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Quality Improvement

Perioperative Tight Glycemic Control: The Challenge of Bariatric Surgery Patients and the Fear of Hypoglycemic Events

By Bellal Joseph, MD
 Jeff Genaw, MD
 Arthur Carlin, MD
 Jack Jordan, MS
 Jean Talley, RN, BSN, MSN, APRN
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Abstract

Background: Tight glycemic control (TGC) is rapidly becoming a standard of care for all hospitalized patients. However, fear of hypoglycemia has proven a potent barrier to adoption of such initiatives by physicians and medical staff. Henry Ford Hospital has pursued aggressive glycemic control for all hospital patients. Because the initial standard TGC protocol (TGCP) was insufficient to improve glycemic control in our bariatric surgery patients, we hypothesized that a more intensive protocol would be necessary to improve glycemic control for this group.

Methods: As part of an institutional quality control project involving TGC, we reviewed medical records for the bariatric surgery patients at our hospital. We divided the populations into three subgroups: prior to TGC (A), initial hospital rollout TGC (B), and intensive bariatric TGC protocol (C). Patient populations were compared using hospital administrative databases and clinical chart review. Metrics for successful glycemic control included percent hypogly-

cemia (glucose <50 mg/dL), in-range percent (glucose 80–150 mg/dL), mild hyperglycemia (glucose 151–250 mg/dL), and major hyperglycemia (glucose >250 mg/dL).

Results: The percent in range for group C improved to 71% but was not statistically different from the values for groups A and B. The incidence of hyperglycemia was significantly decreased in group C as compared with groups A and B at both the minor (20% vs 31% and 27%) and major levels (1% vs 4% and 2%) ($p < 0.001$). There were no differences in the rates of hypoglycemia.

Conclusion: As an ongoing quality improvement process, our institution has pursued TGC for all of its patients. Glucose control in bariatric surgery patients is resistant to standard TGCPs. An initial intensive TGCP can be safely implemented in bariatric surgery patients with no increase in the number of hypoglycemic events. This work represents follow-up of several plan, do, check, act (PDCA) cycles related to improvement with a hospital-wide TGCP.

Introduction

Glycemic control in both diabetic and nondiabetic hospitalized patients is a major therapeutic focus. Reversal of hyperglycemia is now linked to better clinical outcomes in medical and surgical patients.¹ Initial studies of tight glycemic control (TGC) were first reported in specialized centers. Because of improved clinical outcomes, tight glycemic control protocols (TGCPs) have been disseminated throughout the hospital setting, especially for patients having acute myocardial infarction, cardiac surgery, infections, and critical illness.^{1–5} There is a nationwide institutional pursuit

of implementation of improved glycemic control for all inpatients. A standardized method for application of TGC in inpatients outside the previously established patient populations is still emerging.

Redefining the standard of care with TGC has added an exciting new aspect to improved quality of care. The Joint Commission on Accreditation of Healthcare Organizations has listed insulin as one of the five highest-risk medications in an inpatient setting.¹ The fear of hypoglycemia is an important barrier to successful implementation of TGC. The aim of improving patient care while minimizing adverse effects is challenging in

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TGC. Acknowledging, accepting, and applying what we have learned over the past few years will broaden the application of TGC for specialty populations. The absence of a single standard system for TGC in variable patient populations makes it necessary to establish quality improvement measures.

Our objective was to correlate TGC in bariatric surgery patients with system-wide quality improvement initiatives. Our records revealed that the initial standard TGCP for bariatric surgery patients did not lead to an improvement in glycemic control. Glucose level in subset of patients was found to be more difficult to control than in our other postoperative patients. Therefore, we hypothesized that a more intensive TGCP would be necessary to improve glycemic control in bariatric surgery patients.

Methods

We collected data on 461 patients undergoing bariatric surgery at our institution between June 2003 and June 2005. The project was approved by our hospital institutional review board. Data from postoperative bariatric patients were collected concurrently and entered into a database. Information collected included blood glucose measurements, demographics, body mass index, surgical technique, wound infections, and length of hospital stay. The patient populations were divided into three subgroups. These included Group A: prior to TGCP, Group B: initial hospital roll out of TGCP, and Group C: intensive protocol for bariatric surgery patients. Administrative databases were used to perform chart reviews of our patient populations. Minitab version 13 software (Minitab Inc, College Station, PA) and Microsoft Office Excel (version 11, Microsoft, Seattle, WA) were used for data analysis. We defined the metrics of successful glycemic control by defining the ranges as hypoglycemia (glucose <50 mg/dL), in-range (glucose 80–150 mg/dL), mild hyperglycemia (glucose 151–250 mg/dL), and major hyperglycemia (glucose >250 mg/dL). These were the quality metrics chosen for monitoring, levels between 50 and 79 m/dL were not considered “in range” but were not counted as hypoglycemia. The sliding-scale insulin dosing was performed with Insulin Aspart (NovoLog, Novo Nordisk, Princeton, NJ), administered by subcutaneous injection. Initially all patients were started on level 1 TGCP, as seen in Table 1. Blood sugar levels were measured before meals and at bedtime or if patients were not allowed to eat or drink, their blood sugar levels were measured every six hours. The sliding-scale protocol was reassessed after two consecutive blood glucose measurements

exceeding 150 mg/dL or for two consecutive blood glucose measurements less than 100 mg/dL. The TGCP was increased or decreased, respectively, by one level if glucose measurements met the above criteria. The intensive bariatric surgery protocol was initiated after it was noted to be inadequate when reviewed by the system quality improvement committee. It was noted that unlike all other surgical subgroups, bariatric surgery patients demonstrated no significant change in control (based on chosen metrics above) with the standard hospital protocol. A new approach was formulated, and consisted of the same protocol listed in Table 1. However, treatment for all postoperative bariatric surgery patients whose care followed the intensive protocol were initiated at level 2 instead of level 1. Data was summarized using Excel and Access (Microsoft, WA). Discrete variables were compared using χ^2 analysis with two degrees of variability. Statistical significance was assumed at $p < 0.05$.

Results

Data for a total of 461 postoperative bariatric surgery patients, divided into groups A, B, and C, were reviewed. Of these, 379 (82%) were women. The mean body mass index values for groups A, B, and C were 51, 58, and 51 kg/m², respectively. The majority of operations performed in protocol groups B and C were laparoscopic, whereas only open operations were performed in group A. The observed increase in length of stay and incidence of wound infections in group A is likely secondary to changes in surgical technique (Table 2). Both wound infections in group C involved the only two open operations in that group.

Metrics of successful TGC were measured for each group (Table 3). We found no difference in the incidence of hypoglycemia (blood sugar <50 mg/dL) in group C compared with the other two groups. The incidence of hypoglycemia in group C was observed to be 2/591 blood draws (0.31%). The incidence of in-range

The fear of hypoglycemia is an important barrier to successful implementation of TGC.

Table 1. Tight glycemic control protocol

Blood glucose level (mg/dL)	Insulin U level 1	Insulin U level 2	Insulin U level 3	Insulin U level 4	Insulin-sensitive level IS
120–150	2	4	6	10	0
151–200	4	6	10	14	2
201–250	6	8	14	18	4
251–300	8	10	18	22	6
301–400	10	12	22	26	8

U = units, IS = insulin-sensitive.

Level 1 is the initial starting level for the vast majority of patients. The “insulin-sensitive” designation is for those patients with a diagnosis of proven disposition to hypoglycemia or previous issues with hypoglycemia under protocol level 1.

Group	Mean body mass index	Male	Female	Open surgery	Laparoscopic surgery	% Laparoscopic	Length of stay (days)	Wound infection	Wound infection percentage
A (pre-TGC protocol)	51	34	135	169	0	0	4.53	27	16.0
B (hospital TGC protocol)	58	18	73	0	91	100	2.96	0	0.0
C (bariatric protocol)	51	30	171	2	199	99	2.57	2	1.0

	% BS < 50 mg/dL (No.)	% BS 80–150 mg/dL (No.)	% BS 151–250 mg/dL (No.)	% BS > 250 mg/dL (No.)
Group A (pre-TGC)	0.27 (8)	63.76 (1918)	31.02 (933)	3.89 (117)
Group B (hospital TGC protocol)	0.22 (2)	63.39 (580)	27.43 (251)	2.08 (19)
Group C (bariatric protocol)	0.31 (2)	70.87 (455)	19.78 (127)	1.09 (7)
p value	0.939	0.271	<0.001	<0.001

readings (blood sugar 80–150 mg/dL) for group C was 71%, compared with 64% and 63% for groups A and B, respectively. The incidence of mild and major hyperglycemia was significantly lower in group C than in groups A and B (Table 3). The incidence of mild hyperglycemia was 20% in group C, 31% in group A, and 27% in group B; the incidence of major hyperglycemia was 1% in group C, 4% in group A, and 2% in group B.

Discussion

Improved glycemic control has become a benchmark for optimal patient care.¹ This report demonstrates process improvement in glycemic control of a special group of patients. As our hospital implemented a TGCP in phases, it became clear that the bariatric surgery patient group was an outlier. Glycemic control was not adequate in this group with the initial level 1 protocol. Given our goal of achieving TGC in perioperative patients, we decided to intensify the protocol. A barrier to instituting a TGCP is the fear of hypoglycemia.¹ Starting bariatric surgery patients on a level 2 TGCP required educating physicians and nurses to break down their resistance to the idea. With an initial level 2 TGCP, we were able to demonstrate significantly fewer mild and major hyperglycemic episodes, with no increase in hypoglycemic episodes.

Others have demonstrated improved clinical results with better glycemic control. Van den Berghe et al reported a reduction in mortality of the critically ill patients with a decrease in both time spent in an intensive care unit and hospital length of stay with even minor improvements in glucose control.² Furnary et al

have shown a significant improvement in deep sternal wound infections with continuous insulin infusion in diabetic patients undergoing cardiac surgery.⁶ Although Furnary et al used continuous infusions of insulin, the endpoint was a blood sugar level <150 mg/dL, which is consistent with our in-range values. We presume that with follow-up studies in morbidly obese patients after bariatric surgery, we will see improvements also in morbidity, length of stay, infection rates, and possibly mortality from an intensive TGCP.

This report focuses on bariatric surgery patients, all of whom are morbidly obese. The failure to control glucose levels in these patients with the initial level 1 TGCP may be related to insulin resistance, which is known to be common in morbidly obese patients.⁷ A review of the literature did not reveal any studies of TGC in this subset of patients. The pandemic of obesity in the United States has led to an increased number of hospitalizations for morbidly obese patients. These patients may require an intensive TGCP initially in order to achieve adequate glycemic control and hopefully experience reduced morbidity and improved outcomes seen in other subset populations.^{2,4,6} Defining optimal TGC in hospitalized morbidly obese patients may require further modifications of a TGCP.

Conclusion

The evidence that TGC leads to improved patient outcomes has been derived from multiple clinical studies.^{1–6} Performance metrics for special populations are in evolution. The work reported here represents sev-

Improved glycemic control has become a benchmark for optimal patient care.¹

eral PDCA cycles in the optimization of perioperative glycemic control in this population. Although glucose control in bariatric surgery patients is resistant to a standard TGCP, an initial intensive TGCP can be safely initiated in these patients, with improvement in glycemic control and no increase in hypoglycemic events. ❖

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Those That Survive

Great ceramics are not made by putting clay in the sun; they come only from the white heat of the kiln. In the firing process some pieces are broken, but those that survive the heat are transformed from clay into porcelain and are objects of art. And so it is with people, those who, through medical skill, opportunity, work, and courage, survive illness or overcome their handicap and take their places back in the world have a depth of spirit that you and I can hardly measure. They haven't wasted their pain.

— *Howard Rusk, MD, 1901-1989, founder of the Rusk Rehabilitation Center in Columbia, MO, and the Institute of Rehabilitation Medicine in New York, NY.*

Quality Improvement

Decreasing Medication Discrepancies Between Outpatient and Inpatient Care Through the Use of Computerized Pharmacy Data

By Charles S Salemi, MD, MPH
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Abstract

Context: The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) instituted a new regulation in 2006 to improve patient safety by decreasing medication errors. This requires a process for obtaining and documenting a complete list of each patient's current medications at hospital admission and communicating this list to the next clinician ("Medication Reconciliation").

Objective: We sought to determine whether medication discrepancies between outpatient and inpatient care can be decreased through the use of computerized pharmacy data.

Method: We evaluated outpatient medication prescriptions in 2000 and 2004 using computer-generated data for patients admitted from an Emergency Department to a medical ward. The hospital records and pharmacy data were reviewed to determine which ambulatory medications were ordered at admission, continued as an outpatient, and refilled three months after discharge. In 2004 additional computerized pharmacy data were provided to attending physicians. Ambulatory care "essential prescription medication groups" (cardiac, chronic obstructive pulmonary disease, asthma, diabetes, and neurologic) were also evaluated. Medication discrepancies for the years 2000 and 2004 were compared in several categories.

Results: Medication discrepancies were found in all evaluated categories in 2000. The follow-up study showed a decrease in discrepancies for nearly all categories.

Conclusion: Results show that use of outpatient pharmacy data can decrease medication discrepancies in compliance with current JCAHO requirements.

Introduction

As noted in the Institute of Medicine report, *To Err is Human*, medication errors have been a major cause of morbidity and mortality in the United States. Studies of hospitalized patients have estimated that medication errors have caused approximately 40,000 deaths annually.¹ The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a new regulation in 2006 intended to improve patient safety by decreasing medication errors. Called "Medication Reconciliation," it requires health care organizations to develop a process for obtaining and documenting a complete list of the patient's current medications at admission to the hospital and communicating this list to the next clinician.² The Kaiser Permanente (KP) Fontana Medical Center performed an initial medication discrepancy (medication error) study in 2000 and a follow-up study in 2004, prior to the JCAHO regulation of medication reconciliation. The goals were to show the scope of medication discrepancies and the improvements with use of computerized medication information. These studies were approved by the institutional review board of Kaiser Permanente Southern California.

The goals were to show the scope of medication discrepancies and the improvements with use of computerized medication information.

Methods

The Fontana Medical Center had 422 licensed beds during the study years. The major variable used for study of medication discrepancies was outpatient prescription medications. This was obtained from a computerized data system, the KP Patient Data System (KPDS), available to clinicians in the years 2000 and 2004. Hospital

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Care Management Summary Sheet—Printed								
Patient: Patient, Jane			Prov: Sample, Doctor			Date: 08-13-2003		
MRN: 00 0000123			Fac/Dept: Harbor City / Internal Medicine			Appt Time: 08:12 A		
DOB: 02-22-1944			PCP: SAMPD			ENC: 002805		
Last MAM: No date available			Last PAP: No date available					
Diseases:*	Asthma	diabetes	HF	CAD	CKD	Elder		
Risk:	1 Med	VHIGH	MOD	Yes	Stg 4	PPL		
Recommendations:								
Patient in high risk category for pneumonia. No record for Pneumovax in KITS.								
Asthma: High beta-agonist use. Check inhaled anti-inflamm (IAI) adherence, increase IAI dose or potency, and consider adding Serevent.								
HF: Patient never attended a heart failure class. Refer to heart failure class.								
Diabetes: Retinal exam may be overdue.								
Diabetes: Very high risk, Glucose Rx not optimal/check compliance.								
CAD: Should be on aspirin (81–325MG) daily unless contraindicated.								
CKD: Near ESRD. Consider Nephrology referral.								
CKD: Order serum creatinine.								
High CVD risk: Start lisinopril (target 10-40 mg/d). If HF, target highest tolerated dose in range (max 40 mg/d).								
High CVD risk and increased creatinine: Start lovastatin 10 mg daily (carefully increase dose if needed to lower LDL to <100 mg/dL).								
post-MI: Start beta-blocker (eg, atenolol, lopressor, carvedilol).								
CVD risk: Order lipid panel (LDL is missing).								
All meds—last 20 dispenses in 12 mos				Care mgt labs—last 2 in 12 mos				
Rx date	Drug	Qty	Refd	Date	Type	Result	Abnormal	
08/30/03	Albuterol aer 90 mcg	2	7	07/26/03	CR	1.2		
08/30/03	One Touch Test Strips	200	2	09/23/02	CR	1.3		
08/30/03	Glyburide tab 5 mg	400	2	07/26/03	K	4.1		
05/08/03	Cheratussin AC syp AC	240	1	09/23/02	K	4.2		
05/08/03	Erythromycin 500-mg tab	28	1	07/26/03	MAU	5.9		
03/04/03	Allegra cap 60 mg	50	2	09/23/02	MAU	5.9		
09/26/02	FE-Tinic cap 150 mg UD	100	1	07/26/03	A1C	9.5		
				09/23/02	A1C	8.9		
				07/26/03	ALT	27		
				09/23/02	ALT	31		
Asthma meds (last 12 mos)—excludes Serevent								
Controllers	B-AG	WTD	Ratio					
Cans	0	14	0.0					
Nebs	0	0						
Leuk	0							
				Date	Chol	Trig	HDL	LDL
				05/13/02	157	94	63	75
				03/22/02	177	263	51	73
Hosp/ER—last 4 discharges in 12 mos								
Date	Hosp/ER	Care MGMT	DX					
*Electronic point data and guidelines suggest the above (your case review is required to confirm)								
*If member does not have disease, please circle incorrect disease and fax to XXX-XXXX.								
ASTHMA		CHF		DM		CAD		

Figure 1. Example of Care Management Summary sheet showing one patient's medication details.

admissions from the Emergency Department (ED) to a specific general medical ward were reviewed to compare prescribed medications at admission with prior outpatient medications. Outpatient medical records were not reviewed for these studies. Ambulatory care “essential prescription medication groups” (cardiac, chronic obstructive pulmonary disease, asthma, diabetes, and neurologic) were also evaluated.

The follow-up study in 2004 provided admitting physicians with additional computerized pharmaceutical data. These were from an outpatient data system called Care Management System (CMS), which used KPDS pharmacy data (Figure 1). The hospital medical records were reviewed to determine which ambulatory medications were ordered at the time of admission, continued as discharge medications, and refilled three months after discharge. Nursing-home patients were excluded from this study. The term *medication discrepancies* was used rather than *medication errors* because outpatient medication records were not reviewed to determine whether a dosage or medication was changed. When these data were collected, 90% of KP patients used KP pharmacies for their outpatient medications. Only the hospital-discharged patient records that contained a CMS sheet were included for this study. The use of the com-

puterized CMS sheets was an option for the admitting and attending physicians. There were no preceding e-mailed instructions or in-service programs prior to availability of the CMS sheets in the ED.

Results

The data from the tabulations before and after providing CMS sheets (Table 1) show improvement in all categories: 1) admission orders, 2) discharge summaries, and 3) three-month prescription refills. The largest medication discrepancy noted was an omission of the patient's previous ambulatory medication. There were discrepancies in both essential and nonessential medications. Statistical evaluation of the data by the *z* test showed that *p* was < 0.05 for all categories tested except for admission orders of essential medications (Table 2). Figure 2 shows the improvements in graphic form.

