of reform.

A number of recent reformers have believed and hoped that if patients had to pay part of the bill then somehow—with no actual performance data of any kind—those patients would be able to make important decisions about caregivers in ways that would reward the best caregivers and introduce real market forces to health care. That theory is turning out to have some shortcomings. Deductibles obviously do not magically create data. Even financially incented, uninformed consumers have a hard time making truly informed choices. That’s the bad news.

There is also some very good news associated with that particular high-deductible-benefit design experiment. One unintended positive consequence of test-
ing those high-deductible plans was that people who wanted to make informed choices became very aware that they had no real information to use in making those choices. People have begun to appreciate how little data people have to make important care decisions.

People who know health care well now understand that those good old Marcus Welby days were an illusion and that the health care nonsystem we have today is too data free, too often uncoordinated, too often outdated, usually badly structured, and even dangerous for far too many patients. The needs of the quality agenda for American health care are becoming very clear. Simply asking patients to make more choices won’t create a marketplace based on best medical science. Buyers, patients, policy makers and even care providers are all beginning to understand those realities.

The public trust has also been shaken by incidents like the Vioxx recall in 2004 and by a series of visible care direction missteps—like discovering that hormone replacement therapies for women did more harm than good or that autologous bone marrow transplants for women with breast cancer made the death process more painful for the patients and added no length to those women’s lives.

So we have reached a point where large numbers of people are ready to look at change because there is a growing belief that the current pathway is both unaffordable and too often dysfunctional and even unsafe.

Timing is everything. People are losing faith in the old quality agenda for care right at the point when a new agenda is possible.

6. Buyers Are Ready For A Change

In that vein, the sixth major factor that will accelerate the agenda for change is that the primary buyers of health care—the employers and government bodies who already purchase large quantities of health care—are now very ready for a change. It’s hard to find a happy buyer. Companies look at how much their employees’ and retirees’ health care actually costs and they compare those costs to their competitors in other countries. For cars made in the US, health care costs not only exceed the cost of steel—health care costs just for the retirees from American auto companies now exceeds the cost of steel in each car. In 2005, GM spent $5.3 billion on health care; $4 billion covered retirees and their families. Annual steel costs are about $3 billion. The price tag of every GM car built in the United States includes $1525 just for the health care of 1.1 million employees, retirees, and their families. Contrast this to the portion of a Toyota sticker price that accounts for health care: $97 for every vehicle built in Japan and $400 to $425 for each vehicle produced in the US.

Buyers are ready for new answers. So are the government agencies that pay for government employees, as well as the government agencies that provide increasingly expensive health care to public program beneficiaries. This is actually a major sea change for the marketplace. It is needed.

Many employers over the past five to ten years have insisted that stricter versions of available cost containment approaches not be applied to their employees—and many employers relatively recently refused to allow their health plans or benefit administrators to restrict access to certain providers and rejected proposals to channel patients to a select group of proven, cost-effective caregivers. Those particular buyer constraints are fast fading away, and buyers are now cutting benefits and imposing coverage eligibility restrictions. Many are now considering using more tightly managed care networks to significantly reduce costs. On a more drastic level, many buyers are now canceling or freezing health care coverage for their retirees, and, sadly, large numbers of smaller employers are even dropping employee coverage all together. Less than half of all firms with less than ten workers now offer health benefits, compared to more than 90% of firms with 50 or more employees.

It’s a time of change for many buyers. Buyers are ready for new answers—answers that work. That readiness makes change possible. Markets and industries do not change when customers aren’t ready to change. In this case, the buyers are now ready for change a bit before the vendors have figured out how to change. Reform will be possible when that happens. Vendors will, I expect, rise to the occasion. That’s how markets work.

7. Internet Functionality Used for Care

The seventh major factor that is currently strongly enabling an environment of change in health care is the Internet. The Internet has already had a huge impact on other areas of the economy. Purchasing, banking, investing, and education are all areas where the Internet has made massive inroads into how we do business.

Health care is poised to follow. Health and medical Web sites receive the highest number of visits from search engines. As an evolving health care economy learns to use the Internet more effectively, we will soon see more doctor/patient e-connections. E-scheduling, e-visits, e-follow-ups and reports, and e-reminders about
needed care all are rolling out now in various places. The future scope and volume of e-visits and e-connections will, I believe, exceed almost everyone’s expectations. Patients will have various kinds of innovative and easy-to-use testing equipment in their homes and will be making e-connections with their caregivers in multiple ways. The current explorations into supporting some levels of in-home care will, I believe, explode over the next several years as the population ages and the availability of some levels of face-to-face or institutional care become problematic.

That’s a longer-term view. The short-term view involves a lot of Internet use fairly quickly. The new market model for health care will rely heavily on the Internet, as patients both chose real live caregivers based on e-data and then get quick and convenient electronic advice about their care from e-consultants. The very best versions of the new market model will rely on the Internet to get information to patients and to caregivers and to facilitate patient choices relative to caregivers, care strategies, care plans, and actual care. Only the computer can facilitate those levels of choices in any workable way. A paper-based, data-rich health care marketplace would be logistically crippled. We need the Web to reform care.

Also, when all patients have electronic PHRs available on the Internet from their payers—and when the PHRs have each patient’s diagnosis, tests, prescriptions, and lists of each and every care procedure performed for each patient by each caregiver—patients will be able to plug that electronic PHR information into e-consults, getting virtual second opinions from medical experts in the computerized care business who will be obsessively up-to-date on the best available care options for each diagnosis.

The Internet will make medical science more current. Individual doctors in individual practices may currently have a hard time keeping up with each new scientific development in their specialty, but the new companies and care providers who will sell their services on the Internet to provide e-consults will have “keeping up” with current science as a key value they sell to patients. It will transform care when people with asthma bring e-consult printouts to their real-life, in-the-flesh caregivers, to ask why a particular drug is or is not being used for their care.

The e-consults will say, “You have asthma. You have been in the emergency room three times this year. There are three good drugs that might be used at this point. Here’s a list of these drugs and their normal retail prices. You seem to be using the most expensive of those three drugs now. You could save $120 a month by switching to the least expensive drug. Here’s the most recent comparative test data about the relative effectiveness of each of those drugs. Do you have any questions?”

Some very bad medical service is now provided over the Web. Current health care Web sites may be credible, or may be charlatans. My sense is that an industry of credible sites will emerge as an option for many patients.

Even the credible independent e-consultant firms that will be on the Web probably would run into real local license problems if they actually tried to practice free-standing Internet medicine. However, those businesses would probably have relatively easy sailing if they simply shared care protocols, pointed out where current treatment for a given patient differed from those protocols, and then suggested that the patient discuss care options directly with their primary caregiver. Since most primary caregivers will be handling e-inquiries from their own patients over the next several years, the medical issue question-and-answer process for some patients might be entirely electronic—from the patient to the e-consultant through to the live local physicians and then back to the patient.

That level of very direct e-dialogue with patients has the potential to significantly impact the delivery of care. It definitely has the potential to significantly shorten the 17-year time frame that the IOM noted is often the length of time before a new best care approach is uniformly used by all physicians. Even the credible independent e-consultant firms that will be on the Web probably would run into real local license problems if they actually tried to practice free-standing Internet medicine. However, those businesses would probably have relatively easy sailing if they simply shared care protocols, pointed out where current treatment for a given patient differed from those protocols, and then suggested that the patient discuss care options directly with their primary caregiver. Since most primary caregivers will be handling e-inquiries from their own patients over the next several years, the medical issue question-and-answer process for some patients might be entirely electronic—from the patient to the e-consultant through to the live local physicians and then back to the patient.

The Internet, by itself, will help educate people about their medical conditions and their care. The Internet combined with personal health records, virtual consults, and extensive comparative performance data about various caregivers will probably revolutionize some aspects of care.

Couple that functionality with e-visits, e-dialogue, and direct patient e-connectivity with their chosen caregiver or care-teams, and it’s easy to see how health care reform could—and will—be significantly e-impacted.

The best care systems will offer e-connectivity to their patients in ways not even dreamed of today. E-visits will be an expectation, a basic level of patient/provider interaction that will allow for whole new levels of care convenience and care growth. Health care will be an e-industry relatively soon.
8. Lawmakers are Ready for Reform

The final new development that will allow real health care reform to happen is the fact that lawmakers in a great many states have also hit the tipping point on the need for real care reform.

State legislative budgets are being destroyed by the increasing costs of care. Emergency rooms are closing, and innercity hospitals are imperiled. The number of uninsured Americans continues to grow, and the number of underinsured Americans may be growing even faster as high-deductible health plans increase in number.20 Too many of the purely uninsured people do not vote, so it's far too easy for elected officials not to hear their voices.

Underinsured Americans, however—people who are insured but face out-of-pocket costs that are high relative to their incomes20—can create a major new political backlash because underinsured people tend to be fully employed people,20 who are more likely to vote.21 Underinsured people vote and they are getting angry. When enough are angry, they will be heard.

So state after state is now aiming at some kind of health care reform, usually targeted at the twin goals of increasing the number of insured people while cutting costs.

So far, there has been a major shortage of proposals that can meet both of those two goals of increasing the number of insured while cutting costs—but the momentum across the country to pass legislation of some kind to make that kind of progress shouldn't be underestimated. Leaders in legislatures and governors' mansions are ready to act, as are labor unions and major employers—once a solid course of action becomes clear.

So buyers are ready, labor unions are ready, consumers are ready, politicians are ready, academics are ready, and even some caregivers are ready. We now have the potential of a new electronic database that could serve as the foundation for systematically improving many areas of care. How do we get those eight developments to merge into a single agenda to reform care?

An Optimal Health Care Market

Let's revisit one more time what an optimal health care marketplace might look like. As business guru Stephen Covey says, “Begin with the end in mind.”13 What do we want to see in our care delivery system?

- **Consumers should have complete and easy electronic access to their own health information.** A patient should be able to find which medications they have been prescribed, which doctors they have seen recently, and which procedures they have had done over their lifetimes. It's amazing, but consumers don't have an easy way to access this information now.
  - **Consumers should have complete and easy electronic access to the information they need to make informed decisions about their caregivers.**
    - A patient needing knee surgery should have data available to figure out which surgeons are most likely to achieve a satisfactory result. A patient with asthma should know which teams of caregivers are most likely to manage the disease successfully and help the patient avoid the asthma attacks that undermine the patient's quality of life and sometimes threaten life, itself.
  - **Consumers should have complete and easy electronic access to the information they need to make informed decisions about their care.** A patient with heart disease should be able to find out what complications others have experienced from bypass surgery. Patients with asthma should know what drugs are available to best treat their particular triggers. Patients should have the opportunity to get consultations electronically about various approaches possible for their care.

Ideally, consumers should be empowered and educated, supported and encouraged in receiving best care and in making the lifestyle choices that support their own best possible personal health.

Care should be accessible and affordable, with patients having enough appropriate involvement in the cost of care to encourage wise choices by the patients and competitive prices by the caregivers.

Consumers should be able to have confidence that their own caregivers are current relative to medical science and best care and obsessively conscientious about the follow-up needed for their care.

It's not hard to figure out what the ideal health care marketplace might look like. The challenge is to actually make it happen. Someone needs to actually provide the data flow processes and communication infrastructures needed for patients to make those informed choices. The pieces can all be assembled from available components. The need is for a market model that will reward the vendors who can functionally make that infrastructure happen.

The next chapter deals with why market forces have not worked well in health care up to now. The chapter after that suggests a new market model that might work to actually meet our needs for a better system.
For now, the point I’d like to make is that the emergence of a single provider number, electronic personal health records, data portability, and a sense by key parties that change is really needed all work together to set up the best environment and opportunity we’ve ever had for real health care reform in America. We just need to be very clear on what that reform should be. And we should be clear that we need that reform now.


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“Barking Dog Rapids 2”
pastel on pastel paper, 24”x36”
By Terrance Chang, MD

This piece was inspired by Dr Chang’s favorite getaway and adrenaline kick—whitewater kayaking on the South Fork of the American River in Coloma, CA—and sports photographs of similar layout in gyms. Dr Chang first attempted to create this piece in watercolor and acrylics but found that pastels worked the best.

Dr Chang is an allergist in the Department of Allergy and Immunology at the Oakland Medical Center in California.
Transforming Medicines

By Charles Elder, MD, MPH, FACP
Cheryl Ritenbaugh, PhD, MPH

Whole Person
What will it take to transform our health care system? Anecdotal experience and qualitative data suggest that patients undergoing treatment within certain Complementary and Alternative Medicine (CAM) systems (e.g., ayurveda, traditional Chinese medicine, and naturopathy) may experience value nonspecific, whole-person, or transformational changes as essential components of the healing process. Conventional medicine’s limitations in appreciating such phenomena may represent an under-recognized root cause of chronic dissatisfaction with and within primary care. Meaningful progress, then, could require the transformation of our own practice toward selectively incorporating CAM paradigms. Clinical investigators and educators are already responding to this challenge.

“The Experience was Transforming”
At the Center for Health Research, we recently completed a National Institute of Health (NIH)-funded pilot trial assessing the feasibility and clinical impact of a novel, holistic intervention for newly diagnosed type 2 diabetics. We recruited and randomized 60 patients to either allopathic or ayurvedic care. Ayurvedic medicine is the traditional health care system of India, ranking among the oldest continuously practiced systems of natural health care in the world. Patients in the ayurvedic arm of the trial were treated with a multimodal intervention including exercise, a lacto-vegetarian diet, a quality-controlled herb supplement, and instruction in the Transcendental Meditation technique. (See Sidebar: Whole Systems Research: An evolving paradigm for studying CAM interventions.) The allopathic care arm received standard diabetes education with primary care follow-up. As an incentive to patient compliance, we offered raffle entry for a free weekend at the Oregon Coast to participants completing the six-month data collection. At study conclusion, we invited these participants to a social gathering where the raffle would take place. As I mingled among the crowd at this event, one participant pulled me aside and commented:

“Dr Elder, I’d like to thank you for conducting this study. I was in the ayurvedic group. The experience was transforming.”

I found the positive feedback gratifying, but was somewhat taken aback when a few minutes later another participant approached me and, using almost identical language, thanked me for the transformative experience she had enjoyed from her exposure to meditation and the ayurvedic paradigm. Finding this “coincidence” intriguing, I described these conversations on the drive home to my wife, a family practitioner who had served as the study physician for the experimental group. She responded without surprise, noting that she had been getting such feedback from the patients all along.

The anecdote supports the premise that patients may gain whole-person or transformational benefits from certain CAM interventions that go beyond the narrow biomedical markers we are accustomed to measuring.

A Second Trial
As another example, we conducted a clinical trial assessing the impact of two mind-body interventions for weight-loss maintenance. One of the interventions tested was Qigong, a technique from the traditional Chinese medicine tradition involving movement and meditation. Whereas patients in the Qigong group did not achieve benefit in terms of the measured biomedical outcomes (weight loss maintenance), in formal interviews these same patients reported significant improvements in overall well-being:

“Positive thinking and self-affirmation and all of that positive energy—that’s what it amounted to. I don’t know about weight loss or weight maintenance, but I did find a more positive outlook and...”
Whole Systems Research: An Evolving Paradigm for Studying CAM Interventions

The ayurveda/diabetes project represents an example of a “whole systems” study. The general strategy in such a study is to compare an “authentic” multimodality intervention from a CAM system (authentic in the sense that it represents the common community practice) to a usual care intervention matched in terms of contact hours and treatment intensity. The need for this model stems from the growing recognition within the CAM research community that the conventional single modality randomized trial is scientifically inadequate for the rigorous assessment of CAM interventions. Reasons for this are many and include:

- CAM practitioners typically prescribe multimodality interventions. These modalities, from the vantage point of the CAM paradigm, are held to act in synergy. It makes no sense to isolate a single modality for study; the results of such a study would be of little practical application, since the modalities are not intended to be used in such a way.
- In the classic single modality randomized trial, we blind and control in an attempt to “filter out” the attitudes and interactions of patient and practitioner, so as to “isolate” the activity of the “modality” for study. In ayurveda and other CAM systems, the attitudes and interactions among patient, practitioner, and modality are held to be essential features of the healing paradigm, and are thus themselves an important object for study.

The National Center for Complementary and Alternative Medicine’s five-year strategic plan lists the study of “Whole Medical Systems” among its top funding priorities: http://nccam.nih.gov/about/plans/2005/strategicplan.pdf.

pilot administration and appropriate psychometric evaluation.