Discussion

There are relatively few reports in the literature about medication discrepancies. Most studies were conducted by pharmacists and focused primarily on admission medication orders compared with previous outpatient

The largest medication discrepancy noted was an omission of the patient's previous ambulatory medication.

Table 1. Medication discrepancy* percentages in 2000 and 2004

Category	2000 (KPDS only; n = 198 prescriptions)	2004 (KPDS and CMS; n = 212 prescriptions)	2000 “essential Rx” (KPDS only; n = 88 prescriptions)	2004 “essential Rx” (KPDS and CMS; n = 88 prescriptions)
Admission orders	38%	25% ^a	34%	22%
Discharge summary	50%	16% ^b	47%	20% ^b
Three-month prescription refills	53%	29% ^b	55%	19% ^b

^a *p* < 0.01.

^b *p* < 0.001.

* See text for definitions.

CMS = Care Management System; KPDS = Kaiser Permanente Patient Data System; Rx = prescriptions.

Table 2. Z-testing of differences between baseline and follow-up studies

All prescription medications					
	Baseline 2000 n = 198 prescriptions	With CMS sheet 2004 n = 212 prescriptions	Percentage difference	p value	
Admission orders	38%	25%	13	0.006	
Discharge summary	50%	16%	34	0.000	
Three-month prescription refills	53%	29%	24	0.000	
All essential medications					
	Baseline 2000 n = 88 prescriptions	With CMS sheet 2004 n = 86 prescriptions	Percentage difference	p value	
Admission orders	34%	22%	12	<0.111 (NS)	
Discharge summary	47%	20%	27	0.000	

CMS = Care Management System; NS = not significant.

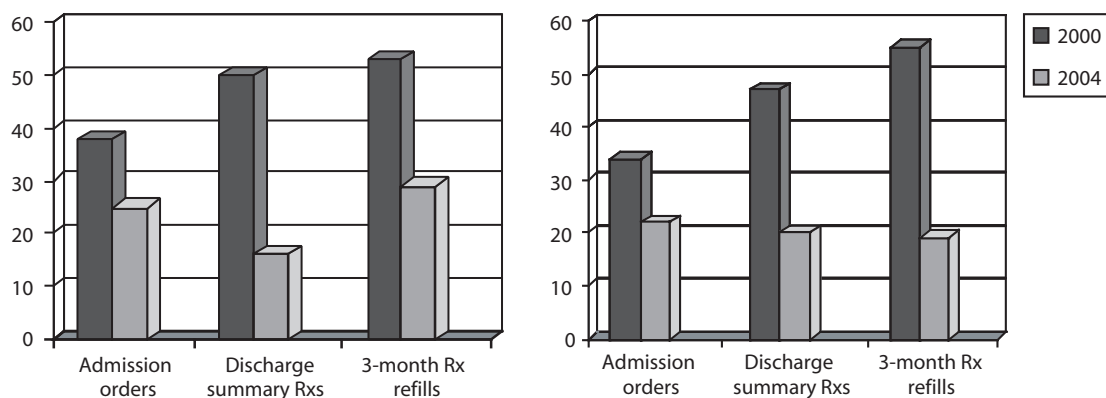


Figure 2. Percentage of medication discrepancies: all medication and essential medication

Left panel: percentages of outpatient medications in a computerized database (see text for description of Kaiser Permanente Patient Data System, or KPDS) prescribed at hospital admission, discharge, and three months (three-month prescription refills) after discharge. Lighter bars are percentages before availability of additional outpatient data (Care Management System, or CMS); darker bars are after the CMS was available. Right panel: similar data for "essential prescription medication groups" (see text for definition). Rx = prescription.

... computerized outpatient pharmacy data similar to ours and showed that computerized outpatient pharmacy data were more accurate than physician-obtained medication histories.⁶

medication. The admission medication discrepancy ranged from 11% to 46%.^{3,4} A report from the Kaiser Foundation Health Plan of Colorado⁵ focused on outpatient medication discrepancies (range, 14%–83%) and found that poor handwriting was the most frequent culprit. That report showed a higher readmission rate at 30 days for patients with medication discrepancies.⁵ A Dutch study used computerized outpatient pharmacy data similar to ours and showed that computerized outpatient pharmacy data were more accurate than physician-obtained medication histories.⁶

Conclusion

Our study demonstrates the value of providing pharmaceutical computerized data to clinicians to decrease medication discrepancies. The data supports the 2006 JCAHO regulations to decrease medication errors by using a medication reconciliation process. Having pharmaceutical data available to clinicians is not sufficient to improve medication discrepancies. The information should be printed and automatically provided to admitting and attending physicians. ❖

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■ clinical contributions

2005 Lawrence Transfer Award Winner

The Southern California Perinatal Patient Safety Project

By Jean Sandoval, RN, MSN
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Suzanne Graham, RN, PhD

The Northern California Perinatal Patient Safety Project (PPSP) won the Lawrence Patient Safety New Project Award in 2004 (See “The Perinatal Patient Safety Project: New Can Be Great!” in *The Permanente Journal* 2005 Winter;9(1):25-7 and “Perinatal Patient Safety Project” in *The Permanente Journal* 2005 Spring;9(2):28-33). With the purpose to create high-reliability perinatal units through the use of human factors, techniques and systems improvements, the project borrowed from the United States Navy, NASA, and similar organizations that operate highly complex systems with few errors over long periods of time. Using the precepts of the “Four As of Adoption” (see “Practical Steps for Practice Transfer” in *The Permanente Journal* 2005 Fall;9(4):50-1), Southern California began implementation of PPSP in November 2003 at the Riverside Medical Center by administering the Safety Attitude Questionnaire (SAQ) to their Perinatal staff and physicians and initiated their PPSP Steering Committee to begin the planning process. The other nine Medical Centers began cyclical implementation in 2004.

The purpose of the Southern California PPSP was to: decrease human error and identify patient care systems in need of improvement; create a safe culture; develop a high-reliability perinatal unit; and apply a “Just Culture” environment to create a safe environment for team members. The project included training in team briefings/communication, assertion, error detection, and situational awareness to include identification of “red flags.” A project tool kit was developed by the Southern California Regional PPSP project managers that described the core elements and was utilized by the medical centers during their start-up and throughout their planning meetings. This tool kit is now available from the National Risk Management Program Office (available at: <http://kpnet.kp.org/qs/nrm/PPSP3/toolkit.htm>) or the Southern California Project

Managers. This project tool kit has been so successful, it is being requested by medical centers outside of Kaiser Permanente (KP).

Following a Leader

In 2003, Southern California Ob/Gyn Chiefs attended the PPSP conference in Northern California and returned enthused and excited to transfer and implement the program in Southern California. Southern California provides funds to each medical center to support innovation replication projects. PPSP used these funds to support staff attendance at the educational components of PPSP and at meetings for one full year. Being able to send champions to visit a medical center that had already successfully implemented the project was of integral value in easing the transfer process.

When Enthusiasm is a Drawback

Although the energy generated by the enthusiasm brought forth for implementing this project was essential and exciting, it also created some difficulties. Planning the transfer while the project was being implemented created some challenges that could have been avoided by fully developing the implementation plan prior to beginning the transfer; however, this might have been at the cost of some of the momentum, in which case transparent and open communication with a shared vision was vital.

... the project borrowed from the United States Navy, NASA, and similar organizations that operate highly complex systems with few errors over long periods of time.

Table 1. Southern California Region PPSP Sponsors

John Brookey, MD, Assistant Medical Director of Quality
Carolyn Days, RNP, Vice President, Quality and Risk Management
Suzanne Graham, RN, PhD, Patient Safety Practice Leader, California Regions
Judy Husted, RN, Executive Director, Patient Care Services
Jean Sandoval, RN, MSN, Senior Consultant, PPSP Project Manager
Janice McDonald, RN, MBA, Senior Consultant, PPSP Project Manager

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... the techniques utilized in PPSP are not exclusive to the perinatal unit.

Educational Components

The four educational components of the transfer included:

- Human Factors Training—to provide new skills to build teams, improve communication, and reduce and capture errors.
- Supplemental **S**ituation, **B**ackground, **A**ssessment, and **R**ecommendation Communication—to establish communication improvements between staff and providers.
- Escalation Policy (“Just Culture”)—to provide for free and open discussions among all PPSP members.
- Critical Events Team Training (CETT) and Debriefing Techniques—to develop a method of practicing for emergencies with a debriefing session to provide emotional support for staff and physicians and to identify system issues. CETT “Train-the-Trainer” Programs have also been implemented.

After completing the education components, staff and physicians almost unanimously felt CETT “brings it all together.”

Conclusion

Implementing a regionwide program within the span of one year is a daunting task. Having committed Project Managers, regional support, and departmental enthusiasm makes the goal achievable and the challenge stimulating. Finally, the techniques utilized in PPSP are not exclusive to the perinatal unit. Other departments throughout Southern California are investigating the possibility of using this project as a model, specifically in the ICU and Medical/Surgical areas at Panorama City Medical Center and other departments at Orange County and Riverside Medical Centers. ❖

Opening To Change

Most important of all, I think you ought to build up your competitive position in this medical world by innovating and opening up to change. We have been doing the same thing far too long. Some of you have heard the talk I gave on the new Medical Care Delivery System. That may not be the only answer, but it is a move to improve service. You should be getting into that—improving service. You know institutions tend to become static; they build walls around themselves to protect themselves from change and eventually die. You should fight that by opening up your thinking and your ideas, and work for change. Improvement of service is very important for the competition you face in the future.

— Sidney R Garfield, MD, 1906-84, founder of the Kaiser Permanente Health Plan to a meeting of Physicians-in-Chiefs and Medical Directors of all six Regions of the Kaiser Medical Care Program in the spring of 1974.

This “Moment in History” quote collected by Steve Gilford, KP Historian

Patient Safety Executive Walkarounds

By Steven P Feitelberg, MD

Abstract

The KP Patient Safety Executive Walkarounds Program in the KP San Diego Service Area was developed to provide routine opportunities for senior KP leaders, staff, and clinicians to discuss patient safety concerns proactively, working closely with our labor partners to foster a culture of safety that supports our staff and physicians. Throughout the KP San Diego Service Area, the Walkarounds program plays a major part in promoting responsible identification and reporting of patient safety issues. Because each staff member has an equal voice in discussing patient safety concerns, the program enables all employees—union and nonunion alike—to engage directly in discussions about improving patient safety. The KPSC leadership has recognized this program as a major demonstration that the leadership supports patient safety and promotes reporting of safety issues in a “just culture.”

Introduction

Since publication of the Institute of Medicine Report, *To Err Is Human: Building a Safer Health System*,¹ increased attention has been focused on patient safety in health care settings. The challenge for health care organizations is to foster a culture of safety and to continually identify opportunities to improve and assure the safety of patients being treated at health care facilities. At Kaiser Permanente (KP), this ongoing process is driven fundamentally by the organization's leaders. As stated by Kenneth Kizer, MD, MPH, President and Chief Executive Officer of the National Quality Forum (NQF) in an NQF consensus statement, “There simply is nothing more important in overseeing a hospital or other health care facility than to ensure that it is as

safe as possible for patients.”² (The NQF—of which KP is a member—is a private, not-for-profit membership organization created to develop and implement a national strategy for measuring and reporting on the quality of health care.) The medical profession has realized that improving patient safety must be among the highest priorities of health care leaders and managers. Nonetheless, only by direct and regular contact with real care delivery can leaders understand the problems of staff and clinicians in delivering safe care. To facilitate this level of involvement, the KP San Diego Service Area launched the Patient Safety Executive Walkarounds Program. This program gives top KP leaders the tools to show KP staff and clinicians that the KP leadership is committed to patient safety and to

developing the infrastructure necessary to ensure responsible reporting of safety-related errors and hazards. By walking through hospital units to conduct face-to-face conversations with any staff member or physician with a safety concern, leaders can learn more about errors or hazards that could or did cause harm; and on the basis of issues identified during the Walkarounds, the leadership can identify opportunities for improving patient safety. These informal discussions are thus an essential catalyst for change because they enable the organization to improve our reporting systems and enhance our knowledge about how to ensure a safe environment.

Program Origin and Components

Recognizing that the Patient Safety Executive Walkarounds program could help the KP San Diego Service Area to become a leader in patient safety (a top-priority strategic goal identified by the Service Area), the KP San Diego Service Area manager encouraged the KP San Diego Medical Center to become the Southern California pilot site for implementing the Walkarounds program. The program subsequently began as a nine-month, day-shift pilot program in San Diego in September 2002. From the beginning, the Medical Service Area Administrative Team (MSAAT) and the KP San Diego Leadership Team

By walking through hospital units to conduct face-to-face conversations with any staff member or physician with a safety concern, leaders can learn more about errors or hazards that could or did cause harm ...

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Table 1. Sample questions asked by the MSAAT representative during Patient Safety Executive Walkarounds at the KP San Diego Medical Center

- Can you think of any events in the past day (or few days) that have resulted in harm to a patient?
- Can you think of any “near misses” that almost caused a patient harm but did not?
- What aspect of the environment is likely to lead to the next patient harm?
- What do you think this unit (or area) could do on a regular basis to improve safety?
- How are you involved in patient safety on this unit?
- When you make an error, do you always report it?
- If you prevent or intercept an error, do you always report it?
- If you make or report an error, are you concerned about personal consequences?
- Do you know what happens with information that you report?
- Are you aware that we are actively promoting a “just” (“blame-free”) culture?
- Have you discussed patient safety issues with your patients or with their families?
- Can you think of a time when your intervention prevented harm to a patient who would otherwise have been harmed by a system flaw?
- What specific intervention could leadership direct to make safer the work you do for patients?
- What would make Patient Safety Executive Walkarounds more effective?

(SDLT) gave their strong support and sponsorship to the program.

In the Walkarounds program, two senior leaders are scheduled to visit each nursing unit, hospital clinical department, and several medical office buildings at least once per year to speak with frontline staff about patient safety concerns, which must be assigned a priority level according to which the concerns will be resolved. The Walkarounds team must include at least one representative from either the MSAAT or the SDLT (these entities participate on a rotating basis), a representative from either the Quality

Resource or Risk Management/Patient Safety Department (or a representative from each department), and a scribe. The Walkarounds team must conduct rounds for at least one hour each month and interview at least three persons.

All members of the staff—members of labor unions as well as nonrepresented staff—are encouraged to participate fully in these discussions, which must focus exclusively on patient safety issues and may not be combined with any other type of unit rounds. In addition to verbalizing the organization’s commitment to improving patient

safety, the leaders obtain feedback from staff and physicians regarding perceptions of a “just culture.” A culture that does not blame people who make mistakes but looks at the root cause of the errors and promotes system improvements that result in a safer environment for the patients and staff.

During the Walkarounds, the team informally approaches the patient care area to meet with available staff and physicians. The MSAAT Representative may take the lead in the discussions, asking questions to solicit information regarding perceptions of safety as well as safety issues that did or could cause harm to patients. An interview tool was developed to assist leaders in facilitating the discussions (Table 1). As these conversations take place, a representative from Risk Management/Patient Safety noted the issues verbalized by staff and physicians and subsequently entered these issues into a database.

Data Analysis

To assess the effectiveness of the Program, three types of outcomes from the Walkarounds Program were measured:

- *Improvement in patient safety (Vincent Factors):*³ This measure used a quantitative (Vincent Model) approach to “counting” the patient safety issues identified and resolved (Table 2). Components for the Vincent Factors (Table 3) were derived from medical publications on error, adverse outcomes, and risk management.³⁻⁷ This framework incorporated factors which influence clinical practice and which are used to categorize, analyze, and prioritize patient safety issues. During each walkaround, issues were entered into a database

Table 2. Total weighted scores of patient safety issues identified or resolved

Vincent category	Total score		% of total
	Identified	Resolved	
Organization/Management	150	115	77
Work Environment	1020	895	88
Team	200	165	83
Individual	50	35	70
Task	170	120	71
Patient	15	15	100

and categorized using the Vincent Model.

- *Effects on the organization's culture of safety (a Just Culture)*: This outcome measured physicians' and staff's perception of the safety culture in the service area. The People Pulse survey was distributed for recipients to assess how everyone worked together to ensure the safest possible workplace.
- *Perceptions expressed by staff about the power of the Walkarounds (Program Survey responses)*: This measure consisted of survey results from Walkarounds participants in various health care delivery and support disciplines, from their immediate supervisors, and from the leadership representatives who conducted the rounds.

The data analysis included type, severity (actual or potential outcome to patient), and frequency (number of participants reporting the safety issue during rounds). When reports were generated, the frequency of each issue identified was multiplied by the severity outcomes to provide a weighted value for each issue. This score was designed to help the organization to prioritize safety concerns according to either the number of individuals concerned about it or the extent of its harmful impact (actual or potential) for patients.

Data collection was identified as critical for determining the success of the program. To record, monitor, and analyze safety issues identified by the Walkarounds program and to identify trends, the program uses a database developed specifically for it by staff at Brigham and Women's Hospital. The database assigns a severity code to each issue after categorizing it as one of the Vincent Model's "contributing

Category	Factors
Organizational and management factors	Financial resources and constraints Organizational structure Policy standards and goals Safety culture and priorities
Work environment	Staffing levels and skills mix Workload and shift patterns Design, availability, and maintenance of equipment Administrative and managerial support
Team factors	Verbal communication Written communication Supervision and seeking help Team structure
Individual (staff) factors	Knowledge and skills Motivation physical and mental health
Task factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results
Patient characteristics	Condition (complexity and seriousness) Language and communication Personality and social factors

factors": team factors, work environment factors, organization/management factors, task factors, individual staff factors, and patient factors.³ The database enables systems-based analysis of these contributing factors, prioritization of urgent interventions, and initiation of special projects. Quantitatively, this analysis enabled KP leaders to routinely track the categories, frequency, and severity of safety issues identified and the percentage of issues resolved. This procedure served as a safeguard against prolongation or neglect of safety concerns. Because participants could present any patient safety concern, data collection was not limited by amount or category of data.

A post-Walkarounds survey was sent to each participant six months after the Walkaround, and responses were collected and analyzed. These evaluations provided participants an opportunity to give open responses that could clarify survey results.

Results of the Walkarounds Program

The Walkarounds Program enabled the KP San Diego Service Area to identify and resolve patient safety

vulnerabilities more effectively and to address staff perceptions of the local service area's safety culture. Compared with responses to the 2002 KP People Pulse Survey question, "In my department or work unit, everyone works together to ensure we make this the safest possible place to work and be a patient," responses collected in 2003 showed a 5% increase in the number of staff who agreed with the statement and a 9% increase in the number of physicians responding favorably. This response indicates a substantial strengthening of our safety culture. In addition, more than 85% of the program participants and managers surveyed reported a better understanding of the KP Safety Program, and all noted that new safety initiatives had been implemented in their area as a direct result of the Walkarounds.

The Walkarounds Program proved to be a unique vehicle for facilitating discussion among staff and physicians about personal safety concerns that might otherwise not be reported. As the only such systematic mechanism available to any staff member or physician available on the unit, the Executive Walkarounds

... response indicates a substantial strengthening of our safety culture.