**Implications**

The availability of a validated measurement tool will enable investigators and health care professionals to better identify, measure, and address whole-person outcomes at the levels of research, policy, and practice. This could prove a tipping point for an allopathic medical system whose primary care clinicians are in perpetual job satisfaction crisis. In conventional medicine, available clinical tools (pharmaceuticals or surgery) generally do little to promote whole-person or transformational change. Additionally, the narrow, dualistic Newtonian paradigm does not allow for sophisticated analyses of such issues. Yet primary care physicians acknowledge that patients commonly present to them with problems requiring a more holistic approach. This discrepancy between the (whole-person, transformational) needs of our patients and the (narrow, materialist) tools available inevitably generates a frustration or dysfunctionality that might lie at the root of the crisis. Charged with this impossible task, job dissatisfaction within primary care has grown so perpetually pervasive as to seem almost an inherent feature of the enterprise. Like a dog barking up the wrong tree, the community expends tremendous resources with little result. The solution, of course, is not to bark louder.

If what patients are requiring for their health are phenomena at the level of holistic and whole-person outcomes, and if CAM systems offer more evolved paradigms for identifying and managing such phenomena, can the study and judicious integration of CAM systems contribute to the solution? Many feel the answer is yes, as evidenced by the broad array of CME programs now available to train conventional clinicians in CAM systems and modalities.

**Global Medicine Education**

As an outstanding example, The Global Medicine Education Foundation (www.globalmeded.org/), in affiliation with The American Holistic Medical Association, offers an 18-month Transformational Medicine training program for health care professionals. The program combines Web-based distance learning with four one-week on-site retreats toward training participants in the tools and concepts of different healing paradigms, cultures, and traditions.

For example, course participants recently engaged in didactic review and interactive discussion of the concepts of western naturopathic medicine. Central to the naturopathic paradigm is the notion of the “healing power of nature”: “The healing power of nature is the inherent self-organizing and healing process of living systems which establishes, maintains, and restores health … It is the … physician’s role to support, facilitate, and augment this process by identifying and removing obstacles to health and recovery …”

This vision of the physician’s primary role as facilitator of the patient’s own innate healing potential generated dynamic discussion among the Transformational Medicine program’s online distance learning participants. One physician, a family practitioner, commented: “One of the tenets of naturopathic medicine is the ability of the body to heal itself. This is a similar theme that is resonated in holistic medicine, integrative medicine, functional medicine, osteopathic medicine as well as some allopathic physicians who are ‘real doctors.’ The object is to support the body in its effort to heal itself and to remove obstacles to health and recovery.”

“It is a strange comparison but in some ways this is analogous to the creation of a very high-end stereo system. One starts out with the source (CD, vinyl, tuner) etc. Components that are later added to the system (cables, pre-amp, amplifier, speakers) can only degrade the source signal. The best systems do the least damage by adding only components that ‘get out of the way’ and support the natural sound. This goes back to the dictum, ‘first do no harm.’ Allopathic medicine in the stereo analogy colors the sound by adding pieces of information that were not originally there. The sound may appeal to some people but it is not ‘truth.’

“… Physicians using naturopathic modalities may include allopathic physicians with a holistic orientation. I feel the main difference between naturopathic physicians and allopathic physicians practicing naturopathic modalities (aside from the detail of knowledge that naturopathic physicians learn) is one of philosophy. Naturopathic physicians evolve into who they are because of the system. Allopathic physicians with a naturopathic approach become who they are in spite of the system.”

(Vondell Clark, MD, MPH, personal communication, November 2006)

Here the allegation is somewhat more serious. Does our model of
care not only underemphasize, but actually inhibit, the healing experience for the patient? A narrowly materialist application of the allopathic paradigm may unduly restrict our power as healers to identify and cultivate whole-person phenomena. Health care is wildly expensive, and purchasers demand to know what they are buying for their dollar. Objective biomedical measures are implemented, empha-
sized, and then overemphasized ad nauseam. Individual physicians inevitably capitulate to the pressure. Consider the example of the routine brief primary care office visit with the diabetic patient. Here the phy-sician may encounter a practically overwhelming checklist of tasks. Is glycemic control optimal? If no, what to adjust? Is the patient taking aspirin, lovastatin, and lisinopril? Proper doses? If not, why? Are eye and foot exams, and microalbuminuria screen up to date? Are vaccines all current? Other concurrent issues? All this in 10-15 minutes? Who has time then to actually talk, let alone listen to (or even look at) the pa-
tient? In our rush to “get everything done,” we may lose our connection with the patient as a human being, thus compromising our effective-
ness as healers.

Physicians’ Own Wellness

This experience is exhausting for us physicians in every way. Global Medicine’s Transformational Medicine faculty have recognized that the physician’s own wellness enables his/her ability to heal and transform others.13 The program includes an entire “personal ecology” block offering experiential training in yoga, meditation, and other self-help strategies and modalities to:

“... apply a holistic framework in one’s own life to enhance personal growth and health, ... to become an example for others in leading a healing life, and to create a path forward for ... continuing physical, mental, emotional and spiritual evolu-
tion and transformation, fueled by a thriving sense of awe.”14

Global Medicine thus transforms physician CME to a new level by recognizing and honoring the healing presence of the physician as an integral part of the treatment process.15

Where can such an approach lead? Physicians can arrive at an understanding that the allopathic model represents not The Medicine, but rather one of many medicines, each with unique history, culture, para-
digm, vulnerabilities, and strengths. Education in a broad range of such systems empowers the experienced physician to address the wide range of patients and pathologies at that level where they need be met. Transforming medicine may require nothing less. ✫

This work was supported in part by a grant (R01-AT003314-01A1) from the National Institutes of Health, National Center for Complementary and Alterna-
tive Medicine.

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The Nature of Narrative Medicine

By Lewis Mehl-Madrona, MD, PhD

The sufferer is a poet in search of metaphors adequate to express his predicament
—Laurence Kirmayer, MD

Speaking to Share Story

“When we speak, we usually speak to others and we speak about something (or about others)—and we do both at the same time, and by use of discursive means (such as lexical devices, syntax, … and gestures).” In essence, we tell a story—short or long. Our conversations are full of vignettes and tales, as are our diversions and entertainment.

Medicine is no exception. When we physicians speak, we speak to each other, to our patients, to representatives of insurance carriers, to administrators, and even to our own family members. When we practice medicine, we are always speaking about something—a patient, a particular medical problem, a procedure, a drug, our own frustrated emotions. And, we are in constant communication with each other and our patients. We are interacting. We are shaping a world as we go. We are using discursive methods to convince others to do things—patients to stop smoking, insurance carriers to pay, administrators to let us have more time with patients, family members to be more understanding about our hectic lives. In this respect, we are no different from healers the world over, though the content of our conversations may vary. We may talk drugs while Bantu healers talk herbs. We may talk surgery while a Dene healer talks about a many-day Blessing Way ceremony, but there is a similarity: we are in dialogue. We are co-creating a shared story of healer and patient/families/communities wherever we go. We are immersed in the art of storytelling.

Constructing Story

Kathryn Montgomery Hunter (1991) has written a wonderful book about the narrative structure of medical knowledge. She notes that the ancient craft of physicians and healers involved “… pondering the ways that predispositions and circumstances meshed with the laws of nature in a particular case” and in encouraging the patient toward recovery or midwifing his or her progression toward death. This approach is not unlike that of traditional North American healers, whether the circumstance involves a curse or the breaking of a taboo or a spiritual attack. Healers construct stories that have beginnings, middles, and ends about people with predispositions who encounter circumstances that lead to illness, progressing toward recovery or death. Medicine’s fascination with eliminating the person from this process and talking about the “natural history of disease” as if it existed independently of the people who suffer with the disease is part of the reification of the disease process into disease entities that has happened in the 20th century and continues into the 21st. We forget that we are still telling a story when we talk about an organ as much as we are telling a story when we talk about a person. The elements of the narrative remain. The characters differ.

Stories have characters who act in space and time within a plot. Stories are ideally performed as is the case for any oral tradition. They are creations or constructions. The histories that we physicians take are actually stories told by our patients about their suffering. The characters (patients, family members, other physicians) interact within the plot of diagnosing and curing the illness. Various saboteurs and adverse circumstances exist to potentially foil the plot and affect the happy ending. The story is enacted in each medical encounter to the extent that time and the doctor’s temperament will allow. And, even when the story is not fully presented (or is re-presented), it lies beneath the surface of the encounter, unexpressed yet just as powerful.