Table 4. Vincent Factor weighted scores of items identified during Patient Safety Executive Walkarounds with weighted scores of items resolved

Vincent category	No. of issues	Total weighted score	% of total
Organization/Management	20	150	9
Work Environment	118	1020	64
Team	19	200	12
Individual	4	50	3
Task	17	170	11
Patient	3	15	1

The Program's improvements in safety culture and patient safety remained consistent even after the pilot program. The Walkarounds continue along with ongoing analysis of the quantitative and qualitative data. Indeed, after analysis of the data, the entire MSAAT and SDLT gave their full support to continuing the Walkarounds program, expanding it to the afternoon shift and eventually to the evening shift. Since the program started, program participation has included all levels of the organization, including executives, department administrators, nurses, patient care assistants, physicians, environmental services staff, technicians, and clerks—all of whom have equal opportunity to discuss safety concerns directly with the top leaders and gain their support to ensure resolution.

Most (56%) of the safety-related issues identified during the Walkarounds were categorized as "Work Environment" (Table 4). The second most common category, "Team Factors," accounted for 17.3% of the issues identified. As can be seen from the following examples, a variety of actions were taken to resolve safety concerns.

- Concerns were voiced by multiple units about intravenous poles being unsteady and tending to fall over. Monies not previously budgeted for this issue were subsequently approved, and intravenous poles throughout the hospital were replaced.
- During the Walkarounds, staff from several clinical departments and medical office buildings discussed concerns about patients who had fallen when leaving the area after receiving tests. A Special Project Team was formed to analyze the issue and implemented a centralized Wheelchair Valet Service.

Program provided an opportunity for face-to-face expression of patient safety concerns and tracking of these issues. For example, nurses might typically never report their concern about the potential for an unstable intravenous pole causing injury to a patient, whereas during the first three months of the Executive Walkarounds Program in San Diego, nine nurses from three different units—Labor and Delivery, DUO, Dialysis, and Orthopedics—individually reported concern about the instability of the intravenous poles holding more than one solution simultaneously. As a direct result of receiving these reports during the Walkarounds, the KP San Diego

Service Area replaced all its intravenous poles with newer, sturdier versions.

By the end of 2005, 181 safety concerns had been identified through the Walkarounds in the KP San Diego Service Area. To date, 84% of these concerns have been resolved. Nearly all the issues identified would never have been identified through other existing reporting mechanisms, such as Unusual Event Reports and hotlines, which staff currently use to report actual occurrences. During the Walkarounds, physicians and staff shared with leaders concerns about near-misses or the potential for an adverse event.

Nearly all the issues identified would never have been identified through other existing reporting mechanisms ...

The following list gives brief highlights of actions taken on issues identified during the Walkarounds:

- *Equipment:* Hospitalwide replacement of intravenous poles; additional oxygen tanks, table straps, portable monitor gait belts, and blood pressure monitors; new wheelchairs; repair of Labor & Delivery Department ultrasound machine; and hospitalwide replacement of brakes on older beds.
- *Process changes:* Abnormal results reporting process (added to Cardiology); SBAR; virtual hallway bed area created in the emergency department; budgeting for bed replacements; improved system for diagnosing proper placement of nasogastric tubes.
- *Services:* Creation of lift teams (and subsequent extension of lift team hours of operations), wheelchair valet service.
- *Environment:* Widening of doorways in the radiology department; no-slip mats purchased for area near ice machines to prevent falls by patients and employees; increased storage area created in Dialysis Unit.

- Malfunctioning brakes on patient beds were mentioned often. The Engineering Department was instructed to conduct a hospitalwide review of the brakes and subsequently determined that all older beds should be replaced. The process of budgeting was then adjusted to include replacement of all older beds.
- Concern with proper after-hours identification of radiological films was verbalized during a Walkarounds tour of the Radiology Department. As a result, an FMEA team was formed to identify these vulnerabilities and subsequently implemented appropriate preventive measures.
- As a direct result of an issue voiced during a Walkaround, architectural review and reconstruction were both approved and completed to expand several doorways in the Radiology department.

Responses to post-Walkaround surveys showed increased attention to, and awareness of, patient safety and an increase in patient safety initiatives implemented after the Walkarounds (Tables 5,6). Whereas responses to the preproject questionnaire administered in 2002 showed that the teamwork climate among nurses in the San Diego Service Area ranked in the bottom 30% of organizations for benchmark measures in 101 clinical areas, responses to a shortened 2004 postproject survey (distributed to a subset of the original cohort) showed that the teamwork climate among respondents ranked within the top 30% of organizations on the same benchmarking scale. And a 2004 survey distributed to KP leaders in the San Diego Service Area showed that 86% of respondents had personally taken actions as a result

of the Walkarounds—an increase of 6% compared with survey results obtained a year earlier. The write-in responses reflected a consensus among all groups that the Walkarounds advanced understanding of patient safety and affected change within their facility or unit. “We are identifying issues that have not come up through any other reporting mechanism,” said one manager.

In response to the People Pulse survey question asking how everyone worked together to ensure the safest possible place, a 6% increase in positive responses was observed among physicians and staff after implementation of the Walkarounds. The high response rate for this survey indicated that the 6% difference was meaningful.

An unexpected positive outcome of the Walkarounds Program occurred during the 2003 Joint Commission on Accreditation of Healthcare Organizations (JCAHO) survey at the KP San Diego Medical Center, where the Walkarounds program was presented as the facility’s performance improvement project. The Consolidated Accreditation and Licensing Survey (CALs) accreditation team gave accolades for a successful and unique process of demonstrating improvements to safety and quality.

Since initiation of the San Diego Walkarounds, the total weighted Vincent score of all the patient safety issues has been identified as 1605. The total Vincent score for resolved issues was 1345 (84%). Survey responses showed overwhelming support for the Walkarounds Program in regard to effective communication of patient safety issues and perception of actions taken to resolve these issues.

Discussion

The Patient Safety Executive Walkarounds Program is KP’s prescribed, systematic process for facilitating regular dialogue between caregivers and senior organizational leaders to improve patient safety and for these leaders to actively show their interest and involvement with patient safety (they must “walk the talk”). The Program thus provides a proactive approach to resolving patient safety issues. As such, the Walkarounds Program has been highly successful in achieving significant sustained improvements in all its core elements. The Walkarounds Program also supports and complements other patient safety initiatives, such as Error Reduction Initiatives, Knowledge Transfer Initiatives, Human Factors Initiatives, and Environment of Care

Table 5. Responses to evaluations distributed to staff, managers, and leaders at 6 months and at 12 months after participation in the Walkarounds

Frontline staff	<ul style="list-style-type: none"> • Most (85%) responded that they had a better understanding of patient safety and the KP patient safety program as a result of the Walkarounds. • Most (76%) indicated that reporting or discussion of errors and “near misses” had increased since the Executive Patient Safety Walkarounds.
Unit managers or DA	<ul style="list-style-type: none"> • Nearly all (91%) said that they have had conversations with staff or physicians regarding the patient safety Walkarounds. • Most (76%) indicated that reporting or discussion of errors and “near misses” had increased since the Executive Patient Safety Walkarounds.
Executives	<ul style="list-style-type: none"> • All (100%) responded that they gained new learnings from the Walkarounds and considered them valuable. • Most (86%) reported that they had taken actions as a result of feedback received on the Executive Patient Safety Walkarounds.

Initiatives. In the San Diego Service Area, the success of the Program was enhanced by the strong support of the Program sponsors.

A strength of the Program is its broad-based participation by all departments and by staff at all levels. Most departments involved in direct patient care have been visited by the Executive Walkarounds Team, and many support departments have been involved in developing and implementing solutions to address safety concerns.

Another strength of the program is its use of a database to organize information so that systemwide problems can be readily identified. Systems-based solutions are far-reaching: They are used by many departments and therefore improve safety for patients throughout the San Diego Service Area. Nonetheless, implementation of a Walkarounds Program requires only

a minimal financial expenditure, and this financial commitment is directed exclusively to resolving concerns about patient safety.

The Patient Safety Executive Walkarounds Program has the potential to strengthen KP's Labor Management Partnership by providing the opportunity for senior organizational leaders and union-represented employees to come together for focused, face-to-face discussions on a common goal: ensuring patient safety. As employees witness their concerns being addressed and resolved, these employees can feel that they are being heard and understood.

Responding to the positive feedback received and the improved outcomes accomplished by the Walkarounds Program to date, the KP San Diego Leadership Team committed itself to continuing the program, which subsequently became

a required 2004-2005 goal for all KPSC medical centers and has already been transferred to nine KP medical centers in Southern California and to other KP Regions. All of the tools utilized for the Walkarounds are now available online, and a video was developed for use in conjunction with training.⁸ Multiple requests have been received from outside of KP for our Walkarounds toolkit, and we have received reports that many of those requestors have started their own Walkarounds Programs. The project was presented at a 2004 plenary session of the NPSF Congress⁹ and has been selected by the Agency for Healthcare Research and Quality for its compendium on best practices.¹⁰

Table 7 shows voluntary survey results from six other KPSC Service Areas related to their experience with the Walkarounds Program. An interesting finding in some other service areas was the expansion of the Program to include patients.

Successful program replication requires minimal fiscal support, partly because the program design has already been completed. Tools needed to introduce and implement this program have been developed and are easily available on the KP Intranet⁸ and include:

- *Orientation Materials:* Presentation templates introduce the concept and principles behind the Walkarounds, explain the expected results, outline the necessary steps, and list the required resources.
- *Communication Plan:* This plan outlines the tactics, dates, and responsibilities for informing and involving targeted stakeholders (executives, managers, and frontline staff).
- *Talking Points for Executives:* This list of key messages for executives who conduct

Table 6. Selected testimonials collected from surveys	
<i>What is the greatest value that Patient Safety Executive Walkarounds brings to the organization?</i>	
Staff comments	<ul style="list-style-type: none"> • Improved patient care through improved patient safety • Finding out the real problem on the floor that needs to be resolved • Allowing those in leadership positions to be aware of the conditions that hinder workplace safety
Manager comments	<ul style="list-style-type: none"> • Visibility of the Executive Leadership Team who show true concern that they care about our staff and our members • Brings "top" and "frontline" people together, making it clear that everyone is working toward the same goals • It has given my staff an improved sense of "value for what we have to say" • It has stimulated an increased attention to safety in the workplace
Leadership Team comments	<ul style="list-style-type: none"> • Open communication and connection with staff • An opportunity to fix a problem before it escalates to a bad event or outcome • Demonstrating to our staff that we recognize how difficult their jobs are and how much our senior leaders value quality and safe care • An opportunity for MSAAT and the AA to discuss unit-specific issues and concerns together on the frontlines
<p><i>Walkarounds learnings reported by the KP San Diego Leadership Team:</i></p> <ul style="list-style-type: none"> • I learned a great deal about the challenges faced by clinical staff around all the patient safety goals. • If you "fixed" it once several years ago, you may have erosion in the process with turnover; go back and check again. • Nursing Department staffing challenges. • That staff doesn't always express their concerns unless given the opportunity to do so. They need to be invited to provide information and feedback. <p>We need to modify our routine process for capital equipment to better identify requests related to patient safety issues and prioritize them higher in our regular process.</p>	

Walkarounds provides guidelines for initiating conversations, explaining the purpose of the visit, and talking to staff about how the information provided will be used.

- *Questions for Walkarounds:* As a second preparation tool for executives, the questions prompt discussion that focuses on systems-based patient safety concerns.
- *Evaluations:* Three versions of an evaluation—one each for executive, manager, and staff—ask participants to consider whether attitudes, conditions, or actions in their department have changed as a result of the Walkarounds.
- *Database* (a replica of the database customized by the KP San Diego Service Area).

The KP Program Offices Director of Patient Safety has provided the support to continually update all these aforementioned tools on the KP Intranet. The San Diego Director for Risk Management/Patient Safety has already provided an overview training of the database to KPSC Risk Managers. In addition, a videotape was filmed during actual Walkarounds and is available to provide additional support for successfully introducing and implementing the program.⁸

It is advisable, but not required, to maintain a part-time (ten hours per week) project support manager to ensure follow-up with and assistance to departments handling resolution of patient safety issues identified during the Walkarounds. Reminders of the Walkarounds' functions are included in the Risk Management/Patient Safety functions.

Conclusion

Only by direct, regular contact with care delivery can our organi-

Data element	Data totals
No. of Walkarounds completed - 2004	90
No. of Walkarounds completed - 2005 Q1	15
Leadership members attending Walkarounds	Area Associate Medical Director, Department Administrator, Risk Management, Service Area Manager, Quality Service Leader, Director of Hospital Operations, Director of Quality, Service Line Leaders
No. of staff involved, 2004	268
No. of staff involved, 2005 Q1	166
No. of unit physicians involved, 2004	19
No. of unit physicians involved, 2005 Q1	4
No. of unit patients involved, 2004	63
No. of unit patients involved, 2005 Q1	7
Shifts included	days and evenings (five medical centers); days only (five medical centers); all shifts (one medical center)
No. of issues identified during 2004	342
No. of issues identified during 2005 Q1	42
No. of issues resolved 2005 Q1	15

^a includes Panorama City, West Los Angeles, Bellflower, Baldwin Park, Orange, and Woodland Hills; excludes KP San Diego Service Area.

zational leaders understand the problems of staff and physicians in delivering safe care. Multiple mechanisms currently exist to identify errors and close calls, but many clinicians have historically reported only what they could not conceal out of fear of disciplinary action. The Walkarounds Program is one tool for promoting change in our organizational culture. Implementation of any program is achieved most effectively when aligned with the organization's priorities. To sustain the momentum of the program, its achievements must be communicated and celebrated. These activities are crucial to frontline staff to assure them that their concerns are not "lost in a black hole" and that their participation can bring change.

To support safety in a just culture, the entire leadership of the San Diego Service Area remains committed to continuing and advancing the Patient Safety Executive Walkarounds

Program. By promoting reporting and by improving systems, we can ensure that the right thing to do is also the easiest. ❖

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The Same Price

We don't want to save any money;
we want to give better, more comprehensive services—at the same price.

— *Sidney R Garfield, MD, 1906-84, founder of the Kaiser Permanente Health Plan to Morrie Collen, MD, regarding the costs of Multiphasic examinations.*

This "Moment in History" quote collected by Steve Gilford, KP Historian

Obesity in the Kaiser Permanente Patient Population and Positive Outcomes of Online Weight-Management Programs

By Keith H Bachman, MD
Trina M Histon, PhD
Carol Remmers, MPH

Abstract

We review what is known about the effects of obesity in the Kaiser Permanente (KP) population and discuss outcomes for two nationally available effective online programs, HealthMedia Balance® (Balance) and 10,000 Steps®. Obese KP patients often have health problems related to overweight and report difficulties with self-care, yet with the proper support, they can avail themselves of effective treatment to manage both obesity and associated conditions that affect quality of life. Clinicians should be aware of potential problems with functional status and self-care in their obese patients, provide brief assessment and advice, and refer obese patients to effective national and regional weight-management programs.

Obesity at Kaiser Permanente: Prevalence, Effects on Quality of Life, and Costs

Nationally representative statistics¹ indicate the prevalence of obesity (body mass index [BMI] > 30 kg/m²) in adults to be 32.2% and the prevalence of extreme obesity (BMI > 40 kg/m²) to be 4.8%. Seventeen percent of children in the United States are now overweight, triple the prevalence in 1975. In the Kaiser Permanente (KP) Northwest and Colorado Regions that have established BMI data in the electronic record, the prevalence of obesity in adults and the prevalence of overweight in children are similar to that seen in national statistics. Extrapolating to the KP population from US

data, we can estimate that approximately two million adult KP patients are obese and more than 350,000 are extremely obese, making obesity the most common chronic condition affecting adult patients and more common than diabetes, coronary disease, and depression combined. In both national¹ and KP-based surveys, African-American and Latina women are disproportionately affected by obesity (unpublished data, Nancy Gordon, DSc, personal communication 2006).^a Given the high prevalence of overweight among youth and adolescents nationally, it is likely that the clinical problem of obesity and related disease will be with us for years to come.

Obesity is associated with an in-

creased prevalence of many chronic health conditions, including diabetes, coronary artery disease, cerebrovascular disease, certain malignancies, and depression. Similar findings are observed in KP settings. More than 40% of KP patients with asthma, chronic pain, and congestive heart failure are obese. The 2003 KP Care Management Institute (CMI) measurement report data revealed that 57% of those with diabetes are obese and 15% are severely obese (unpublished data). Fifty-three percent of obese and 62% of severely obese patients report the presence of three or more comorbid chronic conditions. Depression is also more common in obese patients with chronic diseases. Not surprisingly, the high prevalence of chronic conditions result in lower quality of life and worse functional status in obese patients. The 2005 CMI Self-Care Shared Decision-Making survey revealed that functional status is impaired, with only 18% of severely obese patients and 29% of obese patients with chronic conditions reporting high functional status (unpublished data).

Obesity is costly to the health care system, and the proportion of health care dollars spent on obesity-related

Depression is also more common in obese patients with chronic diseases.

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... behavioral weight management may actually be cost-saving from the perspective of the health plan.

chronic medical conditions is increasing. Because of the increased population prevalence of obesity and more aggressive treatments of obesity-related comorbidities such as dyslipidemia and hypertension, the overall health care costs attributed to obesity in patients with private health insurance has increased from 2.0% in 1987 to 11.6% in 2002.² Obese individuals spend 36% more on health care services and 77% more on medications than people of normal weight and incur costs greater than those of smokers or problem drinkers.³ KP researchers have observed similar findings.⁴⁻⁷ The costs of care for obese KP Northern California (KPNC) patients with a BMI of 30 to 40 kg/m² are 25% higher than for patients of normal weight, and costs of care for patients with a BMI of 40 to 50 kg/m² (extreme obesity) are 78% higher.⁴ Over an eight-year period, obese KP Northwest (KPNW) patients also have increased health care costs and use. The number of primary care visits was 39% higher and the number of inpatient days was 49% higher in obese patients as compared with patients of normal weight.⁵ Pharmacy costs for obese patients were double those for patients of normal weight, and particularly noteworthy was a finding of a threefold increase in costs of cardiovascular medications and a 13-fold increase in costs of diabetes medications.⁵ Weight gains of ≥ 20 pounds are associated with medical care cost increases of $> \$500$ over the following three years.⁶ Data from CMI indicate that costs of health care for patients with chronic conditions such as diabetes or congestive heart failure complicated by obesity increased 30% to 50% as compared with patients with either of those chronic conditions not complicated by obesity (unpublished data).

Less information is available about

how weight-management services impact the cost of health care. However, preliminary results in the KP setting appear to indicate that behavioral weight management may actually be cost-saving from the perspective of the health plan. A study from KPNW⁸ indicates that modest weight loss of 5%, attained by participation in a KP health education program, resulted in cost savings from the perspective of the health care system of more than \$400 per patient per year.⁸ Despite regain of weight in many of the study subjects, health care cost reductions were sustained throughout five years of observation.

Kaiser Permanente's Model for Weight Management

The KP model for weight management is based on recommendations from the US Preventive Services Task Force⁹ and best communication practices developed in the KPNC Health Education Department. On the basis of evidence of effectiveness for behavioral weight-management programs for obese patients, the US Preventive Services Task Force 2003 obesity screening guidelines recommend routine assessment of BMI. When BMI is found to be > 30 kg/m², clinicians should recommend participation in formal weight-management programs. Modest weight loss of 5% to 7% is associated with significant health benefits, including diabetes prevention, improved blood sugars in established diabetes, improved levels of blood pressure control, and decreased dyslipidemia, and is considered a good initial goal for weight-loss efforts.

The KP model of care relies on clinical assessment of BMI, brief positive conversations between patient and clinician, agreement

on a next-step behavior change or program referral, and arrangement of follow-up. Although time is limited during office visits, our experience is that effective conversations can take fewer than five minutes. These motivating conversations are critical, as individuals who are given clinician advice to manage their weight are two to ten times more likely to report a behavior change or weight-loss attempt than those who report not being given this advice.¹⁰

Outside the office-visit setting, patients can access weight-management information, message boards, and regional and national program listings at www.kp.org/weight.

Although physician advice is essential, it is often insufficient to result in the long-term behavior changes necessary to promote weight loss and maintenance. Data from a recent CMI survey of patients with chronic medical conditions shed light on this issue. Obese patients with chronic conditions report that they know the lifestyle changes they need to make but that they have difficulty following these recommendations and actually making the changes needed to better manage their chronic illness. They are much less likely than normal-weight patients with chronic conditions to report regular activity, maintaining healthy eating patterns such as eating adequate fruits and vegetables, or adhering to a low-fat diet. Critically, the CMI Self-Care Shared Decision-Making survey also revealed that obese patients with chronic conditions report lower self-confidence in the ability to follow their physicians' recommendations, particularly under times of stress. Structured behavioral programs offer appropriate support to patients struggling with self-care or self-efficacy problems

	Behavioral weight management	Activity programs	Pharmacotherapy programs	Bariatric preparation programs	Pediatric/teen program	Other
Colorado	+	+	*	+	+	Spanish-language program
Georgia	+	+	#	+	+	Single-session introductory class; "Art of Cooking Healthy" class
Hawaii	+	+	#	+	+	"Overcoming Emotional Eating" class
Mid-Atlantic States	+			+	+	Emphasis on community-clinician partnerships
Northern California	+	+	#	+	+	Weight-maintenance newsletter; Spanish-language classes; diet class targeted to African Americans
Northwest	+			+		Phone-based triage counseling available
Ohio	+			+		Emphasis on community-clinician partnerships
Southern California	+		# *	+	+	Medically supervised weight-management programs that use meal-replacement products

* Formal programs using pharmacotherapy are available in Colorado and Southern California.

*# Georgia, Hawaii, Northern California, and Southern California have limited coverage for pharmacotherapy when certain conditions are met. Data from Care Management Institute WMI Web site; accessed January 21, 2006.

and maximize the probability of weight loss and maintenance.

Weight-Management Programs Available to KP Patients

KP patients are fortunate to have a wide variety of regional and national programs available. Most KP regions have behavioral weight-management and activity promotion programs in health education settings. Some regions offer obesity pharmacotherapy or intensive meal-replacement programs outside the primary care setting (Table 1). Online and community-based programs broaden the reach of these regional programs by their wide availability, convenience, and low cost compared with standard behavioral group programs or individual counseling. All KP patients receive discounts for community and worksite Weight Watchers programs and the 10,000 Step Program and free access to online healthy lifestyle

programs, including Balance. KP patients also have access to weight-management information and tools included in the online KP health encyclopedia. The discounted community- and worksite-based Weight Watchers group programs have been evaluated more comprehensively than other commercial weight-loss programs.¹¹

Evaluation: KP Healthy Lifestyles: HealthMedia Balance Program

Balance is an online weight-management program that uses tailored messages to provide customized motivational behavior-change advice to support weight loss. Messages are tailored on the basis of data that participants provide during completion of a baseline questionnaire. For instance, if a participant indicates a personal or family history of hypertension, the program will advise the participant of the beneficial effects of weight loss on

blood pressure. Development of a personalized action plan, e-mail reminder prompts, and the option for naming a support person to facilitate behavior change. Because of its online format, the program is available in every KP region and community

Description of Methods for the Care Management Institute Self-Care Shared Decision-Making Study

At Kaiser Permanente, 4108 patients with chronic conditions such as asthma, heart disease, diabetes, heart failure, and chronic pain completed a survey on how well they can manage their own condition(s), how satisfied they are with their health care, and about their quality of life and functional status. Persons with chronic conditions were identified during 2002 using administrative data sources and surveyed during the fall of 2003. Weight and height were self-reported in the survey. Chi-square estimates were computed to determine a level of significance. Of the 97% of respondents who reported their weight and height, 38% were obese (body mass index [BMI] ≥ 30 kg/m²) and 8% were extremely obese (BMI ≥ 40 kg/m²).

and is delivered free to patients.

Since August 2004, more than 65,000 KP patients have participated in the Balance weight-management program, and six-month outcome data are available for 7% of initial participants. Eighty-one percent of participants are female, 53% are obese, and 13% are extremely obese, indicating that program participants are more likely to be obese and more likely to be female than in a typical KP population. At six months after program entry, 26.0% of obese participants (BMI = 30–39 kg/m²) have lost >5% of their starting body weight and 8.6% have lost more than 10% of their initial body weight. Fourteen percent of participants with a BMI >40 kg/m² have experienced a weight loss of ≥10%. During program participation, 43% of participants reported improving their physical activity and 51% reported improving their eating habits. Seventy-eight percent of participants rated their satisfaction with their result as excellent or good. Data from more than 3000

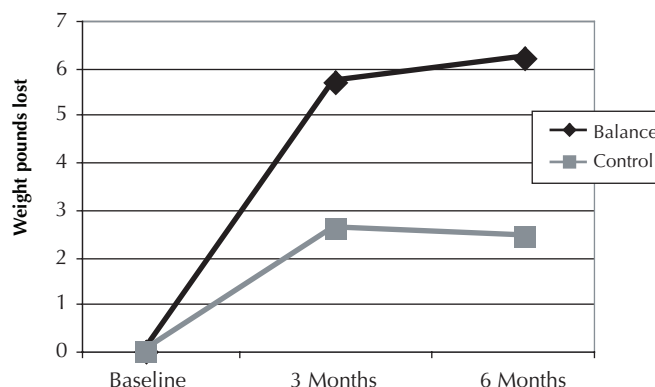


Figure 1. Weight loss at three months and six months after entry into the HealthMedia Balance program.¹²

participants with diabetes and 16,000 participants with hypertension show similar weight loss and satisfaction outcomes (unpublished data from HealthMedia, April 2006).

The effectiveness of this intervention was studied in a multicenter, randomized, controlled trial performed in four KP Regions involving 2800 patients. This study compared participation in Balance to a control in-

tervention of self-selected weight-management information in the KP online health encyclopedia. At six months, participants in the Balance intervention significantly lost more weight on average (6.2 pounds) than did participants in the control intervention (2.4 pounds) (Figure 1).¹² Participants in the Balance intervention also reported a significantly lower number of office visits and higher



Participant Comments on Balance

My name is Sheri Olivas. I was about to turn 40 and decided I needed to do more for my health. I was looking at the new Thrive site on Kaiser Permanente's Web page and followed a few links to the Healthy Lifestyles page.

The first thing I did was to take the Nourish questionnaire. I learned what I was not eating right—and what I could do to change it. So a few weeks ago I started actively making better food choices. And I began drinking nothing other than water—no more soda pop or sugared beverages. Funny, but the more I drank water, the more I was thirsty. I have never been very thirsty and was a huge soda drinker.

That was going so well that the next week I took the Balance questionnaire and discovered I was over my ideal BMI [body mass index] and needed to lose 27 pounds. I took that to heart and started walking on the treadmill during my lunch hour. I started with just 30 minutes and only managed three days the first week. Over the next few weeks I was

able to increase to a 45-minute weight loss program on the treadmill.

After four weeks I did my measurements and weight again. I was surprised to find I had already lost five pounds and two inches off my waist and three inches off my hips. Now I know this doesn't sound like much, but I have tried lots of diets, Herbalife, Slim-Fast, etc ... and never had much as far as results. I might lose a little weight, but then I gained more back. I have been overweight since 1999 when I developed Hashimoto's thyroiditis and have gained more over the last few years. This is the first time I have had fast and easy results. And I feel better. I think it is wonderful that Kaiser Permanente is offering these options to its patients and employees.

Sincerely,

Sheri Olivas, RN
Medical/Surgical Arena Nurse at Kaiser Sunnyside Medical Center,
Clackamas, Oregon

Source: http://internal.kpnw.org/insidekpnw/center/spotlight/stories/thrive_sheri_olivas.html

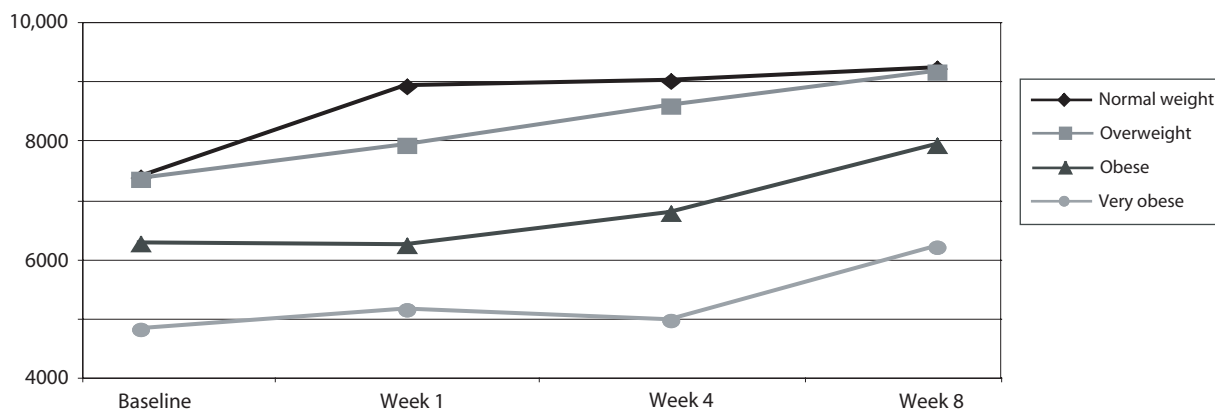


Figure 2. Daily steps taken by participants who completed the 10,000 Steps Program.

satisfaction with KP (unpublished data from the randomized control trial data collected by HealthMedia). Although follow-up rates in this study were low (20%), telephone calls to nonrespondents indicate that they achieved weight-loss levels similar to those of respondents.

Evaluation of the 10,000 Steps Program

Improved daily activity is a key activity to prevent weight gain and is critical to maintaining weight loss. The 10,000 Steps[®] Program^b is a physical activity pedometer program promoting increased daily steps as a route to improved fitness and weight control. After enrollment, participants are mailed a pedometer and gain access to online support resources, tips on healthy living, and electronic ways of tracking their progress. As of August 2006 more than 20,000 KP patients had participated in this program. The average age of participants

is 49 years and the average BMI at the start of program participation is 32 kg/m². The average increase in participants' daily step count was 1749 steps, nearly a mile per day. Obese and severely obese participants were found to take fewer steps daily but to have higher relative increases in daily steps as compared with normal-weight participants. Daily steps in normal-weight participants increased by 9.8% and in obese participants and severely obese participants by 18.8% and 20.9%, respectively (Figure 2). Small daily lifestyle changes such as this are critical to helping participants balance their daily "energy in-energy out" equation, thereby preventing weight gain or assisting with weight loss and weight-loss maintenance.¹³ Although detailed weight-loss outcomes from this program are not available, 16% of participants report that the main benefit has been that they "fit into clothes better,"

whereas 31% report their main benefit being that they are "more fit" after program participation.

Conclusions

Obesity is common in the KP environment and adversely affects quality of life and health care costs. Regional and national weight-management programs support obese patients' self-care and confidence in their ability to make lifestyle changes to better manage their health. On the basis of the data presented here, KP physicians can confidently refer their patients to the many effective KP weight-management programs. ♦

Acknowledgments

The authors acknowledge the support of colleagues at CMI, particularly William Caplan, MD, and Denise Myers, RN, MPH. The partnership and assistance of Nico Pronk, PhD, and staff of HealthPartners' 10,000 Steps Program and Sally Petersen of HealthMedia in providing KP-specific data has been critical in helping us assess program effectiveness. Further information about Balance can be obtained at www.healthmedia.com, and information about 10,000 Steps can be obtained at www.10k-steps.com/.

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

... 16% of participants report that the main benefit has been that they "fit into clothes better," whereas 31% report their main benefit being that they are "more fit" ...

Where to go for more information about weight management at Kaiser Permanente

- Member and public site for weight management resources: kp.org/weight
- Care Management Institute Weight Management Initiative site on the Kaiser Permanente Intranet: <http://cl.kp.org/pkc/national/topics/cmi/wmi/index.htm>

^a Nancy Gordon, DSc, researcher with the Division of Research, Northern California.

^b HealthMedia Balance® and 10,000 Steps® are registered trademarks of HealthMedia and HealthPartners, Inc, respectively.

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An Opportunity

To have lived through a revolution, to have seen a new birth of science, a new dispensation of health, recognized medical schools, remodeled hospitals, a new outlook for humanity, is an opportunity not given to every generation.

—Sir William Osler, MD, 1849-1919, physician, professor of medicine, and author

■ culturally competent care update

Quality Translations: A Matter of Patient Safety, Service Quality, and Cost-Effectiveness

*“The directions on the bottle of blood-pressure pills read simply enough: ‘Take once a day until finished.’ But a Mexican immigrant still wobbly in her English, misreads just one word. In her native Spanish, ‘once,’ means 11. The pills, if taken too many at a time, make her dizzy—or worse. They could kill her.”*¹

The lack of comprehensible and usable written and spoken language is a major barrier to health communication targeting primary and secondary disease prevention and is a major contributor to the misuse of health care, patient noncompliance, and rising health care costs.² Without appropriate and quality language services, limited-English proficient (LEP) and non-English proficient (NEP) patients experience compromised health care—often relying upon “safety-net” public and nonprofit providers, and using alternative or underground sources of care.³

At Kaiser Permanente (KP), we have an opportunity and an obligation to improve the health and quality of life of our members. KP’s membership is a microcosm of the diversity of our nation and our world, representing over 100 dif-

ferent languages. For members whose primary or preferred language is other than English, our ability to provide patient-centered care is often challenged when we cannot communicate effectively in their languages. For example, how do we manage informed consent? How do we ensure that LEP/NEP patients have correct and complete information to follow pre-operative instructions as well as access to medical benefits and coverage information? The availability of qualified interpreters and comprehensible written in-language material is thus paramount to ensuring equal access to health information and crucial for treatment adherence, patient safety, and quality care.

Current State of Translations

Our current systems are in a state of chaos when it comes to translating written materials. KP, as with other health care organizations, is overwhelmed by the task to provide high-quality translations for members while maximizing efficiency and containing costs. Mounting pressure from federal and state regulations and mandates pertaining to cultural and linguistic services (*ie, Title VI of the Civil Rights Act,*⁴

Culturally and Linguistically Appropriate Services (CLAS) Standards,^b and state-specific cultural and linguistic regulations) has created an urgency to translate member-informing materials for our linguistically diverse membership. Yet, little or no guidance is offered from legislative and accreditation agencies to help health care delivery systems comply with regulatory requirements.² Additionally, there are no established health care industry standards for ensuring quality translations. Thus, the reaction throughout the industry has been to translate materials immediately and arbitrarily.

A myriad of processes and systems exists among different health care organizations, and even within KP. Variations in translation protocol can be found at all levels of operation: regional, facility, and departmental. The translation of materials often ranges from asking a “bilingual” staff person or family member at hand to hiring independent contractors with varying degrees of health care and translation expertise. Therefore, the accuracy, literacy level, cultural appropriateness, and other components of in-language materials are often unpredictable. In some languages, health care con-

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Oscar Lanza
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Annie Chang

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Table 1. Inaccurate translations	
Inaccurate translations when terms do not exist in the target language(s):	
Term	Translation
Co-payment	Coping
Behavioral health workshop	Day program for lunatics
Nurse practitioner	Nurse in practice, nursing aid, physician's assistant
Literal word-for-word translation errors:	
Safe sex	Sure sex (Spanish)
Patient	Sick person ^a (Chinese)

^a A patient is not always someone who is sick, especially in a preventive health care environment.

cepts and terminology used in the US do not exist, creating the need for commitment and resources to standardize approaches for meaningful and appropriate translations. Table 1 illustrates some errors in translations, which contribute to consumer confusion.

Programwide Assessment

As part of a Programwide initiative to ensure quality translation and equal access to in-language materials, in 2005, National Diversity's National Linguistic & Cultural Programs (NLCP) implemented a survey to examine how providers and staff accessed translated materials at the department and facility levels. NLCP directed this survey to providers and staff Programwide,^c who reflect diverse cross-functional groups and work with translated materials in various capacities. The survey was developed as a Web-based tool that was completed and returned through an online survey provider.

Survey Findings

Survey data showed that little has been formally documented at KP about its translation work (ie, supply, utilization, and processes), particularly since the responsibility of translating materials has been left to facilities and/or departments. Furthermore, translations usually are done in arbitrary, at-hand, or quick-fix

means due to the lack of translation infrastructure, systems, and protocols.

Survey respondents identified various challenges, including:

- Lack of knowledge on how to access translated materials.
- Lack of departmental and/or facilitywide budgets to translate materials.
- Lack of organizational structure in general to share and access materials.
- Questionable quality of available translated information.
- Significant delays in getting translations completed.
- Materials in Spanish and Chinese are limited, and other language materials are more sparse.

Additionally, many survey respondents expressed frustration and a sense of powerlessness in dealing with translations. A few respondents shared that:

"Employees have to spend hours trying to find the right contact for something that is outside of their daily routine."

"It is difficult to find excellence in translation service, as there are often a multitude of errors in translation."

Furthermore, the NLCP Translation Survey found that providers and staff desired guidance and resources to obtain high-quality and cost-effective translations for their patients. They offered various solutions to begin ad-

ressing the challenges faced. Many stated that KP should:

- Adopt a centralized process for translations that is organized on a regional or national level.
- Build a system that would increase access to existing available language materials. Specifically, create a document repository or clearinghouse of translated materials.
- Develop a standard, formal procedure for coordinating the translations process.
- Establish a pool of KP-approved translation vendors that meet various business requirements (ie, cost, quality, efficiency)
- Standardize key documents such as consent forms, member letters, etc, to minimize the number of documents to be translated.