Changing Your Story

An example will help illustrate this concept. Terry is a woman, age 44 years, with a 24-year history of severe, relatively intractable, irritable bowel syndrome (IBS).
Terry came to see me because she had tried every conventional and unconventional approach to IBS and none had worked. She had been to gastroenterologists, the Mayo Clinic, the Cleveland Clinic, the local general practitioner, naturopaths, homeopath, acupuncturists, herbalists, kinesiologists, psychic healers, shamans, energy healers, reiki masters, chiropractors, osteopaths, and more. The center character of her story was IBS, perhaps even more central than she in her initial narrative. What was remarkable was how appreciating and helping her change her story about herself allowed her IBS to greatly improve.

Physicians do not usually pay attention to the person’s life story, and perhaps we should.

In a narrative approach, the identity of the person is a “master narrative,” a composite of all the stories that the person has accepted and repeated about him or herself. Sometimes we are only vaguely aware of the source of some of the “morals of the story.” We can remember the point and forget the source.

Through a combination of guided imagery, dialogue, and ceremony, Terry’s story emerged. She remembered being a seventh grader in a Catholic School and being very angry at God. She had learned to view God as a white-haired old man on a throne in charge of everything. She was angry at God for not making her life and her family’s life better. She thought if she were only more perfect and better behaved, God would smile upon them and make things better for them. This idea seemed to pervade her life—that God would reward you and take care of all the problems in your life, if you are only good enough. We found a five year old suffering under these beliefs as well as a three year old, barely aware of the concepts yet projecting the idea to pervade her life—that God would reward you and take care of all the problems in your life, if you are only good enough. We found a five year old suffering under these beliefs as well as a three year old, barely aware of the concepts yet comprehending the injunctions to be perfect. We went looking for other important characters in her internal mental world—characters who were telling stories that affected her life. One, whom she labeled the Saboteur, did everything possible to keep her from being happy because: “You don’t deserve it. You haven’t earned it. You aren’t good enough to be happy.” She began to reflect on the voices of all her relatives as she grew up; the meaning behind the stories they told her, their notions of life, their misery and pain. These characters resolved into those relatives and their stories that supported the ideas that she had internalized. The message she learned was “Be like us. Be unhappy. Day after day, life is the same old thing. Life is drudgery. You live for retirement; then you retire; and then you die.” How depressing, she thought.

The other theme underlying the stories with which Terry grew up was the security theme. Her parents were children during the Great Depression and therefore insisted that security was the ultimate value and goal. Terry was admonished against ever taking a risk, however small. She realized that she didn’t have IBS until she began working as an IT (computer) consultant, a profession that she hadn’t wanted, and only took because her parents insisted that it was secure. She remembered her mother scaring her into being dependent, living at home, not venturing out into the world. She dreamed of escaping. She recalled everyone in her family throughout her childhood saying, “No, you can’t (won’t, don’t, etc). You can’t do anything unless you’re perfect first.” These voices included her mother, maternal grandmother, maternal grandfather, father, and seventh- and eighth-grade teachers.

When we countered this story and co-authored a different story about being able to follow her passion, being able to take risks, and not needing God to fix her, the IBS began to change. Her symptoms improved as she became someone different from the voices left behind by her family. She re-evaluated her job and found a different position in which she had less pressure and anxiety. She re-evaluated her relationship and broke with a boyfriend who insisted that security was the ultimate value and goal. Terry grew up was the security theme. Her parents were children during the Great Depression and therefore insisted that security was the ultimate value and goal. How depressing, she thought.

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Constructing Our Truths in Story

Stories are made for audiences, and that is the role of the physician—to be a good audience, to help rewrite the story toward one in which healing seems more plausible to the patient. The physician must also be a storyteller and a healer. This is because people’s illnesses are grounded in discourses or stories which contain the meanings and values which we live.4,6 Culture and experience helps us to weave a coherent thread out of the many sometimes contradictory voices that bounce off the inside of our head.

Illnesses are part of the identities that we perform.7,8 They make or mark us as we wish or are wished to be.
seen. We evolve through our relationships and interactions with others. Illness is dynamic because we are dynamic. Some changes improve illness; others worsen illness. Patients and doctors position themselves with each other through their interactions. Through the doctor-patient dialogue, patients learn how to be patients, what to expect from life with an illness, and how to approach their illness. The conventional paradigm takes all accountability away from the sufferer except for taking medications as prescribed. The life story is not exploited. Unfortunately, expectation is important in predicting outcome. A pessimistic expectation leads to a more pessimistic outcome. The “patient’s story” has huge effects on the course of the illness.

Narrative approaches rely more on the expertise and resourcefulness of the sufferer than does conventional medicine, which relies on the expertise of the practitioner. Narrative approaches resemble what has been called eclecticism or integrationism in psychotherapy circles. Norcross described synthetic eclecticism, which attempts to synthesize many perspectives into one unifying theory, and technical eclecticism, which picks and chooses from various techniques without any need to accept the theory that generated these techniques. Integrationism strives to put together different schools of psychotherapy. What differs about these approaches is the assumption that there is a truth that can be discovered. Within a narrative approach, we realize that we are constructing our truths in story form because we simply cannot live without beliefs (truths) and we cannot function without making up stories to contain those truths. We explain our beliefs to each other by telling stories about how we came to accept these ideas. Some of these stories are highly technical, as in a biochemist explaining how he came to understand the structure of a receptor, yet they are still stories. They have temporal sequence; they have plot; they have characters; there is a logical movement through the story; and a value is discovered at the end (good science prevails). The value of the narrative perspective is its relevance to biological as well as psychological phenomena. When we realize that we are inevitably telling a story, even if that story is a mathematical proof, then we have a common language to move from field to field. Even if I do not understand the elements of the proof, I can appreciate the temporal movement of the argument; I can appreciate that the variables are the characters; I can appreciate that the mathematician is the narrator. I can see the plot unfold until, like a suspenseful murder mystery, the conclusion proves the theorem, and all is well in the world. Epidemiological investigations read the same way. All human communication is storied, even our communication with ourselves (what cognitive therapists call self-talk).

Why Does this Matter?

When we see the story behind people’s actions and statements, we can bring tremendous resources to bear on the problem. This is because we are all experts in story construction and interpretation. We have been doing it for longer than we can remember. We critique movies in accordance with the quality of the story. We tell stories about friends and colleagues. We read novels, attend plays, struggle to make sense of operas, and generally are immersed in story. When we understand that all problems, even cancer, are storied, we have many more resources to help us understand them.

How is Cancer Storied?

In its most simple form, cancer is a story about the rebellion of a single cell from the whole. A single cell mutates or is changed in some way and begins to replicate those changes. A drama occurs in which the immune system fights those changes and loses. The cancer spreads to clinical recognition. Then begins a human drama in which physicians use all the means at their disposal to attack and kill the cancer cells. Sometimes this kills the patient as well. Sometimes the patient mysteriously recovers. Sometimes the patient succumbs to the cancer. All this occurs in a context—on a stage, to paraphrase Shakespeare. When we see cancer as a story, I think it’s easier to see the potential interconnectedness of everything. For example, some people miraculously recover from cancer. My friend Alice is nine years cancer-free after a diagnosis of glioblastoma multiforme. This is highly unusual, though, because of my interests and lectures, I know a number of other people who are in her situation. Andrea’s story is one I never tire of telling. And, when I tell it, I mention the huge role in her recovery played by the large and amazing changes that she made in her life, her relationships, her work, and her spirituality. That’s my story and hers as well. I don’t downplay the chemotherapy and the radiation therapy, though I know from the data at the time of her diagnosis that...
these modalities were only expected to prolong her life by 4%. Every one of the patients who died received these modalities, though not all the patients who lived did. When I tell Andrea’s story, I can keep it as a story. I don’t have to explain exactly why it happened. I can make a meta-story which goes like this: some people make huge changes in their lives and these changes have physiological consequences and their cancer disappears. Can I predict in advance who these people will be? I have made such predictions, though I’m not entirely sure on what I base them. A neurosurgical colleague, Allen Hamilton, MD, of the University of Arizona, told me he could predict surgical outcome for brain cancer on the basis of the number of people present in the room at the first appointment, how many hugs he got before he left the room, and how much his mood improved while he was in the room. I think I can predict who will not have a miraculous recovery with better than chance odds. While transformation is unpredictable, the results of pessimism and despair are not. What I cannot understand and can only describe in story, is the process that people go through to arrive at the personal and interpersonal transformations that change lives.