The survey findings shed light on the Programwide operational reality that translations are often being duplicated within each region, facility, and even department because there is little or no communication or coordination on what has been or what needs to be translated. To date, there is no readily available data on existing translated materials to make ac-

... translations usually are done in arbitrary, at-hand, or quick-fix means due to the lack of translation infrastructure, systems, and protocols.

Table 2. Select examples of translation errors in KP documents
<p>Discharge policy <i>English:</i> To ensure a timely and smooth departure, please prepare for an 11AM discharge. <i>Spanish translation:</i> To ensure an opportune and soft game (or match, as in soccer match), please prepare for an 11AM discharge.</p>
<p>Calcium for Health pamphlet <i>English:</i> These ideas may make it easier for you to digest milk products. <i>Spanish translation:</i> Maybe with milk products it would be easier to digest.</p>

curate assessments of their demand and supply, version updates, quality, and accessibility. Absent the mechanisms or processes to share, track, and monitor the quality of translated materials, duplication and inconsistency (including brand) will persist throughout the organization often creating poor quality in-language materials (Table 2).

Addressing Some of the Challenges with Translations through Key NLCP Initiatives

National Coalition for Quality Translation in Health Care

Since there are no nationwide benchmarks nor agreement on how to ensure quality health care translation, NLCP led the development of and convened the National Coalition for Quality Translation in Health Care (NCQTH or Coalition) in 2004, with funding support from The California Endowment.^d The formation of this Coalition represented a groundbreaking effort to bring together diverse key stakeholders and content experts (Figure 1). By leading the efforts of this Coalition, KP hopes to inform and influence industry policy and practice.

Some of NLCP's major accomplishments to date include establishing a quality process for health care translation and working towards standardizing health care terminology in languages other than English. With the help of the Coalition, a standardized Spanish Health Care Glossary was completed and field-testing is in progress. The next phases of the Coalition's work include standardizing KP's glossaries in Chinese, Vietnamese, Korean, Russian, and Armenian. By providing tools and expertise, the Coalition serves as a valuable resource to help health care and language professionals adopt guidelines and standards for translation. Thus,

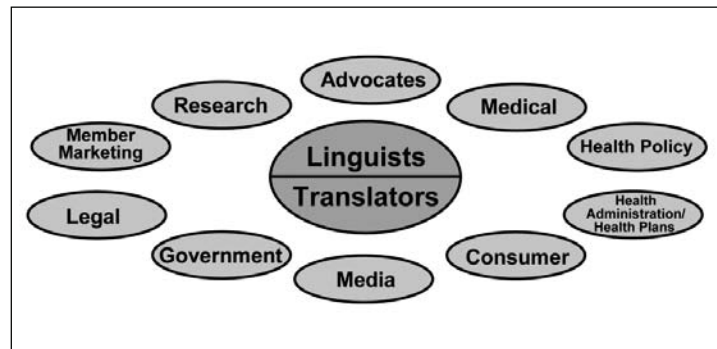


Figure 1. National Coalition for Quality Translation in Health Care organizational structure.

the Coalition's work impacts both KP and the community at-large by improving comprehension and consistency of in-language materials.

Research Agenda: Quality and Cost Study

With a grant from The California Endowment,^d NLCP examined whether instituting a quality assurance process yielded higher quality, saved turnaround time, and decreased costs for translating written materials. The process compared the error rates of four well-known independent vendors with a model developed by the San Francisco Center of Excellence for Linguistic and Cultural Services (SF COE). This study found that KP's model for assuring quality translation yielded the lowest average error rates compared with the other vendors, 38% cost savings and an average time saved of 51%.^e Interestingly, highest quality does not correlate with highest cost, however, the least costly vendor produced the lowest quality translations.

Strategic Directions

On the basis of clinical, operational, and field experiences, along with validation from our translation survey and research, the necessity of a translation infrastructure has become an organizational imperative.

As an integrated delivery system, KP is well positioned to leverage cutting-edge technology, operational expertise, and a proven quality translation model. Instead of functioning in silos, medical facilities and departments Programwide can benefit from utilizing a centralized translation infrastructure and a standardized quality translation process.

NLCP has created an enterprisewide infrastructure model, and leads the strategic collaboration, partnership, and contribution of all regions. As such, our organization will be able to ensure quality review, eliminate redundancy, contain costs, and share resources across the Program. More importantly, our diverse membership will benefit from accurate, consistent, and culturally and linguistically appropriate written materials throughout the Program. Thus, the enterprise approach can positively impact and improve service quality, and address health and health care inequities related to language barriers.

What Providers and Staff Can Do Now

As NLCP continues to advance the development and implementation of the centralized translation infrastructure, providers and staff can take some

As an integrated delivery system, KP is well positioned to leverage cutting-edge technology, operational expertise, and a proven quality translation model.

Action Steps

Before using translated materials:

1. Make sure that an English source document is available for your review.
2. Verify that there is a match between the English version and the translated version (ie, an English version of a genetics questionnaire was updated, however, the translated version still exists in the older version).

In the absence of these two criteria, the quality of the translated documents is highly questionable. Please alert your facility/department designee responsible for translations.

Be a change agent and get involved in improving patient-centered communication:

- Participate in the National Coalition for Quality Health Care Translations and other NLCP initiatives.
- Seek opportunities to increase your cultural and linguistic skills to create a sense of welcome and trust with your LEP/NEP patients.

For more information on the progress of the Enterprise-wide Translation Infrastructure, the Coalition, and consultation, contact National Linguistic and Cultural Programs, National Diversity at 510-271-6386.

immediate action steps. (See Sidebar: Action Steps.) ❖

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- ^a For more information, please visit the Department of Justice Web site at: www.usdoj.gov/crt/cor/coord/titlevi.htm.
- ^b For more information, please visit the Office of Minority Health Web site at: www.omhrc.gov/templates/browse.aspx?lvl=2&lvlID=15.
- ^c The majority of responses were from Northern and Southern California.
- ^d The California Endowment Grant Number 20012268
- ^e This study tested a sample set of documents in Spanish representing topics in health education and member marketing.

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**NATIONAL
DIVERSITY**

*Simply put, diversity is how
we achieve our mission,
and how we grow the business.*

—Ronald Knox, VP and Chief Diversity Officer

Total Panel Ownership and the Panel Support Tool— “It’s All About the Relationship”

By Gerard Livaudais, MD, MPH
Robert Unitan, MD
Jay Post

Frank Brennan, MD, a primary care physician, arrives at work at 7:00 am, to get a head start on the day. It’s a Monday and he knows his schedule will be full of patients wanting his care and attention. He enjoys being with his patients, but always needs more time. He diligently works through his schedule, focusing on one patient at a time. Dr Brennan worries about all the patients on his panel who need to come in but haven’t. He would like to get back to why he became a physician in the first place: to be with, talk to, and care for his patients in a personal way. But by the end of the day he is exhausted trying to stay on schedule. It’s only Monday. Simply running faster will not work. Dr Brennan thinks there’s got to be a better way.

Rob Unitan, MD, a pulmonologist from the NW Region, Samir Patel, MD, a family practitioner, and Gerard Livaudais, MD, an internist, both from the Hawaii Region, wondered about that “better way” and developed bold visions of how a new approach would work. Through a chance meeting in 2005 at the Institute for Healthcare Improvement (IHI) Summit on Clinic Redesign in Washington, DC, they discovered their common interests. Dr Unitan, Dr Patel, and Dr Livaudais created a new program to dramatically change the way they work that changed forever how they view “care delivery.”

“Our work is not the schedule” Dr Livaudais quoted Doug Eby, MD, whom he met at the Washington, DC, conference. “The work should really be our panel, not just those who come in sick.”^{1,2} Dr Livaudais knew that seeing one patient at a time didn’t work and that incremental refinement of our existing system would not get us there. “What we need,” Dr Livaudais continued, “is to totally rethink our methods of delivering care. We should redesign our system with a forward-looking concept that anticipates what we need to succeed to improve the health of the entire population we serve.”

What resulted was Total Panel Ownership and an easy-to-use Web-based member database called the Panel Support Tool.

—Tom Janisse, Editor-In-Chief

Total Panel Ownership

Responding to the challenges of the existing system, the Northwest and Hawaii Regions (Table 1) embarked on the transformation of the Care Delivery System, referred to as Total Panel Ownership. Beginning with Primary Care, this implementation began in 2005 with two pilot sites in the Hawaii Region; widespread implementation will continue in 2006 for both Regions.

Although there is no single definition of Total Panel Ownership, the following are its main elements:

- **The focus is on relationship.** This includes the relationship with the members of the panel as well as among members of the core team. It

has been statistically demonstrated that members who have a close relationship with their Primary Care Physician (PCP) are more satisfied.³ A strong relationship generates trust with the physician and other team members. In this environment, team members are able to function to the best of their ability.

- **The needs of the panel are met in the most efficient and convenient way.** In addition to the face-to-face office visit, a resource-intensive option, panel members are given more flexible access options: phone consults, phone advice, phone and e-mail-based care management, self care, group appointments and more.



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Jay Post, (right) is Director of Management Engineering for KP Hawaii. E-mail: jay.post@kp.org.

Opening Day Congratulations

December 9, 2005

Dear Panel Support Tool Team,

On behalf of the Hawaii Region’s executive team, chiefs, PIC’s, and Board of Directors, please accept our heart felt “mahalo nui loa” for your astounding collaboration, expertise, and will to succeed that allowed for the Panel Support Tool to be piloted this week. It’s fast, beautiful, and useful!!

It was my privilege to attend the Nanaikeola Clinic’s “day 1” experience and I am reassured that you have given our physicians, practitioners, and staff an outstanding tool to identify and treat “care gaps,” engage our members in the context “we know you and care about you,” and demonstrate improved evidence-based clinical outcomes.

I am flat out amazed and grateful. When KP talks about our “integration advantage,” I’ve always envisioned miraculous productivity. Your diverse expertise, passionate, synergistic design and product implementation is so appreciated. In Hawaii, “no ka oi” signals the very best. Congratulations all, no ka oi.

— Geoff Galbraith, Vice President, Quality Improvement,
Hawaii Permanente Medical Group

- **A dedicated core team owns the care of the panel.** With “ownership,” the core team has the autonomy and freedom to innovate how care is delivered with an emphasis on being proactive, not reactive. Ownership means the team is responsible for the delivery of care, reaping the benefits or accepting the consequences. There is a strong personal incentive to care for the panel in the most effective and efficient manner.
- **The team has tools to support the care of the panel.** The primary tool is the *Panel Support Tool*, which graphically displays “care gaps” for each member of the panel. The care gaps are based on the latest evidence of recommended care for members with various conditions and recommended preventive care on the basis of gender and age. The team works to close the gaps for all members of the panel. The team is encouraged to be creative in how the gaps are closed, including addressing the maximum number of nonacute needs during an acute visit.
- **The team is proactive in meeting the needs of the entire panel.** Each member should be afforded value in return for his/her dues. One objective is to have an “annual touch” with each member of the panel. Offerings are customized on the basis of each member’s needs. A member with diabetes and heart disease may need intensive RN-based care management; a young member with no illnesses may need only basic information on maintaining a healthy lifestyle.

Table 1. Total Panel Ownership and Panel Support Tool team

Leslee Budge, MBA, Program Manager, Population Care Information Services, Care Management Institute
Ken Forbes, Care Management Analyst, Hawaii
David Gardelius, MS, IT Program Manager, Northwest
Monty Glover, MSIS, Database Application Developer, Hawaii
Jean Hartman, KP-IT, Database Administrator, Northwest
Dawn Hayami, Director of Population Care Support, Northwest
Gwen E Houser, Consultant from Accenture Consulting
Kathleen Keller, Population Care Support, Northwest
Pat Killow, KP-IT Web Developer, Northwest
Harold Kurt, KP-IT Project Lead, Northwest
Rick Leffler, KP-IT Database Administrator, Northwest
Gerard F Livaudais, MD, MPH, Physician Lead Internal Medicine, Hawaii
Leilani Longa, Operations Consulting Database Analyst, Hawaii
Chris Lutz, MBA, Clinic Manager, Hawaii
Rick Morse, KP-IT, Database Administrator, Northwest
Twila Mysinger, KP-IT Solution Design Consultant, Northwest
Samir A Patel, MD, Family Practice Physician, Hawaii
Jay Post, MS, Project Coordinator, Hawaii
Jada Snyder, KP-IT Web Designer, Northwest
Patti Stone, KP-IT Web Designer, Northwest
Kati Traunweiser, Primary Care Project Manager, Northwest
Robert Unitan, MD, Physician Lead Data Warehouse, Northwest
Trung Q Vu, Strategic Planning Database Analyst, Hawaii
Peter Weiser, National PCIS IT Program Manager, Program Offices
Guy Yamada, OD, MBA, KP-IT Database Analyst, Hawaii

The team tailors resources to meet individual needs and preferences.

- **Innovators are allowed to emerge and try new experiments.** Total Panel Ownership needs a nurturing environment in which "independent agents" move quickly and freely to explore new ground and try new "rapid-cycle" experiments that may lead to new solutions. An evolving concept, Total Panel Ownership is a flexible and open program that allows solutions to arise out of practice.
- **The natural "power" of the team is unleashed.** Total Panel Ownership's intrinsic "attractors" make it inviting for teams. It thus becomes a self-sustaining change program generating its own power to continue, rather than relying on an external force-feed to keep it going.⁴
- **Total care is coordinated.** Total care means that primary care and specialty care should be seamless in providing services. Using the Panel Support Tool as the common ground for coordination, specialty and primary care can each identify the intersection where primary care and specialty care services meet.
- **There is accountability for resources.** Panel ownership includes the responsibility to manage panel resources and their associated costs. It is our cost structure that puts us at risk in the health care marketplace and presents the greatest challenge to the organization. Rather than

implementing a straight percentage reduction in the budget, our chosen method is waste elimination. Waste adds cost without adding value; therefore waste elimination does not compromise care. The Panel Support Tool is a natural place to reveal cost information and potential waste and make this information available for teams to use.

These are the core building blocks that the teams in Hawaii and the Northwest will use to help create the new care delivery system. Each clinic/team is self-governing and therefore free to create/design an improvement effort that supports one or more of these elements. Ideally, all of the above elements will be covered in the process and the best aspects of each will be combined to create the new, transformed care delivery system. Most of these teams will begin with the adoption and implementation of the Panel Support Tool.

The Panel-Support Tool

A Case of Then and Now:

Then: *James is a 39-year-old diabetic patient last seen by Dr Frank Brennan two years ago. Quiet and reserved, he recently quit his job and withdrew from all social interaction. Although his wife orders his medicine regularly, he throws it away. He hasn't been monitoring his glucose for many months now. James is aware of a 'nick' on his shin that is looking angry but he remains impassive to his wife's concerns.*

A Historic Moment Now Realized

One can envision a new health care system of the future, which will begin with a basic comprehensive health evaluation for each individual The result of that evaluation will chart each individual's personal pathway through our health care resources toward optimal health. Periodic updating of health evaluation profiles will monitor the homeostasis of vital body systems and significant deviations will trigger computerized warnings and corrective instructions. Health evaluations will alert and advise measures to be taken against individual predictive risks be they lifestyle, hereditary, environmental or age/sex linked through time. Such individualized continuing health care would greatly reduce patient uncertainty and could, in large part, replace today's chaotic random-entry demand with a smooth regulated use of appropriate resources that would not only be cost effective, but also would optimize the health of each individual through his lifetime. It should be clear this new medical care delivery system in this health care of the future could never be fully achieved without the large amount of individual information, cybernetic data feedback, protocols, advice rules, monitoring and surveillance that systematized health evaluation and computerization makes possible. That is the great promise of this new delivery system for medicine of the future.

— Sidney R Garfield, MD, 1975, co-founder of Permanente Health Plan, in a talk to medical students at the University of Southern California

Unfortunately, no one at the clinic knew about this, nor had they picked up on his depression, brought on by the anniversary of his father’s death five years ago. There simply hadn’t been enough time in the rushed visits to do more than a brief physical and a review and ordering of labs and medications. With an overloaded schedule every day, it’s not clear when anyone will notice that he hasn’t had his labs drawn, until his leg becomes serious enough to force him to come in for debridement and antibiotics.

Now: *James is a 39-year-old diabetic patient of Dr Frank Brennan who saw him one year ago. He’s in good control of his diabetes and though naturally reserved, has a good relationship with his physician and has great rapport with his physician’s medical assistant. He receives an e-mail from his team every three months, and expects a phone call every three to six months, as well. His progress, and that of every patient on the panel, is monitored by the team via the Panel Support Tool. Last week, while reviewing the diabetic portion of the total panel, the team was surprised that James was on the list. When they called him they recognized his remarkable lassitude, and encouraged James to come in. During the call, the team used the Panel Support Tool to uncover his overdue labs and medications, which had been ordered. Behavioral health, copied on the telephone encounter with a request, prepared to meet with James on the day of his visit. All in all, the combination of an existing relationship and a tool that prevents patients from “falling through the cracks” proactively averted a disaster with remarkable efficiency.*

The primary difference between these *then-and-now* case vignettes is the Panel Support Tool. As shown in these vignettes, the Panel Support Tool gives providers the capability to quickly and easily assess the health needs of any single member or any cross-section of the physician’s panel without awaiting the availability of analytic resources. The tool then helps providers take the needed action with the support of evidence-based systems of care.

The Panel Support Tool was created through a collaboration between clinicians and Kaiser Permanente Information Technology (KP-IT) from the Northwest and Hawaii Regions with support from the Care Management Institute’s Population Care Information System (PCIS) workgroup. Web-based, the Panel Support Tool was designed to compliment KP HealthConnect by giving us efficient and effective summary information at the PCP’s *panel* level rather than at the *patient* level. This required that the Panel

Support Tool be developed so that it: 1) is easily available online, 2) needs little or no training to use, 3) is powerful enough to do Standard-of-Care type screening, 4) provides instant analysis, and 5) enables immediate patient intervention. Significant support is also being received from the Institute for Healthcare Improvement (IHI) and the 21st Century Care Redesign, which is contributing ways to quickly develop, test, and implement ideas using PDSA improvement cycles.

The “Care Gap”—The Total Panel Ownership Measure of Quality

Care gap identification and calculation is a primary feature of the Panel Support Tool. The care gap is a numerical score representing the difference (or “gap”) between needed care and provided care. For example, patients with a history of diabetes, coronary artery disease, peripheral vascular disease, or cerebrovascular disease who have not filled a prescription for a statin or an ACE inhibitor in the past six months, or have no documentation of aspirin use, receive four points for each deficiency (ie, 12 points if they are missing all three drugs). If they are found to have poorly controlled hypertension, another two points are added. If they haven’t had their LDL checked in the past 12 months, this earns one more point.

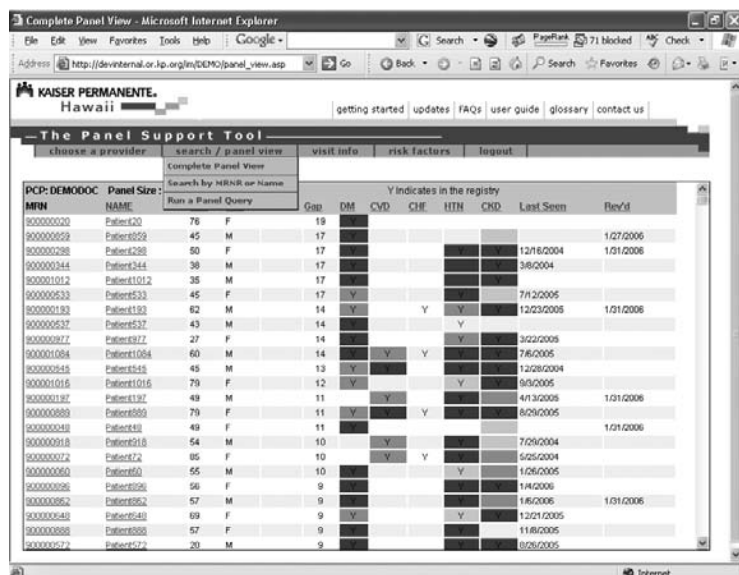
Each night the Panel Support Tool extracts a set of specific data elements from KP HealthConnect and the regional data warehouse and displays the information on a dynamic spreadsheet with various color and numeric coding for easy reading (Figure 1). For example, the tool automatically sorts members with the highest calculated care gap to the top of the list for quick identification and action. The clinician and/or their support staff can sort for any number of conditions or parameters to identify common or prevalent health needs that may be addressed many-at-a-time instead of one-at-a-time. Total or composite care gaps can also be calculated for each panel and thus the net improvement in the health of the panel can be measured over time.

Navigating Through The Panel Support Tool

The Panel Support Tool is designed to be intuitive enough to require little or no training. The following describes the ease by which a user can navigate the tool and exercise its basic features:

After entering an ID and password, the tool opens to a list of all of the primary care providers in the Region. Clicking on a clinician’s name brings up the *Complete*

Panel View (Figure 1), which is a grid that stratifies the panel members according to their individual weighted care gap scores and disease severity classification, graphically displayed for diabetes mellitus, cardiovascular disease, congestive heart failure, renal insufficiency, hypertension, primary prevention screening (breast, cervical, and colorectal cancer screening, immunizations, blood pressure and lipid), and risk factors such as hyperlipidemia, obesity, and smoking.



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Figure 1. The Complete Panel View.

From the *Complete Panel View* spreadsheet, clicking on the member's name takes the user to a *Patient Detail Screen* (Figure 2), which, in addition to care gaps, displays their most recent vitals, relevant medications, and core laboratory values. Hovering over the result displays the trend. Clicking on a member's medical record number, however, takes the user to a *Patient Snapshot Screen*, which lists each care gap contributing to the score. Hovering over most gaps with the cursor brings up a small window, which further defines the criteria for that specific deficiency.

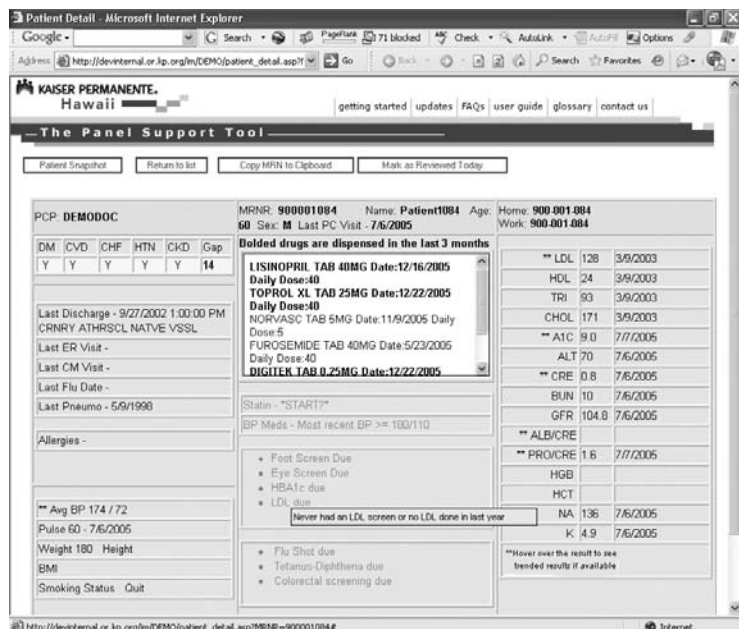
The *Complete Panel View* grid is configured with each disease in a single column. The presence and severity of each disease, together with monitoring/guideline compliance is indicated by the color coding of each cell (or square) formed by the intersection of the disease column and the patient's row. For example, in a patient with diabetes and a glycosylated hemoglobin (HgbA_{1c}) less than 7% in the past six months the diabetes cell will be green. An HgbA_{1c} between 7-9% turns the cell yellow, and >9% turns it red. A diabetic without an HgbA_{1c} result in the past 6-12 months will be identified with a yellow square, and >12 months since the last HgbA_{1c} earns a red square. Detailed descriptions listing the parameters used in determining the color coding for all diseases are found in the *Glossary* (Figure 3).

While designed for the primary care provider, the Tool also supports users focusing on a specific disease, such as case/care managers. Clicking on the disease name at the top of each column stratifies all members of the panel in descending severity for that disease. Red indicators are found at the top of the grid, followed by yellow, then green. Patients identified in a specific disease registry are designated with a 'Y' in that cell. Panel members not identified as having that specific disease fall to the bottom of the grid.

Although the Panel Support Tool runs on the desktop outside KP HealthConnect, the user can easily toggle to and from the medical record for documentation and ordering. Work is ongoing to embed the tool within the HealthConnect home-space to facilitate greater integration with the medical record. The goal is to be able to launch Review or an Encounter for a specific member in HealthConnect directly from the tool.

Patient Activity Tracking

An important and useful feature of the Panel Support Tool is its ability to track panel activity by the PCP, specialist, or other caregiver on each member. These "ticklers" help the provider remember where s/he last worked on the panel. For example, the tool keeps track of which patients were "touched" within the last year



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Figure 2. Patient Detail Screen.

and which ones weren't. The tool can also identify all members of a panel seen in the Emergency Department in the past week, and displays each member's most recent hospitalization information. It also lists the date of their last primary care visit and can easily identify all not seen in the past year.

A Cross-Functional Team-Based Approach

The Panel Support Tool is designed to allow teams to maximize their support of the PCP. The team closest to the PCP is the Core Team: In Total Panel Ownership, a core team typically consists of a PCP and a dedicated support team, which includes: a Registered Nurse (RN), a Medical Assistant (MA), a Nurse Practitioner (NP), and a receptionist, although the exact composition is still in flux (for example one core team may have one PCP, one MA, and a .5 RN and another core team may have one PCP, .5 MA, and one RN.) Team members are empowered to self-organize and find creative ways to meet the needs of their panel.⁴ Over time, the core team will develop close-knit relationships among the members of the core team as well as between the core team and the panel of members. These relationships will lead to trust.

Future Directions: Specialty Care/ Primary Care Integration

The Panel Support Tool has great potential to promote better integration and care coordination between specialty and primary care. Work is in pro-

cess to provide views that can cut across panels and display data on all patients with a given disease. Its potential to support proactive coordinated care programs that can be led or managed by various teams who have access to the tool is tremendous. A fully functional demonstration version of the tool is available at: <http://devinternal.or.kp.org/im/demo/login.cfm>.

Chronic Conditions	Color	Specifications
DM	Red	In the DM registry and no A1C value or A1C > 12 months ago or A1C >= 9.0
	Yellow	In the DM registry and A1C is between 7.0 and 8.9 or A1C date is between 6-12 months ago.
	Green	In the DM registry, HbA1c < 7 and done within the last 6 months.
CVD (CAD, PVD or Stroke)	Red	In CVD and last LDL >=130 or GFR <= 30
	Yellow	In CVD and last LDL between 100 and 129 or gfr between 30 and 90
	Green	In CVD and last LDL < 100
Heart Failure	Red	EF <=40
	Yellow	In HF and EF between 41 and 55
	Green	In HF and EF > 55
Hypertension	Red	Avg Systolic >= 140 or Avg Diastolic >= 90 and last BP < 180/110 or last BP Sys >= 180 or last BP Dia >= 110 or in HTN and last BP date is > 12 months
	Yellow	Avg Sys between 135 and 139 or Avg Dia between 85 and 89 AND last Sys between 135 and 139 or last Dia between 85 and 89
	Green	None of the above and last BP date < 12 months ago.
CkD	Red	GFR <= 60 or Nephropathy flag is not null
	Yellow	GFR between 61 and 90
	Green	GFR > 90

Figure 3. Glossary: Red, Yellow, Green Color Specifications.

Potential Benefits and Savings

The benefits and savings from Total Panel Ownership and the Panel Support Tool are significant. They include:

- **Avoidance of expensive acute care.** This is possible by allowing a competent analysis of the panel for developing needs.
- **Elimination of costly waste.** Large benefits are possible from improved coordination between primary care and specialty physicians working on the panel in an aligned, coordinated way.
- **More effective use of staff time.** By working more efficiently at the panel level rather than the one-member-at-a-time level staff can be more productive.
- **Increased member retention.** By better targeting and promoting programs, low-utilizing or healthier members will get more value for their paid dues and will be more inclined to renew. This obviously maintains/increases our market share.
- **Increased physician retention.** As the various PCP support teams join in, assess the PCP's panel and do additional corrective or preventive care under the PCP's general direction, the PCP receives a greater feeling of support in the workplace. This helps to avoid physician burnout and attrition.
- **Improved staff retention.** Staff are happier when given more sustainable and fulfilling work.
- **Better use of less expensive associate and support providers.** This can occur with better review of panel needs for identification of appropriate opportunities.
- **Less reliance on the resource-intensive clinic visit.** By giving the patient a greater range of options for access, they will naturally select those that are more efficient for themselves and the organization.
- **Greater involvement of staff on managing resource costs.** This capability begins with the provider level cost data.
- **Better overall delivery of quality care** due to all of the above.

It's All About The Relationship

A core value to absolutely maintain is the time-honored "relationship" with the patient. Why is relationship important? Relationship is the hidden link between the member, staff, and PCP. Its power and presence is always there and exists in many ways, but isn't necessarily noticed, appreciated, or understood. Although quality health care is delivered, the member cannot always judge that; however, the member does judge the quality of the relationship. That is what is valued. If the relationship isn't good, the patient feels it. The member's self worth is reflected in the relationship, eg, how the PCP values what the patient says. Patients with low self worth feel less empowered to change. Relationship is the "magic" element that can make operations special. Behind what is said and done, the patient notices the deep heart-based feeling that only comes from relationship. What ultimately lies at the core of operations, principles, and strategies, is the personal and professional relationship between members and physicians, team, and staff.

Grounded with a relationship focus, the team channels all interactions toward the PCP team. This requires patient education, external and internal marketing, agreements with the other PCP teams, and receptionist and scheduling support. Over time, systems such as scheduling have unintentionally evolved to obstruct panel ownership and relationship by appointing patients into the next available slot. The result has been that patients of Dr Jones saw Dr Smith even though Dr Jones was in clinic that day and vice versa (because Dr Jones' appointments were filled with Dr Smith's patients). Similarly, centralized call centers, disease management programs, mass mailings from "Kaiser" or "your doctor" all subtly replace the patient's primary relationship with their PCP team. This does not diminish the merit of call centers, but simply points out the missed opportunities of more efficient, effective, and personal interactions occurring through an existing, trusting relationship.

How does Total Panel Ownership support "the relationship"? Relationship is intrinsic to the design in many ways:

- Flexible modes of access—relating to patients in ways other than the clinic visit
- Annual touches—maintain regular contact
- Personal health agreements—built on trust from an effective working relationship
- Panel support specialists—staff empowered and encouraged to establish a relationship with each member

- PCP team support—through team relationship
- Personal change—relating to the individuality of each patient
- Education and self-care—not as teacher but as partner in their health
- Panel database—through the panel database, we KNOW each patient better. To know each patient better is to relate to each patient better.

How Provider "Sustainability" Is Supported

Total Panel Ownership ensures provider sustainability in many ways:

- Work efficiencies—the Panel Support Tool provides an easy, satisfying way to work.
- Efficient access—less intensive use of appointment provides more breathing room in schedule.
- Work enrichment—the variety of access types makes work more interesting.
- PCP team support—team support is the highest physician satisfier.⁵
- Quality of work-life—physicians can do what they became physicians to do.
- Enjoyment of relationships—physicians have more opportunity to enjoy patients, team members, and colleagues.
- Energy generation—Total Panel Ownership encourages a culture of support for our providers that continuously recharges their battery.

Implementation to Date

As of February 2006, two clinics in Hawaii have gone live on the Panel Support Tool with about 100 users (half physicians and half support staff) signed up. The Northwest will begin rolling out its version of the Panel Support Tool in early March 2006, and has identified nearly 50 clinicians to pilot the tool by late April. The Hawaii Region is basing its 2006 Strategic Plan on Total Panel Ownership and the Panel Support Tool, with all clinics developing innovative plans to support its implementation. For example, the Hawaii Region is now planning a new "21st Century" Clinic on Windward Oahu, whose bold design will promote superior communication and relationships within the core team and between the core team and the patients. Fredrick Sands, MD, an internist at the Maui-Lani clinic, says, "The Panel Support Tool is great! It helps me track and manage my patients with chronic diseases, and it gives me a quick and efficient assessment of my patient's preven-

tive care needs. Now I feel much more confident that I’m taking care of all my panel patients.”

Summary

Total Panel Ownership and the Panel Support Tool is a promising answer to the serious challenges of escalating costs, competition, and member demands. Under Total Panel Ownership, physicians and staff can become an integrated network of dedicated professionals, empowered to make changes they control, supported by efficient programs that take care of all their patients, with relationship-based care at the core. The Panel Support Tool is the breakthrough that allows us to look at all members and relate to them in an efficient, value-added way. By moving away from the one-patient-at-a-time concept, allowing more effective and efficient use of our resources and managing them in ways that add the greatest perceived value to each of our members, we will have greater capacity and capability to compete and thrive in the health care marketplace (and Dr Brennan, our PCP, will then have a sustainable and enjoyable practice within reach).

Conclusion

The intent of Total Panel Ownership goes beyond operational improvement—it’s really about creating an environment where the organization’s power can be focused on supporting true member needs. We want to do more than just focus on those who come to see us for their physical health issues. We want to know and satisfy the needs of each of our members—the high-utilizing members with multiple medical conditions and the low-utilizing, healthy members—and then

foster those behavior patterns that will keep them healthy and happy. This will allow those low-utilizing, healthy members, most at risk of leaving KP, to see value for their premium dollar. These outcomes are most possible when we are able to develop trusting relationships. That is the goal of Total Panel Ownership. Enabled by the Panel Support Tool, Total Panel Ownership makes it possible for us to know each and every one of our members and achieve a unique relationship with each. When it comes to care transformation, we believe it’s all about the relationship. ❖

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Opening Up

You know institutions tend to become static; they build walls around themselves to protect themselves from change and eventually die. You should fight that by opening up your thinking and your ideas, and work for change.

— Sidney R Garfield, MD, 1906-84, founder of the Kaiser Permanente Health Plan
This “Moment in History” quote collected by Steve Gilford, KP Historian

Innovation

People Using Technology to Transform Care: The 21st Century Care Innovation Project

By Hannah King, MPH
Ruth Brentari, MHA
Leslie Francis, MBA, MHA
Charles M Kilo, MD, MPH

I feel like this is the 'doing things differently' that we've been talking about for the past 20 years.

– Sandra Barton, MD, Tualatin, Oregon
(Northwest Region)

What is Dr Barton talking about and how is this possible? Dr Barton and many other primary care clinicians across Kaiser Permanente (KP) are part of a pilot project called the *21st Century Care Innovation Project*. The purpose of this project is to leverage the use of KP HealthConnect™ (an organizationwide electronic health record system) to transform care and create thriving physician practices.

The Health Plan and delivery systems of KP, like the rest of the nation's health care systems, are facing significant cost pressures from employer groups and the largest single purchaser—Medicare. There is increasing risk of losing customers who can't afford insurance premiums. Adding pressure to KP's cost position in the market is its multibillion dollar strategic investment in KP HealthConnect and the need to rebuild aging facilities.

For primary care practitioners, the model for delivering care is still based on a production model where patients move through a complex system. The majority of work for physicians and staff revolves around dealing with what is in front of them in the moment. There is little time, room, or incentive for changing work to create flexibility and capacity to meet the growing needs of members. Now more than ever, there is a need to transform care delivery so that health care is more cost effective, convenient, and satisfying for KP members and provides a fulfilling work environment for clinicians and staff.

The majority of work for physicians and staff revolves around dealing with what is in front of them in the moment.

Design

In September 2005, the KP Partnership Group (KPPG)^a chartered the 21st Century Care Innovation Project in collaboration with the Institute for Healthcare Improvement (IHI). The project outcome is to improve patient care delivery by making primary care more patient centered, and simultaneously developing a more fulfilling and sustainable work environment for physicians and staff (Table 1 and Figure 1). This collaboration of KP labor partners and nine innovation teams from five KP regions and Group Health Cooperative focuses on changing the work they do, not just improving efficiency (Table 2). The overall direction for designing a new primary care model was established by leaders from the Permanente Medical Groups and Kaiser Foundation Health Plan and Hospitals and built from the tenets of the Blue Sky vision.¹

Innovation Teams

While each of the multidisciplinary 21st Century Care Innovation teams works locally on redesign, representative team members meet together frequently by phone and in person to share ideas, successes, and failures. This collaboration speeds the rate of change and multiplies the innovative ideas that teams test and transfer. IHI faculty^b attends team meetings and works individually with each team to understand their work and help them refine their changes.

At least one labor representative participates on each team, and regional labor partners have been involved in all the teams' work. *"The Strategic Labor Management Partnership is extremely important when introducing an innovation project. The 21st Century Care Innovation Project has been successful because people are working in an integrated fashion. People on the*

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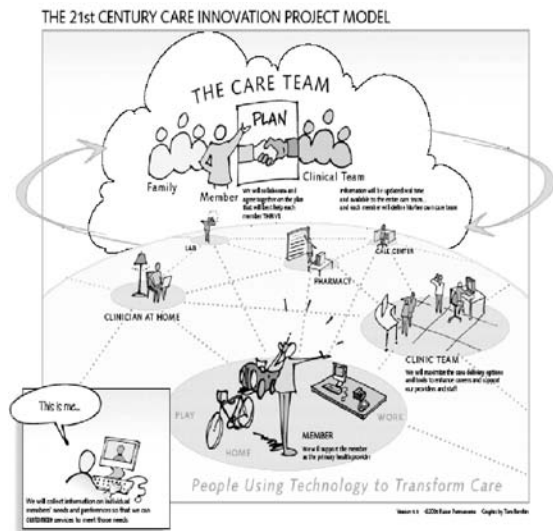


Figure 1. The 21st Century Care Innovation Project model.