Could any of us accomplish this? Few of us have been so challenged, and so we don’t know of what we are capable. This is where healing and recovery and their associated stories lack the capacity to be replicated on command. There is a mysterious, somewhat hidden process of transformation that involves shifts in multiple relationships and is perhaps better addressed through the principles of quantum physics than the classical mechanical, cause-and-effect models that are so familiarly used by us.

**Story or Evidence**

Here is another story. My friend Bernard developed a malignant astrocytoma (a brain cancer). We shared Andrea as a mutual friend. Bernard had seen what radiation therapy had done to Andrea’s cognitive capacity. He was a professor of mathematics and engineering. That was his passion. He would rather die than not be able to do mathematics. He declined radiation therapy. He had two injections of chemotherapy and decided that this would destroy his life as readily as radiation. He threw himself into making all the changes that we had seen Andrea make. He left a bad marriage. He fell in love. He quit his job that bored him and found a more exciting position a continent away. He returned to his homeland where his love lived, where he was surrounded by family and support. He had most of the cancer removed, but not all could be safely taken. It disappeared over the next two years and he is now seven years cancer-free. What a story!

Does it prove anything? Not in our usual hierarchy of evidence from the evidence-based medicine movement. But maybe that movement has missed the boat. It values most the evidence that is sometimes of limited clinical significance. If I have two drugs to prescribe, then I turn to evidence-based medicine to learn which is the better of the two for the patient I am treating (unfortunately, most drug studies have such rarified patients that I almost never find a study applicable to the patients I treat because they are far sicker and have more illnesses and other difficulties than study patients would ever be permitted to have.) If I want to ask the question, can people survive cancer, then I turn to stories like Andrea’s and Bernard’s. I say yes they can, but under conditions that are somewhat mysterious and hard to duplicate. That leads me to tell stories to patients, to inspire them to make their best effort. I have confidence that when they make that best effort, the ensuing meaning and purpose that results, the story that they and their family eventually tell about their challenge of cancer, contributes to a better quality life whether they live or die. If healing involves transformation and improvement of potentially every aspect of one’s life, from the spiritual through the relational to one’s own body, then, by definition, quality of life will improve through efforts at healing, even when the disease is not cured.

**Meaning and Purpose**

Perhaps this is the essence of narrative medicine—of appreciating the rich stories we have gained in our training, of appreciating the stories our patients and their families bring us, and of seeing ourselves as coauthors in the creation of new stories that have uncertain endings, at least while they are being written. Let us be eclectic in the sense of applying treatments that make sense within the story lived by our patients and their families. Let us be cognizant of our own “truths” as being just preferred stories for our lives, and not necessarily the gospel, even when our truth is the Gospel. Let us interact with people to foster transformation, to increase a sense of meaning and purpose, to weave together a rich tapestry of human lives, and within that story, let us rely upon evidence-based medicine to pick the best drug when we have a choice, but not to tell us that being human and collaborating in the richness of life has no value, when we know from our own stories, our own illnesses, our own life challenges, that it does. ♦
References

To Be Well
To wish to be well is part of becoming well.
— Lucius Annaeus Seneca, 3 BC-65 AD, Roman dramatist, poet, philosopher, and orator
Homecoming

By Geoff Galbraith, MD

Listen …

Bright linoleum tiles reflecting the fluorescent glow, monitors quiet, yet persistent blinking and cooing—me? Trepidation, on call, Saturday night in the ICU (… will there be something I can’t handle?) … quiet, patients “tucked in.” “Hmmm, may be a good night.”

Beeping … clarion call, ER—“58-year-old tourist in transit, collapsed, possible chest pain.” Down the stairs, ten floors, no waiting for elevators, too anxious to wait, chance to think, plan, imagine what might happen, glad to trot down.

Arrival, ambulance, urgent fanfare—gurney rolling, in position, quick team lift, “Watch the head.” Report out: “sudden collapse at the Kaiser Hawaiian Village, pulse rapid, thready, perspiring on arrival, not responding.” (Are we OK? Can’t really ask if there’s anything I’m forgetting?) “Is the family here?”

I entered the waiting room, just outside the unit, unlikely juxtaposition to an outdoor balcony lanai, with daytime oceanfront views over the Ala Wai Yacht Harbor, down the Waikiki coastline, to Diamond Head—city lights, soft breeze. Prepared to be confident and considerate. So many tourists crash on their well-deserved Hawaii vacations, sad. Husband seated on the edge of a chair, daughter in her twenties, standing, looking anxious. I introduced myself and confided, “It looks like she’s had a heart attack. She’s doing as well as can be expected. We shocked the heart once and she came right out of it, but she’s quite ill.” The history: “seemed like indigestion or maybe a flu. We’re all tired.”

“Doctor, my wife is a Christian with strong faith. We’re Oklahoma Baptists. We have strong faith and trust in God’s will.” (Reassurance? How should I relate to this declaration of faith?)

“I’ve got the head, tube please, 7 Fr—extend, “… little glottal pressure please, see it (hope ...) IN! breath sounds bilaterally.” (Ooh, that was pretty slick, you’re getting good ...) Pressure’s down, no real pulses—“OK, let’s take her up.” “Family?” “Husband and daughter following.”

The rush was consuming. Dire straits, but things were going well, so far. Lights brighter, new energy. Lines in: arterial, CVP, drips, vent settings, Foley, fluids, not unlike initiating a sea journey, sails up, rudder, trimming into the wind, watching the flutter disappear, clear the lines, no confusion. “Is the family here?”

I reviewed the medical equipment to reassure, in some way lessen the horror. “I’ll be here with her all night and will keep you informed of any changes.”

Around 2 am, things getting better. Blood pressure up and able to decrease toxic pressor meds, slowly, gently, watching the monitors. “She’s got urine.” (Good sign, kidney perfusion ... she does seem to be moving forward on her own).

I spoke with the daughter and husband several times that night, another visit to the bedside, this one lighter, more hopeful … her heart seemed to be coming back, life force (… and I was feeling relieved, with not a little pride; me, the nurses, the team felt encouraged in our mission to save a life). On the last stop, I heard the husband softly say, as if to himself, “I hope this is what she wants.” (Leaving, hmmm ... what did that mean? … I misheard ...)

In the early dawn, I had just been outside ICU, breathing the fresh air, GEOFF GALBRAITH, MD, is an internist and Vice President of Quality Improvement for the Hawaii Permanente Medical Group. E-mail: geoff.t.galbraith@kp.org.
watching the light revealing colors, contrasts, a sense of awakening, my pager beeped. “Doctor, she’s waking up.” Quizzical anxious look, darting eyes, gently tugging against wrist restraints. “Hello, you’re in the Kaiser Hospital, you’ve had a heart attack and are really doing well.” To allay her concerns, I explained the breathing tube, a plan to remove it, the tubes for medications, the urine catheter ... an expert orientation on this waking nightmare; she may really pull through ... Nodding her understanding and willing assent, we removed her restraints, and promised to call RT to confirm the OK to remove the ET tube. (I have to let her family know, this is soooo good!)

As I was walking from the bedside, I felt a sudden energy, quickly looked back. As if in slow motion, she was up, and with a definitive sweeping gesture, “my patient” (daughter, wife, mother) dramatically removed the ET tube and screamed at me, “MURDERER ... MURDERER!! YOU ... WILL ... NOT ... BRING ME BACK!!”

CRASH … quick, rush to the bedside, reach out to hold, to control, to reassure, to comfort ... no words, shocking interruption on the sail to survival, get technical, art line’s OK, CVP? Re-intubation worked, O2 on (What just happened?).

No return to the ‘trimmed sailing,’ skills aren’t working, BP’s falling, despite pressors—all three fluids. (What is happening? This should be working! I’m losing her! Why did she do that?) In minutes, before the surprise and shock could be fully resolved, before I could understand, the life force was leaving her body.

Nothing worked in the irrevocable, fatal transition.

“I do not know how to tell you this. I’m so sorry. Your wife expired.” (Do I dare tell them what really happened? Yes—I have nothing else to tell them, no good explanation, and I’m embarrassed by my optimism and swelling confidence during the night.) After telling every detail, including her exact words to me, they were quiet. She reached out, touched his arm, he looked down. His communication was clear, not knowing, open. “I think this is what she would have wanted.” She was home now.

Listen …

Coming Home Again

There’s nothing half so pleasant as coming home again.