Table 1. Conceptual model for the 21st Century Care Innovation Project
<p>Teams are encouraged to test a variety of changes in order to create a new paradigm of health/health care delivery that:</p> <ul style="list-style-type: none"> • Transforms the delivery system to be patient centered • Cares for our patients as total beings—caring for the whole person, not just a disease or condition • Empowers patients to be more proactive and engaged in their care • Includes all members of the care team in supporting the patient’s care—because information is available • Ensures that the work environment is sustainable and healthy for our physicians and staff • Integrates and leverages technology to improve care delivery • Eliminates waste in the system by doing things right the first time

frontline have great ideas for improvement and they are giving those ideas to their team to make changes,” says Claudine Salama, National Project Coordinator—KP HealthConnect, Coalition of KP Unions, AFL-CIO.

The innovation teams also include one or more KP members who attend weekly meetings to ensure the work stays patient centered. “Just having a member in the room changes the conversation. I can no longer say, ‘Our patients want X; I need to ask first,’” says Internist Sean Riley, MD, of the Skyline team in Colorado. Members’ suggestions have included: the expected response time for return messages, what they want accomplished in group visits, and how clinicians and staff can develop stronger relationships with them.

What is Changing?

After 12 months of quality improvement work, a new paradigm for primary care delivery is emerging. By leveraging KP HealthConnect the teams have created new workflows that have resolved some patients’ problems without a face-to-face encounter. This creates capacity by reducing the demand for traditional office visits. Health care teams now organize the work of the day, week, and month instead of reacting to the daily visit schedule.

1. The Telephone Appointment Visit

In Hawaii, Internist and Pediatrician Todd Kuwaye, MD, and Family Practitioner Samir Patel, MD, used to start each day with a room full of patients waiting to see them and the pressure of multiple member messages and appointment requests building up throughout the day.

Today, these physicians spend the first two hours of their clinical day returning messages from patients who either want an appointment or have some other need. The doctors resolve many medical issues on the phone, and, if necessary, schedule a telephone or office visit for later in the day. “I love the variety... It’s not all one-to-one, face-to-face visits anymore. We are doing a lot more visits by phone and group visits and therefore there are fewer office visits. This helps keep things fresh and different,” explains Dr Patel from the Nanaikeola Clinic. “I feel like, as a team, we can meet the needs of the panel much more adequately than before. We’re able to be proactive. Our job isn’t to just take care of the people in front of us. We can meet more needs, even the needs of people who haven’t contacted us, and we can feel good about this.”

In the Southern California Region’s Whittier facility, José Goncalves, MD, a family medicine physician, has a similar experience. He now spends one 1/2-day per week on scheduled telephone visits. This approach allows him to care for 15 patients in a half day versus 11-12 in the old system. His patients are satisfied that they have greater access to their primary care physician (PCP) and they avoid a copay and avoid travel on Los Angeles’s crowded freeways.

“The new work of the 21st Century Care Innovation Project has increased my flexibility. I feel closer to my patients,” says Dr Goncalves. “When they don’t need to come in, I can take care of them by phone or e-mail.

I can no longer say, ‘Our patients want X; I need to ask first,’ says Internist Sean Riley, MD, of the Skyline team in Colorado.

Table 2. 21st Century Care Innovation Teams
Colorado: Skyline, Southwest
Group Health Cooperative: Burien
Hawaii: Nanaikeola, Maui Lani
Mid-Atlantic States: Camp Springs
Northwest: Longview-Kelso, Tualatin
Southern California: Whittier

Patients who have received these calls express surprise and are thrilled to talk to their doctor and resolve their problem quickly versus having to come in to the medical office to receive care.

When they do need to come in, I can say, 'Why don't you come in right now; I have time.'

The Evolution of the Telephone Appointment

While most physicians have made telephone calls to patients throughout their careers, there are some important changes the teams are testing. In some cases, patients are being offered a choice of a scheduled office visit or a scheduled telephone appointment visit (TAV) when they call the call center. TAVs are also being scheduled by the clinic staff for a follow-up visit. Internist and Pediatrician, Chris Shaw, MD, from the Longview-Kelso, Washington team (Northwest Region) says, *"What's nice with booked telephone visits is they say, 'Dr Shaw will call within this time period,' so it gives me a cushion and I don't feel the pressure of people waiting in the waiting room. This makes my day better and patients think phone visits are great."*

In other cases, patients are offered a call back from their physician (in a one-to-four-hour time period) instead of immediately booking an appointment. TAVs are also occurring on an ad hoc basis when a physician looks at his/her schedule several days in advance and notices a scheduled appointment for something that could be handled over the phone. The teams call this "fishing." Patients who have received these calls express surprise and are thrilled to talk to their doctor and resolve their problem quickly versus having to come in to the medical office to receive care.

In general, telephone visits are increasing and office visits are decreasing (Figure 2).

2. Secure Messaging

Use of secure messaging (confidential e-mail) by clinicians and patients is similarly changing demand for care and creating new capacity. Teams are experimenting with sending previsit e-mails to patients to begin a dialogue prior to the office visit, to better plan the visit, and to nurture their relationship. Patients are pleased to converse with their PCP through secure messaging. Physicians have commented that they can resolve patients' needs through secure messages. With the resulting reduction in office visits, more time is available for patients who need a face-to-face visit. This experience is consistent with the formal secure messaging study conducted in the Northwest Region.

3. Population Care Management

Missed opportunities for better patient care now appear through the use of tools like the Panel Support Tool (PST), KP HealthConnect, and registries. With the increased capacity through the use of the telephone and secure messaging, the 21st Century Care Innovation teams are exploring ways to care for their whole panel of patients. Medical assistants who previously spent considerable time rooming patients for office visits, now have time with clinician team members to experiment with patient outreach (population care management) and engage patients in their own care (collaborative care management).

The PST—a sortable, Web-based member database populated with the medical information of a physician's entire panel of patients—was codeveloped by Northwest, Hawaii, and KP-Information Technology to pro-

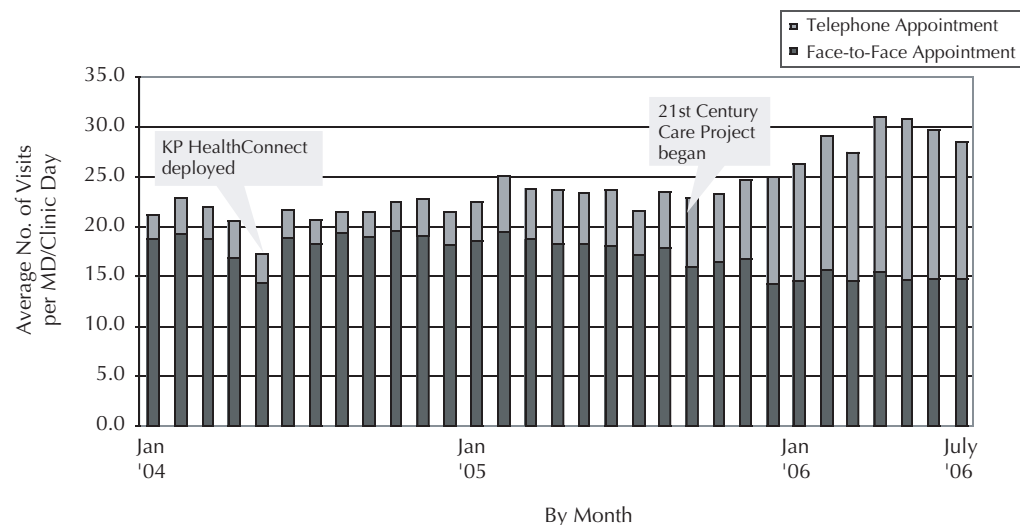


Figure 2. Trend of office visits and telephone visits at the Nanaieola Medical Office in Hawaii.

vide a stratified snapshot of unmet medical and preventive needs for each patient.² Currently available for the Hawaii and Northwest teams, this tool assists the physician and the care teams in prioritizing the outreach activities for the physician, nurse, and medical assistant to improve patient care.

Dr Shaw says *“MAs and LPNs are calling members (on behalf of the physician) who are overdue for a mammogram, cholesterol check, or Pap smear.”* He continues, *“On a short-term basis, we are doing more so it isn’t saving time, but in the long term, taking care of all of the patient’s needs will reduce enormously the unfilled care needs, or even worse, complications.”*

Stacey Johnson, Clinical Assistant on the Camp Springs, Maryland team (Mid-Atlantic States Region), says, *“The patients are surprised when I call. Working with them outside of the office makes them more comfortable with me. I like it because I get to do more in my day than checking blood pressures and weights; I’m more connected to the patients.”*

Involving the Entire Care Team

As the teams’ gain a better understanding of caring for their whole panel, they are also trying to utilize all the members of their care team within their licensure to address unmet needs. Nurse Practitioners are taking a key role in providing group appointments and outreach for patients with multiple comorbidities. Nurses are making outreach calls regarding medication compliance and relaying lab results. Many MD/RN/MA teams are now located in close proximity, often in the same office, to exchange information more easily, which equips the team to more effectively handle questions and messages from patients.

In addition, KP HealthConnect ensures all medical and health care is documented and available to team members when they need it. This has served to increase the competence and confidence level of everyone on the team.

“Having a nurse share my office has really increased our team work. We can share information and I don’t feel like I alone have the responsibility to provide care to my entire panel. I can count on any member of our team to pitch in. Everyone works at their highest scope of practice and potential,” states Dr Samir Patel from the Nanaiekeola Team.

Dr Shaw concurs, *“We are sharing the workload. When there are complex health care issues to talk with the patient about, I make the call. When there are suggested tests and advice, others on the staff are making the calls. We all help patients get what they need. The*

big benefit of working as a team is to be able to do more with limited time and resources. We have the flexibility to double, sometimes triple, how many problems we can solve for patients.”

Many of the teams are extending the traditional view of the care team beyond the MD, RN, LPN and MA, to include receptionists. At one facility, the Medical Intake Specialists (MIS), who greet and register patients, remind them of overdue preventive care needs and, with the patients’ permission, schedule an appointment with the ancillary department on the spot. Teams are also experimenting with expanding team membership to integrate other caregivers, including pharmacists, phlebotomists, nutritionists, behavioralists, and call center agents.

The Voice of Members

Although member satisfaction with telephone visits is being evaluated using a new survey developed by KP National Market Research, the results from existing Medical Office Visit surveys demonstrate that the changes the teams are making have an impact.

The Whittier team has shown improved satisfaction in “Seeing a Provider When Needed,” Appointment Access, and Overall Visit Experience (16%, 8% and 7% respectively) between September 2005 and June 2006. The Longview-Kelso team has seen similar patient satisfaction improvement during the same time frame with an increase in Overall Care (from 71% to 86%), Receptionist Courtesy and Respect (89% to 92%), and Physician and Clinician Interest and Attention (83% to 91%).

Where Do We Go From Here?

Can we draw conclusions about primary care transformation from the 21st Century Care Innovation Project work today? The nine months of available feedback and data indicate short-term improvement, but to effectively evaluate the impact of the changes requires more results.

The project team is collecting a consistent set of utilization, cost, quality, and member and physician/staff satisfaction data across all of the teams. These results should be available in the first quarter of 2007. The innovation teams are refining their new workflows to validate that they are sustainable over time. Teams will continue to test new ways to engage members in managing their health including more expansive use of KP HealthConnect Online features. In 2007, the package of changes developed by the original nine teams will be given to a new set of medical office teams to determine if the experience can be repeated and even improved.

We have the flexibility to double, sometimes triple, how many problems we can solve for patients.

Teams are in the early stages of transformation: something new is taking place. The 21st Century Care Innovation teams are gaining confidence that the changes they are making build upon each other to provide a new and better care system for members, and a more satisfying, sustainable work life for physicians and staff. Physicians and staff are energized, and members are very interested in the new ways KP can deliver care. With support from their local and regional leaders, the teams have had the opportunity to understand what the work is and should be, rather than simply accepting inherited processes. *“I feel like this is the ‘doing things differently’ that we’ve been talking about for the past 20 years. We have preliminary data to show that we are meeting the needs of our panel with fewer office visits and that they are not going to other PCPs or urgent care. We are ‘touching’ more patients than we used to be able to,”* says Dr Barton, MD, internist. *“I can say, ‘I love my job.’ I wouldn’t have said that before. If we spend the time to perfect this over the next 6-18 months, it will be sustainable.”*

... members are very interested in the new ways KP can deliver care.

For more information contact project co-leads Ruth Brentari at ruth.brentari@kp.org or Leslie Francis at leslie.francis@kp.org. ❖

- ^a The KPPG chartered a subgroup to oversee the work. The subgroup includes Louise Liang, MD, Senior Vice President of Quality and Clinical Systems; Jack Cochran, MD, Executive Medical Director, Colorado Permanente Medical Group; Bruce Perry, MD, Executive Medical Director, The Southeast Permanente Medical Group; Mary Ann Thode, President, Northern California Kaiser Foundation Health Plan and Hospitals; Claudine Salama, National Project Coordinator—KP HealthConnect, Coalition of KP Unions, AFL-CIO.
- ^b IHI faculty include Marie W Schall, MA, Director; Kevin Nolan, MA, Senior Fellow; Charles M Kilo, MD, Greenfield Health System; and Gordon Moore, MD, University of Rochester Department of Family Medicine.

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What is it about KP HealthConnect that makes this Work Possible?

“See the work. Share the work. Change the work.”

While **telephone visits** could have been (and were on a small scale) provided previously, the teams have found that KP HealthConnect enables greater ease, efficiency, and scale. With KP HealthConnect all the relevant patient information is easily accessed by the provider during a telephone visit. “Real-time” processing (notes, lab orders, Rx orders) is possible during a telephone visit. Work is completed during the telephone visit with few or no hand-offs required.

KP HealthConnect makes handling **incoming patient messages** more efficient. Each member of the team can access and resolve any request or problem within their scope of practice when s/he has time. For example, a physician can attach to messages in the RN/MA’s in-basket between seeing patients in the office and resolve problems then and there. For requests requiring communication among team members that communication can happen asynchronously—eliminating the need for both parties to be available at the same time in the same space.

For **patient outreach and population care management**, addressing health maintenance alerts can become more than just the clinician’s responsibility. The receptionist can schedule overdue screening appointments for patients. MAs can pend orders for the physicians that will address care whenever they have an interaction with the member (eg, flu shot clinic). In addition, health maintenance information available to the care team is simultaneously available to the member via kp.org.

For **collaborative care planning**, teams are experimenting with using the After-Visit Summary to provide patients with documentation of their goals and personal action plans. Colorado is leading the development of a simple tool for recording (via drop-down menus) personal action plans in the chart (aka a “smart widget”).

For **e-Visits**, one Hawaii team is experimenting with sending electronic questionnaires to patients to more effectively capture key clinical signs/symptoms from the patients via secure messaging.

Systems Approaches to Improve Quality, Performance, and Efficiency in the Care of Older Adults

By David B Reuben, MD

... data from the Centers for Medicare and Medicaid Services demonstrate that across the states, as more money is spent, the quality of care is worse.⁶

Introduction

In the early years of the 21st century, the US health care system is in a state of both feast and famine. New scientific breakthroughs and advances in technology have cured diseases and extended lives beyond what was imaginable even a decade ago. Yet despite these riches, the health care system is fundamentally broken. It fails on three measures of care, especially in the treatment of older persons.

The first measure is *cost*. In 2004, the cost of health care in the United States grew at a rate of 7.7%, compared to the overall consumer price index of 4.4%.¹ In fact, many US economists have accepted—but do not like—that health care spending will rise at a rate of 2% to 3% higher than the general economy.

The second measure indicating failure is *patient satisfaction*. When elderly patients were asked in a recent survey about their physicians, they reported that physicians listen carefully 65% of the time, explain things clearly 59% of the time, and spend enough time with them only 54% of the time.² Of course, patient satisfaction will never be 100%, but it should be 80% to 90%.

The third measure on which health care fails is *quality*. In a study published in 2003, performance on

quality indicators for 30 conditions and preventive care was measured. Only 55% of recommended care was provided—and there was tremendous variation in the quality of care provided. For cataracts, 80% of recommended care was provided, whereas for hip fractures, it was only 23%.³ The Assessing Care of the Vulnerable Elderly (ACOVE) study began by developing an instrument to identify vulnerable elders—older people at higher risk of dying or having functional decline within two years.⁴ The ACOVE team then created quality indicators, on the basis of literature review and evaluation by an expert panel, for 22 conditions (eg, coronary artery disease, dementia, falls, urinary incontinence). Finally, they performed a medical records review and structured interviews for each condition for patients enrolled in two health plans—on the East and West Coasts. The overall results were virtually identical to those of the first study. Only 55% of quality indicators were met.⁵ However, they also found that the care for geriatric conditions such as falls, urinary incontinence, and dementia was much worse than for general conditions such as atrial fibrillation and stroke. For geriatric conditions, only 31% of recommended care was provided, again

with high variability in quality of care; for example, 82% of recommended stroke care was delivered, but only 9% of end-of-life quality indicators were met.

Physicians say they could provide better care if there was more money and more time. However, data from the Centers for Medicare and Medicaid Services demonstrate that across the states, as more money is spent, the quality of care is worse.⁶

To address these failings, it is important to review the current state of health care to identify barriers to good health care and to review individual and systems efforts to improve health care.

Barriers to Good Care Insufficient Cognitive Capacity

Despite extensive training and the availability of continuing education for physicians, it is almost impossible for physicians to keep current. There is simply too much to know. During 2001, the US National Library of Medicine added more than 12,000 articles to its collections per week. To maintain current knowledge, a general internist would have to read 20 articles per day, 365 days a year.⁷ The second problem is that there is too much to remember when providing clinical care. In providing



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care for a patient with heart failure, there are ten angiotensin-converting enzyme inhibitor options, seven angiotensin-receptor blockers, three beta-blockers, and two aldosterone antagonists. Each medication has a different starting dose, target dose, and dose titration schedule. It is unreasonable to expect a physician to remember all of this information.

The Health Care System Is Not a System

The first principle of health care delivery is that the American health care system is not a system. Rather, it is a collection of providers and vendors that is fraught with inefficiency and waste. By some estimates, one-third of all health care spending is waste.

- The first waste is *duplication*. How many medical histories and physical examinations does a patient really need? For example, at many teaching hospitals, there are four different sets of medical histories and physical examinations for each patient—one from a medical student, one from an intern, one from a senior resident, and one from an attending physician.
- A second area of waste is *re-ordering tests rather than looking for results*. This is frequently caused by the unavailability of clinical information at the time it is needed. For example, consultation notes are not on the chart, and neither are procedure reports, inpatient records, discharge summaries, or Emergency Department records. This problem may occur less often in a group or staff-model managed-care system, but medical records are very fragmented in most clinical settings.
- A third waste issue is the *wrong*

person doing the job. The most expensive employees are physicians, much more costly than office staff. The time that physician and patient are in a room together is the most expensive time. The second most expensive time is during the office visit—before and after the patient sees the physician. The least expensive time is the time that patients spend at home preparing for the visit, such as completing a previsit questionnaire. This is an excellent way to collect needed information at minimal cost. To run an efficient practice, physicians must delegate tasks whenever they can and reserve the physician–patient visit time for the elements of care that require a physician.