— Margaret Elizabeth Sangster, 1838-1912, American writer and editor
Volunteerism and Homeless Health Care

Dear Dr Jacobs,

Thanks for writing an article about volunteerism, and homeless health care, and for encouraging physicians of all specialties, and their families, to get involved. (Jacobs L. Looking for an opportunity to serve your community? Suggestions on volunteering at a homeless medical clinic. Perm J 2007 Winter;11(1):70-1.)

The homeless represent a diverse group of people that includes some vulnerable patient populations, with special needs. Some of these needs include mental health, care of developmental disabilities, and substance abuse. I would refer you to American Family Physician’s recently published review in: The Homeless in America: Adapting Your Practice1 and editorial: Health care for the homeless in America.2

I’m concerned that your editorial will have the indirect effect of trivializing the needs of the homeless, and defining their health care needs in terms of what individuals can provide for them through “volunteerism.” Furthermore, I am disappointed that The Permanente Journal, representing the largest physician group in the country, is not addressing the larger issue of the responsibility of health care professionals and health care corporations for creating sustainable systems of care for vulnerable patient populations.

Organizationally, we should strive to create and promote sustainable systems of care that provide comprehensive primary and preventive services for all people. In our zeal for “volunteerism,” we should not support the creation of a secondary standard of care for any population, on the basis of their social circumstance. We should instead encourage individuals to be part of larger structures that do a better job of providing comprehensive services. We should also push our corporation to sponsor our volunteer activities in this direction.

Looking forward to further communication.

Brian Hertz, MD
Family Medicine
San Rafael, CA; San Francisco, CA

References

— Reply
Dear Dr Hertz,

First of all, I want to thank you for taking the time to respond to my editorial on practitioner volunteerism at homeless clinics. The sooner there is an extensive dialogue on this important subject, at both the individual and corporate level, the sooner a solution will be forthcoming.

In response to your specific comments, I don’t believe that readers of my editorial will in any way feel that the needs of the homeless are trivial. On the contrary, I suspect that by serving they will develop a richer understanding of the complexities of this challenge. I’m sure you agree, gifted practitioners should not wait for a governmental or corporate solution before they get involved in providing care at a homeless clinic. Practitioners who have experienced firsthand the special needs of the homeless person are much more likely to become the passionate advocate for these people in need who, as you mentioned, are in need of a more sustainable system of care.

What is the role of large medical groups in the solution? Are there societal obligations that mandate that they provide a solution? I’m glad you raised the question; I’m anxious to hear what our readers have to say on the subject. Although I don’t have the answer, I have also wondered if churches, synagogues, and other religious organizations might also have obligations to be part of the solution.

Finally, I believe that it is important that volunteer efforts remain personal, including both finances and time off, otherwise it would not truly be volunteerism. Although organizations might promote volunteerism through organized efforts such as encouraging employees to take part in corporate-sponsored events (eg, the Susan G Komen Race for the Cure) and organized corporate responses to disaster (eg, the Northern California Tsunami response). However, any further involvement would necessitate leadership having to make judgments on what type of volunteer activity might be subsidized and what might not.

Again, thank you so much for your letter. I hope that this dialogue increases awareness and encourages physicians and other practitioners to get involved in care systems for the homeless patient.

Lee D Jacobs, MD
Associate Editor-in-Chief
With this issue, we include abstracts from the 2007 13th Annual HMO Research Network Conference held in Portland, Oregon, which focused on: “Building a National Research Model: The Future of HMO-Based Research.”

From: Geisinger Health System and Lund University

Worse diabetes control in US compared with Swedish patients from similar populations despite more rigorous intervention.

Langer RD, Lindblad U, Melander A.

Objectives: To evaluate diabetes control in regions with similar racial/ethnic mix, infrastructure and physical environment in Pennsylvania served by the Geisinger Health System (GHS), and Skaraborg, Sweden, with comprehensive care through a public health service.

Methods: Using longitudinal electronic health records containing similar detail we identified 26,433 GHS patients (12,829 men and 13,614 women) with diabetes seen within the prior two years, and 10,391 patients (5,473 men, 4,918 women) in the Skaraborg Primary Care Database (SPCD). Equivalent data on demographics, HbA1c, height, weight, and medication use were extracted for both populations. We defined Uncontrolled Diabetes (UD) as HbA1c > 7.0.

Results: Mean HbA1c was 7.54 in GHS (n = 17,958) and 6.29 in SPCD (n = 9945). UD among patients with HbA1c measured within two years was more than twice as high in GHS (60%) versus SPCD (25%) patients. Including patients with no HbA1c in two years as UD, the GHS rate increased to 73% and the SPCD rate was unchanged. GHS patients used a mean of 1.6 diabetes drugs compared with 0.9 for SPCD (p < 0.001). In logistic regression adjusted for age, sex, BMI, number of diabetes drugs, and insulin dependence, the odds for UD in GHS patients compared with SPCD was 6.9 (p < 0.001). Restricting the analysis to patients with similar medical coverage (Geisinger HMO and all SPCD), the odds ratio (OR) was 5.9 (p < 0.001). Models restricted to users of a specific class of drug demonstrated similarly robust differences. With adjustment for all factors above plus insurance, or all factors above restricted to GHS HMO and SPCD patients, ORs were: Biguanides 5.6 and 5.2, Sulfonylureas 6.1 and 5.5, insulins 6.2 and 5.5, glitazons 9.1 and 8.5, meglitins 4.9 and 4.4, combinations with metformin 12.4 and 14.1, and other less common drugs 5.3 and 4.8; all p < 0.001.

Conclusions: These marked differences in diabetes control between similar populations in the US and Sweden are robust to control for BMI, treatment and access to care. Diet, compliance with treatment, other physical and social environmental factors, or gene-environment interactions may be involved and should be explored.

From: HealthPartners, Minnesota Community Measurement, Preferred One, Blue Cross Blue Shield, HealthPartners Research Foundation

Improved diabetes care using a single comprehensive diabetes quality measure: The Minnesota experience.

Amundson GM, Chase JA, Frederick JP, Hiza DJ, O’Connor PJ, Sulberg LI.

Objective: To describe a comprehensive diabetes quality measure used by Minnesota Community Measurement (MNCM), and recent trends in diabetes quality of care.

Methods: MNCM classifies each patient with diabetes as meeting or not meeting all these measures: glycated hemoglobin (A1C) ≤ 8.0, low-density lipoprotein cholesterol (LDL-chol) <130 mg/dL, blood pressure under 130/85 mmHg, documented nonsmoking status (NSMK), and regular aspirin (ASA) use in those over 40 years of age. Performance data is derived electronic data or manual chart audits for a random sample of at least 60 adults with
diabetes at each provider group. Chi-square tests and nested multivariate logistic regression models were used to assess trends.

**Results:** Provider groups are making vigorous efforts to improve diabetes care. The proportion of diabetes patients who achieved recommended levels of all five components of the comprehensive diabetes measure was 7.6% in 2001, 11.7% in 2002, 12.0% in 2003, and 15.4% in 2004. There is considerable variation in the composite measure across provider groups; in 2001 the range across provider groups was 1% to 20%, and in 2004 the range across provider groups was 1% to 40%. In 2001, 6% of provider groups had over 15% of patients meeting this measure, and in 2004, 46% of provider groups had over 15% of patients at this goal ($X^2 = 20.8$, $p < .0001$). In 2005, among the five measures, the one with the lowest proportion of patients at goal was BP (41.7%), followed by ASA (60.3%), A1c (62.3%), LDL (62.9%), and NSMK (63.6%).

**Conclusions:** These data show substantial improvement in diabetes care in a short period of time in a large geographically defined community. It is likely that at least part of the medical group motivation to improve diabetes care was related to implementation of a commonly agreed-upon publicly reported comprehensive diabetes control measure. The remaining variation across medical groups suggests that further substantial improvement in community levels of diabetes care are possible, and that special attention to BP control may be indicated for many of the participating medical groups.

**From:** Marshfield Clinic Research Foundation

**Childhood overweight and the incidence of distal forearm fracture.**

Coleman LA, Mukes BN, McCarty DJ.

**Background and Aims:** A rising prevalence of obesity among children and adults over the past several decades has been accompanied by an increase in the incidence of distal forearm fractures among individuals <35 years of age. Reasons for this trend in fracture incidence are unclear and likely to be multifactorial. The objective of the current study was to report the incidence of distal forearm fractures by childhood weight status among participants of the 1982 population-based Heartwatch study.

**Methods:** In 1982, 3106 children ages 5-15 years from 16 public and private schools in Marshfield, WI participated in a cardiovascular disease risk factor study (80% response rate). Baseline measure included a health, dietary, and family history questionnaire, blood pressure (BP), height, weight, and fasting serum lipid and lipoprotein measurements. Ninety-nine percent of the cohort received medical care at the Marshfield Clinic. Baseline data were merged with Marshfield Clinic data on distal forearm fracture (ICD-9 codes 813.00-813.93) identified from electronic medical records to determine fracture incidence in the cohort over time. Subjects with <5 years follow-up ($n = 255$) were excluded from analysis.

**Results:** Overall distal forearm fracture incidence was significantly greater in males vs females (11.4 vs 7.7%, respectively, $p = 0.0002$). For males, there were no differences in fracture incidence by childhood weight status. For females, the incidence of forearm fracture was greater among overweight subjects compared with healthy weight subjects (odds ratio: 1.78, 95% CI: 0.94, 3.2), particularly after age 11 years.

**Conclusions:** Among female members of the Heartwatch cohort, the incidence of distal fractures was greatest among subjects who were overweight during childhood. This finding is consistent with the literature showing that overweight, in combination with site-specific bone weakness, contributes to fracture risk.

**From:** Meyers Primary Care Institute

**Patterns of care, medication use and drug expenditures for the oldest old with diabetes mellitus.**

Tjia J.

**Background and Aims:** American Geriatrics Society guidelines for diabetes mellitus treatment suggest individualization of care for older adults based on health status, patient preference and life expectancy. Benefit from aggressive medical therapy for diabetes in the oldest old is unclear and patterns of preventive care, pharmaceutical treatment and medication spending for diabetes in the oldest old are not well described. The aim of this study is to examine, among the oldest old ($\geq 80$ years) compared to younger old adults (65-79 years), differences in the receipt of preventive care, patterns of medication use and overall drug spending, controlling for potential confounders including comorbid conditions and diabetes complications.

**Methods:** Using data from the 2001 Medical Expenditure Panel Survey (MEPS), we examined patterns of care, medication use, and drug expenditures of adults with diabetes aged 65 years and older, controlling for sociodemographic characteristics, health status, and complications from diabetes. Drug expenditures adjusted to 2006 US dollars were stratified by age.

**Results:** Overall, the oldest old had a higher burden of retinal and renal complications from diabetes (40.6% vs 30.5%, $p = 0.05$). The oldest old were less likely to have podiatry exams (29.7% vs 37.0%, $p = 0.17$) and were not less likely to have at least one HbA1c checked in the past year (37.7% vs 40.4%, $p = 0.48$). Of the oldest old, 15.9% used innovative hypoglycemic agents compared to 16.4% of the younger older people ($p = 0.89$). Innovative hypoglycemics included thiazolidiones, meglitinides, alpha-glucosidase inhibitors and rapid-acting insulins. The oldest old with complications were less likely to use lipid-lowering drugs (22.05% vs 48.5%, $p = 0.003$) than their younger old counterparts. Overall drug spending adjusted for sociodemographic and clinical characteristics was not significantly different between oldest old and younger old adults ($\$2410$ vs $\$2298$, $p = 0.30$).

**Conclusions:** Quality of care for the oldest old with diabetes appears to be no different than for younger old adults with the exception of the use of lipid-lowering drugs. In addition, overall adjusted drug spending was no different for the oldest old. Further investigation is necessary to understand whether this pattern of care is consistent with the patient care goals and whether this leads to prolonged independent functional status, and improved health outcomes.
BOOK REVIEW

How Doctors Think: Clinical Judgment and the Practice of Medicine
by Kathryn Montgomery, PhD

Kathryn Montgomery, a Professor of Medical Humanities, has written a book about the way physicians think and how we came to think that way. Her book is an unusual combination of highly readable academic erudition with fascinating observations and insights. Its origins lie in a college course she once gave in the origins of scientific knowing, and the fact that a number of her advanced placement students sought letters of recommendation from her to medical school. Seeing her former students after their acceptance and entry to medical school, she quotes a pediatrician’s description of first-year medical students as “looking like children who had been abused.” But perhaps the nidus upon which this book crystallized was the diagnosis of breast cancer in her 28-year-old daughter. Professor Montgomery is on two medical school faculties where she has spent many years studying how physicians come to know what we know, do what we do, and think the way we think. “Misunderstanding the epistemology of medicine—how doctors know what they know—has damaging consequences for patients, for the profession of medicine, and for physicians themselves … . The costs are great. It has lead to a harsh, often brutal, education, unnecessarily impersonal clinical practice, dissatisfied patients, and disheartened physicians.”

This is a profound and important book that will be of interest to those many physicians who have gotten beyond the anxious burden of acquiring the core scientific knowledge of medical practice. She makes it clear that medicine is not a science, but a science-using practice with a collection of well-honed skills involving a special familiarity with death. “The physician’s best clinical instrument—diagnostic or therapeutic—is the physician herself. How in the world is that capacity acquired?” Michael Balint made a similar observation in the introduction to The Doctor, His Patient, and the Illness: “… by far the most frequently used drug in general practice was the doctor himself.” How this pharmacology of the human comes to be, even largely unconsciously, is the theme of the book.

The author describes how “What counts clinically is the ability to sort through incomplete and potentially imprecise information to determine what is going on with a particular patient and then, often without much in the way of certainty, to choose an effective course of action. This may come to seem like common sense, but, if so, it is common sense about very uncommon matters.” Her productive re-exploration of her early statement that medicine is not a science, but a science-using practice, reminds me of a wonderful comment by Walsh McDermott: “Science is what validates 20th century medicine. I don’t mean what it’s based on; that’s a totally different matter” (1974, comments in a post-graduate address).

She also explores why medical education is frequently brutalizing, leading to an impoverished clinical practice. Chapter 10, The Self in Medicine, makes good background reading for those administratively concerned about physician morale in the Permanente Groups. “Patients seen hurriedly, one by one, are likely to pose only diagnostic and technical rather than human or social problems. Physicians … are distracted from the social and economic components of the maladies they treat.”

“How best to live one’s life is the central moral question for every human being, well or ill. Life-defining illness only sharpens the need for an answer.” Standing in witness to that problem is not the least of our responsibilities. In a time where evidence-based medicine has become the new mantra if not shibboleth of the engineering model of the physician, Kathryn Montgomery’s analysis of the subtleties of the development and meaning of clinical judgment, and its relationship to the complex nature of medicine, is a welcome counterpoint.

* Walsh McDermott, MD. Professor of Medicine and Professor and Chairman of the Department of Public Health Cornell University. Extemporaneous comments in a post-graduate address at the Johns Hopkins Hospital.

References

Vincent J Felitti, MD, FACP, is an Internist in the Department of Preventive Medicine at the Clairemont Mesa Medical Office in San Diego, CA. He is a Clinical Professor of Medicine at the University of California, San Diego. He is also an Expert Reviewer for the Medical Board of California. E-mail: vincent.j.felitti-md@kp.org.
Many physicians will find that this impressive book reveals what we do in clinical practice in an unexpectedly refreshing way. The view is as seen through the eyes of a learned woman, an English professor, who took it upon herself to spend a number of years with physicians and medical students in order to study the use of narrative in medicine. Her book is practical, erudite, interesting, and philosophical in the best of ways.

The author's observations on the role of narrative in medicine are helpful; her comments on the role of science in medicine are insightful, as are her observations on the nature of what we accept as evidence, and how we deal with uncertainty. She explores the limits of “evidence-based” and how we came to “present” patients in the stereotyped way we do. “Medicine is not a science. Instead, it is a rational, science-using, inter-level, interpretative activity undertaken for the care of a sick person.”

Overall, this is a book about what we do, how we do it, and why we do it that way. It is dedicated to thinking about the implications of our routine processes, processes that are so ingrained that it is hard to imagine there might be other ways of carrying them out. It is quite helpful to see all this through the eyes of such an intelligent and attentive observer. That view helps us better understand what we do and how others see it. It also exposes problems, and sometimes the basis for failures.

Two quotes exemplify the nature of this book. The first is L. J. Henderson’s (of Henderson-Hasselbach Equation fame) comment in an article in *Transaction of the Association of American Physicians* (1936) titled, “The Practice of Medicine as Applied Sociology.” “In an interview listen, first, for what the patient wants to tell, secondly, for implications of what he does not want to tell, thirdly, for implications of what he cannot tell … I suggest that it is impossible to understand any man as a person without knowledge of his environment and especially of what he thinks and feels it is, which may be a very different thing.”

The second quote is from Leon Kass, physician, biochemist, ethicist, and Henry Luce Professor of Philosophy at the University of Chicago: “Medicine … is a fertile ground for understanding the moral relation between knowledge or expertise and the concerns of life.” Indeed, it has often seemed that the great gift of medical practice is to allow us participation in the great dramatic moments of other people’s lives, the better to understand our own, and the world.

For those wishing a thoughtful exploration of the nature of what we do, technically and humanistically, this is a book to be welcomed.

Reference


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**The Birth of Ideas**

A library, to modify the famous metaphor of Socrates, should be the delivery room for the birth of ideas—a place where history comes to life.

— *Norman Cousins, 1915-1990, American editor and author.*
Parenting: The First Three Years
A Group-Based Positive Parenting Program
by Juvata Rusch, MA, MS, and Laura Backen Jones, PhD

Adverse events in childhood have been linked to later addiction, disease, disability, and early death, suggesting the importance to public health of programs supporting parents and families in the early years. The Birth To Three organization, founded in Eugene, Oregon in 1978, provides support groups and dissemination of scientifically validated information on child development to new parents. Birth To Three has now served many thousands of parents in the US and abroad. Parents learn how to raise competent and caring children in a socially supportive environment. With Birth To Three’s recent publication of Parenting: The First Three Years, other organizations and communities can implement this novel and exciting approach to improving the early lives of children. Pediatric services, health prevention programs, hospital and home nursing services, community parent education and extension services will all benefit from this support-group-based curriculum.

Parenting: The First Three Years is a user-friendly package made available through Parenting Now!, a division of Birth To Three. The curriculum, written by two parent educators and carefully reviewed and edited by both developmental scientists and cultural review committees, includes guides for parent educators, booklets for parents, and illustrative videos/DVDs for each of three age-graded programs (the “Incredible INFANTS,” “Wonderful ONEs,” and “Terrific TWOs,” with ten sessions in each program). Meeting plans are provided for each session, allowing parents to learn from other parents and from the scientific literature, and from observations of and interactions with their own and other children.

Parent groups in the program are set up according to the date of a child’s birth; each group includes a broad range of parental socio-economic status, culture, and education and both mothers and fathers enjoy the program. Infants attend meetings with their parents, and ones and twos play in a separate room. A major goal of the program is to respect diverse cultural backgrounds and values. Within this atmosphere, parents are guided toward understanding their child’s developmental stages and individual temperament, and how their values can be implemented in a problem-solving framework. The support group aspect of Parenting: The First Three Years is critical. There are no lectures, and parents often model problem solutions for other parents. In Birth To Three, most parent groups have continued to meet well beyond the program years, with some continuing even after their children have graduated from high school or college.

The curriculum includes materials for parent educators and information on how to set up a new program. The Parent Educator Guide covers a broad set of topics, ranging from the program’s philosophical underpinnings to how to develop group process skills. There are background notes on each session’s topics, discussion questions, exercises, information on what to expect, and a script that can be adapted to the group. The curriculum includes a four-minute overview video to be used with sponsoring groups or agencies, funding sources, and potential parent participants. When further questions arise, the Birth To Three organization is available for consultation.

It is not possible to convey the full richness of this program, other than suggesting that you examine materials from the package. Parenting: The First Three Years can provide either a well-developed, stand-alone service or an exciting component of a broader program. The curriculum is available through www.parentingnow.net.

Reference

Mary K Rothbart, PhD, is a Distinguished Professor of Psychology, Emerita at the University of Oregon in Eugene. E-mail: mary-roth@uoregon.edu.
Play Golf Forever
by Michael Jaffe, DO; Brian Tarcy (sportswriter) and Ron Brizzie, DO

Filled with clear, concise descriptions, practical advice, and simple instruction, Play Golf Forever uses this popular sport as a way to address the chief cause of disability for many of us: low back pain (LBP). Most importantly, the book provides an effective map to recovery from this difficult problem.

Michael Jaffe, DO, an experienced physiatrist with the Southern California Permanente Medical Group in San Diego, Brian Tarcy, and Ron Brizzie, DO lighten the physiology lecture with real-life examples of famous golfers as well as some ordinary patients. Their statistics reassure us that although back pain is very common, most people improve without treatment, and that less than 1% of LBP is due to life-threatening illness or requires major surgery.

Play Golf Forever is divided into three sections: The Back, The Game of Golf, and The Program. In the first section, the authors explain how we express ourselves through movement of our bodies, and how complex those movements really are. Then, they define “functional training,” the revolutionary new approach to sports fitness, and why it works so well. We learn how both prevention of injury and recovery are not based on bed rest, but on getting moving again.

Next, the authors describe the four basic causes of LBP and how they relate to playing golf. The book clarifies how to recognize when back pain requires immediate medical attention (thankfully not often) and details effective treatments, from medications and injections to electrothermal therapy, and, as a last resort, surgery. After establishing a firm foundation, the authors analyze the golf swing itself, dividing it into specific components to improve performance.

In the final section, we learn that it’s better to do the most challenging exercises first, because sports injuries occur more often when we’re tired. Another helpful chapter describes the proper way to do many basic movements—including sitting, standing, getting up, even lying in bed. We see that doing simple physical activities correctly can protect and strengthen us over time.

Finally, they lay out “The Program.” Simply put, this set of low-tech but challenging exercises can change your life, golfer or not. My brief experience in working with Dr. Jaffe has taught me that functional training improves all sports and balance activities I’m involved with, and pays off quickly. If you fill this exercise prescription, you get results, period. The program includes chapters on stretching before being active, and “low impact” modifications for those needing a slower start back to fitness.

To sum it, Play Golf Forever gives golfers of the world a tremendous gift: not only to play longer, but to play longer (ie, hit the ball farther); a link from relief of pain all the way to their “Inner Tiger” (or Annika). For the rest of us, this easy read is a powerful guide to injury prevention and substantially improved performance in whatever we do. As the authors say, “motion is life.” Now we have a clear guide to doing it right.

Loyalty
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**EDITORIAL OVERVIEW**

4 Quality through Sustainability and Translatability, Tom Jarniak, MD

The Original Articles in this issue demonstrate the importance of sustainability and transferability in the process of quality innovation.

**ORIGINAL ARTICLES**

2007 James A Vahs Award for Quality Second Place Selection

5 Early Start: An Integrated Model of Substance Abuse Intervention for Pregnant Women, Christa Stallar, LCSW, BCD, Nancy Geller, MD, Mary Anne Armstrong, MA, Kathleen Halsey, MD, Veronica Ojyo

Because of prior limited success with substance-abuse problems in pregnant women, a new program was developed, tested, and widely transferred. Key elements are universal screening and embedding of substance-abuse specialists within Obstetrics Departments.

12 Understanding Panel Management: A Comparative Study of an Emerging Approach to Population Care, Esther (Esta) B. Neuwirth, PhD, Julie A Schmittdiel, PhD, Karen Tallman, PhD, Jim Bellow, MD

This report examines the successes and problems of this rapidly spreading form of team assistance to primary care physicians in management of populations of patients. An important component consists of communication, largely by telephone, by highly knowledgeable medical assistants.

21 Church-Based Heart Health Project: Health Status of Urban African-Americans, Lisaann S Gitter, MSc, Salwa E Hassamion, PhD, RN, Patricia L Murphy, MD

In 2004, a community project was implemented to address the cardiovascular health disparity in the African-American population of greater Cleveland, Ohio.

2006 David M Lawrence, MD, Chairman’s Patient Safety Award

26 Promoting Patient Safety: The Rapid Medical Response Team, Dawn Gould, RN, MBA, CNS

With teams of an ICU charge nurse and a respiratory therapist and directed primarily at non-ICU medical and surgical patients, this program reduced adverse events, death, and need for ICU transfers. Readiness to initiate the process and education of the staff were major elements.

**REVIEW ARTICLE**

Clinical Evidence Review: Best Practices for Pregnant Women of Substance Abuse Intervention within Obstetrics Departments, Patricia delia, MD, David W Price, MD, FAAFP

In this review of a common and dangerous illness consideration is given to definitions, diagnosis, risk stratification, and acute and longer-term treatment.

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