The next sign that health care is not a system is the work-around—fixing the situation but not fixing the problem. For example, a patient does not receive a test in a timely manner. The physician makes a phone call, insists that the test is done promptly, and it is performed the next day. The same problem occurs the next week. The physician has not fixed the basic underlying problem. Telltale signs of a systems problem include clinicians, schedulers, and technicians making frequent exceptions; physicians pulling rank to get tests or consultations performed; and covering physicians deferring treatment decisions until the primary team returns.

Finally, the health care system is far behind the times. As noted by the American Geriatrics Society, “information technology and the electronic health record hold great promise for improving patient care. Yet, this promise largely remains unfulfilled. Only a minority of health care providers currently has access to systems that truly facilitate care Elec-

tronic documentation of the content of patient visits remains behind that of most American commerce.”⁸ In fact, the most common use of the electronic health system is for billing, not to improve care.^{9; slide 4}

The Rewards Are Wrong

In a 2003 survey of physicians by the Commonwealth Fund, physicians reported that productivity and billing was the most commonly reported (by 72%) factor affecting their compensation.^{9; slide 54} Physicians are paid for the number of visits they complete and the complexity level of those visits. The least commonly cited (by 19%) factor affecting compensation is a quality bonus. Few reported being paid for doing the right thing—improving quality.

Improving Health Care

Given the current situation and barriers to change, what can be done to improve health care? There are two broad categories: individual changes, which a physician can initiate, and systems changes, which require an organized delivery system.

Individual Practitioner Approaches

At the individual practitioner level, several small steps can yield big dividends. First, delegate data collection; second, run a more efficient office; and third, delegate plan implementation.

Delegate to Office Staff

For some reason, many physicians have difficulty delegating clinical care tasks to office staff. Perhaps they fear that the staff are not conscientious enough, have too much to do, or do not want to perform functions outside their usual roles. In fact, many staff welcome the notion of being more instrumental in facilitating office visits. Physicians can

By some estimates, one-third of all health care spending is waste.

delegate tasks such as screening and case identification, history gathering, recording current medications and allergies, taking orthostatic blood pressure readings, testing visual acuity, and providing patient education.

Delegate to Patients

In addition to delegating tasks to staff, physicians can delegate activities to patients. For example, the University of California, Los Angeles (UCLA) Geriatrics Practice uses a 15-page, previsit questionnaire for elderly patients. This reduces the physician's history-gathering time from 30 to 40 minutes to 8 to 10 minutes. Also, patients can prepare a list of what they want to discuss (if it is not on the list, it is probably not important) and a patient diary—a calendar on which the physician writes the symptom to monitor and the patient returns it, completed, at the next visit. Frequently when patients keep symptom diaries, the symptoms go away. If the symptoms persist, these diaries can illustrate a pattern, and sometimes this helps clinicians discover the reason.

Minimize Data Recording Time

Dictation is the most efficient means of recording information but has the drawbacks of transcription expenses and the inability to easily link the content of the dictation to monitoring the process of care rendered and to quality-improvement efforts. Many offices use paper-and-pencil templates that allow the physician to document care quickly, often using check boxes. Contrary to popular belief, electronic health records do not save physicians time in recording clinical information. However, such records do help physicians find information needed for clinical care and prescribe more easily, and the records can be valuable in monitoring and

improving quality. Nevertheless, electronic health records are an essential part of the future of health care, so we need to construct them so that they facilitate quality rather than simply document care.

Keep Readily Available Information Needed for Decision Making

Every time a physician leaves the examining room, the flow of patient care is interrupted. Once outside the room, the physician may be further distracted by staff or colleagues and may be delayed in returning to caring for that patient. Physicians can be more efficient by staying in the examining room until the patient leaves. Thus, information needed for clinical decision making needs to be available in the examining room, including pocket guides, such as *Geriatrics at Your Fingertips* (The American Geriatrics Study, published annually); personal digital assistant programs that provide drug doses, interactions, and side effects; and computerized reference systems. However, the latter tend to be too slow for use in the context of an office visit and may be more useful as homework for the physician to seek information during unscheduled time.

Delegate Plan Execution

Efficient physicians establish a network of allied health professionals such as social workers, dietitians, physical and occupational therapists, and health educators. They use the same people over and over again, people they can trust. They build a team.

Systems Approaches

Systems approaches are more comprehensive methods overcoming problems in providing health care. They often require multiple levels of change, such as recrafting

job descriptions, making changes in work flow, and integrating a variety of information sources into clinical care. For example, a systems approach may begin with identifying frequent users of health care through any of several paper-and-pencil scoring systems or administratively calculated hierarchical classification systems. Systems approaches may employ alternative methods of delivering health care such as group visits, an innovation that was pioneered in Kaiser Permanente (KP) and that has had rapid diffusion,¹⁰ in-home assessments by nurses, including preventive and posthospital discharge visits; disease management programs; and health care self-management classes.

Quality Improvement

Quality improvement focuses on the process of care and emphasizes standardization. If health care providers are delivering care the same way every time, even if it is not perfect, care processes can be systematically addressed and error rates and costs will decrease. When everybody is doing something different, it is very difficult to improve health care. Quality improvement requires measurement—the physician needs to know how s/he is doing—and frequently use protocols. To get started with quality improvement, physicians should select a care process problem that will be useful to improve and simple, work with small representative samples, and then build measurement into the physician's daily work.¹¹ Physicians must ask themselves, "What do we want to improve? Which care processes do we want to ensure that all persons with specific diseases receive? What is the care product we—the organization—want to deliver?" For example, to create the KP formulary, physicians agreed on

Frequently when patients keep symptom diaries, the symptoms go away.

the drugs that are the first line of treatment for each condition. But when treating individual patients, if a physician wants to depart from the list, s/he can order different medications. The guiding principle is to eliminate variation among clinicians but allow variation, when indicated, among patients.

There are limitations to quality improvement. The targets are typically easy-to-change, low-lying fruit. Quality improvement focusing on frail, elderly patients is particularly difficult because their conditions, often multiple, and the systems to support their care are so complicated. Quality improvement also takes a considerable amount of effort, and some of the results have been less impressive than hoped for.

Redesign of Care

The second phase of the ACOVE project (ACOVE-2)¹² created an intervention that fundamentally changes the office visit for geriatric conditions. In addition to changing what happens in the physician's office, the intervention is characterized by different roles for patients and their families, and partnership with community-based organizations. The ACOVE-2 project identified a target population of outpatients aged 75 years with untreated conditions—urinary incontinence, falls, and cognitive impairment. If a condition was detected, a standard multicomponent intervention was triggered, including medical record prompts that encouraged performance of essential care processes and collection of condition-specific clinical data by office staff. Some practices also allowed office staff to perform simple procedures, such as urinalysis for urinary incontinence, before the physician saw the patient.

Medical History and Physical Examination

For each condition, a structured visit note led the physician through the appropriate data-collection and care processes. The structured visit note (Figure 1) was one page with check boxes, so the physician could quickly and legibly document the care provided. On the same note, office staff completed some medical history items and simple procedures (eg, obtaining orthostatic blood pressures, conducting visual

acuity testing). For example, the history of present illness for a patient who has fallen requires asking a series of questions to obtain important clinical information and satisfy quality indicators for falls. All of these questions can be, and have been, delegated to office staff so that the physician sees the structured visit note with the appropriate boxes already checked. Physicians then collect more detailed clinical data (eg, a gait and balance examination and a brief neuromuscular examina-

VISIT FORM: FALLS/MOBILITY PROBLEMS (L4)

Reason for Visit: Fall (Go to Q1) Fear of falling ONLY (Go to Q3)

History:

1. Last fall: In past 4 wks More than 4 wks ago

2. Circumstances of fall: YES NO

Loss of consciousness.....

Tripped/stumbled over something.....

Lightheadedness / palpitations.....

Unable to get up within 5 minutes.....

Needed assistance to get up.....

3. Knee or hip pain.....

4. Currently uses device for mobility?

Cane.....

Walker.....

Wheelchair.....

Other, specify: _____

5. 2 or more drinks alcohol per day.....

6. Other medical conditions: _____

7. Vision:

Noticed recent vision change.....

Eye exam in past year.....

Examination: NAD

→ If fall and no dementia, administer 3-item recall

1. Cardiac auscultation: _____ ABNL NL

2. Pulse: Irregular Regular

3. Lung auscultation: _____

4. Respiratory effort: _____

8. Gait: ABNL NL

Abnormal if: -Hesitant start -Heels do not clear toes of other foot

-Broad-based gait -Heels do not clear floor

-Extended arms -Path deviates

9. Balance: YES NO

Side-by-side, stable 10 sec....

Semi-tandem, stable 10 sec....

Full tandem, stable 10 sec....

If indicated: Can pick up penny off floor..... YES NO

Resistance to nudge.....

10. Neuromuscular: YES NO

Quad strength: Can rise from chair w/o using arms..... YES NO

If indicated, hip ROM and knee exam: Rigidity (e.g., cogwheeling)..... YES NO

Bradykinesia.....

Tremor.....

11. 3-Item recall: PASS (2-3 words) FAIL (0-1 word) → Cognitive status: Judgment/insight: ABNL NL

Lab/Tests: EKG Bone mineral density Impression: Strength problem Parkinsonism

Holter Other: _____ Balance problem Severe hip/knee OA

Other: _____ Gait problem Other: _____

Treatment:

Exercises: Upper body Lower body

Community exercise program

Home safety checklist given

Community resource list given

"Falls" handout

Footwear discussion/handout

Vitamin D 800 IU/day

Ca carbonate 1200-1500 mg/day (Ca citrate if on PPI)

Hip protectors

Provider's Signature _____ Date of Service _____

PATIENT LABEL

8. Psychotropic medications (specify): YES NO

Neuroleptics: _____

Antidepressants: _____

Benzodiazepines: _____

a) IF YES to benzodiazepines, discontinued?

b) Reason for benzodiazepine continuation: _____

5. Visual Acuity: OS: 20/____ OD: 20/____ OU: 20/____

(if no eye exam in past year)

6. Orthostatics:

Lying: BP: ____/____ Pulse: ____

Standing: BP: ____/____ Pulse: ____

7. LE edema: _____ YES NO

Timed-Up-and-Go: _____ sec

(Normal ≤ 15 sec)

-Stand from chair NOT using arms.

-Walk 10 feet.

-Turn around.

-Walk back.

-Sit down

Figure 1. The structured visit note.

In 2011, the first baby boomers will be 65 years old; 75 million will follow.

tion) and complete the impression and the plan. The duration of the entire physician evaluation and plan formulation can be reduced to a few minutes.

Patient Education and Involvement

The next component of the multicomponent intervention was getting the patient more involved through patient-education materials and in an active role in follow-up care. These materials, assembled for each condition, were available for the physician in the examining room.

Patient-education materials included general lay-language summaries and other resources from organizations such as the National Institute on Aging and the Alzheimer's Association. The materials also included names and addresses of local community resources, such as tai chi programs to help prevent falls. These summaries were particularly useful because the specific referral information was at hand when the physicians needed them.

In addition, patients were given follow-up questionnaires developed for each condition that were to be completed before the next visit to indicate whether the treatment was working and prompt the physician to take the next steps if it was not. The top part included instructions for the patient, and the bottom part included questions such as "Did you have any problems with the treatment that your doctor prescribed? Have you fallen since that last visit? Is this treatment working?" These forms keep the patient involved and active.

Decision Support

Finally, the intervention included decision support for the physicians, small-group working sessions that

were not traditional lectures. Rather, they focused on how to use the structured visit notes and supporting documents and how to get these care processes incorporated into their visit in two minutes or less.

Effectiveness of the ACOVE-2 Intervention

The ACOVE-2 practice redesign intervention was implemented and evaluated at two sites in California: a desert and a coastal community. As a result of the intervention, the care provided for falls and incontinence was much better compared to that provided by other physicians within the same groups. However, the quality provided was still less than optimal. Why? First, the physicians did not want to delegate data collection, as for orthostatic blood pressure. Some believed they needed to do everything themselves. Second, the intervention did not provide enough early feedback on changes that were not effective at improving care. The physicians did not know that the care was suboptimal and did not take steps to modify it. Third, there was not enough patient empowerment. Many physicians did not like patient follow-up sheets. They were afraid of patients asking questions about these conditions because it would add more time to the visit.

Building on the lessons of the ACOVE-2 study, several new studies, in conjunction with the American College of Physicians and the Alzheimer's Association, are in progress to develop products for physicians to use in their offices to improve quality of care. In another study at UCLA, the intervention has been modified by delegating management of five conditions—falls, incontinence, depression, dementia, and heart failure—to a nurse practitioner. All of the other elements of the ACOVE-2 intervention remain intact and the phy-

sician continues to manage the overall care of the patient. Physicians love it, and patients love it.

The Future Demographics

In 2011, the first baby boomers will be 65 years old; 75 million will follow. Several important trends will affect their health care.

Population-Based Health Care

Health care in the 21st century increasingly will be delivered by health care systems—some will be exclusively managed care and others will be a blend. Today, more than 50% of internal medicine practices consist of five physicians or fewer. Over the coming decades, this will likely change so that the vast majority of physicians will be part of larger-practice groups.

Medical practice will be increasingly consumer oriented and consumer driven. Baby boomers are more empowered than their parents were and will demand more from their health care.

The future of health care will be focused on populations. There will be three distinct populations of older persons: people who are not sick but may have chronic diseases, people who are sick and have multiple chronic diseases (and are functionally impaired), and people at the end of life. These populations will be cared for in three settings of care—hospital, nursing home, and community (including assisted living). Because people transition in and out of different care settings and have specific diseases that will be managed differently, the challenge will be to build systems of care for each of these groups.

People who are not sick but who may have chronic diseases need good preventive care—as compre-

hensive and inexpensive as possible—and good episodic care. In the future, most preventive care will be out of the physician's hands entirely. Episodic care, such as treatment of a minor injury or a urinary tract infection, will increasingly be provided by the health care system and not necessarily the patient's personal physician. This will require patients to trust the health care system rather than just the individual clinicians. KP probably most closely approximates this model at the beginning of the 21st century. People with chronic diseases, whether sick or not, need team care—with an identifiable physician on the team—employing principles of disease management, health care self-management, and shared decision making.

For people who are sick and functionally impaired, the physician will have to be intimately involved with the care management team. The health care system has to adopt these people—they are our responsibility and we cannot let them stray off the beaten path. An important part of their care is ongoing active discussions about prognosis, quality of life, and preferences for care.

End-of-life care should begin early, identifying people who are in the last couple of years rather than last couple of weeks or months of their lives. KP is again in the lead. Patients need to trust that their physicians will not deprive them of needed care. They must feel confident that the care provided will be comprehensive and aggressive, albeit with different goals. For these patients, care will have to be so well orchestrated that when the patient dies, everyone—the patient, the physician, the team, and the family—would say that everything was done right.

Finally, care for all three of these

populations will require a flow of clinical information such that care is seamless among all health care providers.

Technology

Technology is still a genie in the bottle—the full use of technology has not been realized. The electronic health record is the most prominent and most imminent. However, many other kinds of technology are also coming, particularly those that use remote monitoring and telemedicine (eg, robotic surgery and virtual intensive care units) and those that use machinery to perform human functions (eg, artificial retina, hepatic dialysis). All of these will change the way physicians practice medicine.

Physicians' Roles

Medicine has been on a relentless march toward specialization, which has been a core economic principle for centuries. As Adam Smith said in 1776, "Each individual becomes more expert in his own peculiar branch, more work is done upon the whole, and the quantity of science is considerably increased by it."¹³ In plain English, that means that we do well what we do often, and we cannot keep up with everything. In the future, there will more specialists—both traditional specialists and emerging disciplines such as palliative care, which received approval for American Board of Medical Specialties certification in 2006. In the future, there may be certification or focused recognition for new specialties such as women's health and HIV diseases and for care focused on specific settings. The hospitalists are the first of these, but skilled nursing facility specialists and home-carists may follow. Moreover, primary care physicians (PCPs) *are* specialists. Coordinating care of the entire patient and

being the patient's advocate is a unique and special discipline.

While continuing to provide some direct one-on-one care, in the future, more PCPs will be leading teams that are comanaged with other clinicians. In these care models, physicians will focus on the tasks that they do best. They are very good at determining the patients' objectives, collecting and synthesizing selective data, determining the medical realities, negotiating a treatment plan, monitoring and revising a treatment plan, and being the patient's advocate. The last of these tasks is particularly important. For frail older persons, sometimes the PCP will call the surgeon to argue for an operation on a patient and at other times will call the surgeon to argue against an operation.

Consultants will increasingly advise on extremely complicated and rare cases, provide support for PCPs by placing consultant notes on the chart, help PCPs and teams develop protocols, give curbside consults, and perform procedures.

Conclusion

Current health care is lacking. Reorganizing health care is not only possible but also necessary to achieve better outcomes. Physicians' roles will be very different over the next two decades: they need to think differently, be more innovative, encourage experimentation, and fail. It is okay to fail. If you experiment and fail, you can learn what did not work, and then you can try again. Eventually, you get it right. If you stop experimenting, if you stop innovating, you can never get any better. ❖

Acknowledgment

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... primary care physicians (PCPs) *are* specialists. Coordinating care of the entire patient and being the patient's advocate is a unique and special discipline.

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In All Things

In necessariis, unitus;
In necessary things, unity;

In dubiis, libertas;
In doubtful things, liberty;

In omnibus, caritas.
In all things, compassion.

— *Augustine of Hippo, 354-430,*
Catholic saint and preeminent Doctor of the Church

MyChart—A New Mode of Care Delivery: 2005 Personal Health Link Research Report

By Carl A Serrato, PhD
Sally Retecki, MBA
David E Schmidt, MD

Introduction

MyChart is one of the new, innovative features of Kaiser Permanente (KP) HealthConnect—the comprehensive, integrated, organizational, and personal electronic health and medical record. *MyChart*, an Epic Systems Corporation (Verona, WI) product, is a secure member Web site where registered patients can view portions of their medical record, and exchange secure messages with their primary care physician (PCP) and other recently visited clinicians.

The KP Northwest (KPNW) Region, in Portland, Oregon, was the first KP Region to implement *MyChart*. Starting in late 2002, KPNW initiated a pilot project of *MyChart* as a stand-alone Web address in two medical offices.¹ KPNW named this feature Personal Health Link (PHL). By early 2005, all adult primary care physicians and affiliated clinicians (both groups are PCPs in this paper) were trained and set up to use PHL. Patients who registered for PHL could

send secure e-mail messages directly to their primary care clinician, incurring no copayment or fees. *MyChart* is now available to KP patients in all Regions, except Ohio, through KP HealthConnect online at www.kp.org.

Methodology

In 2005, a comprehensive evaluation of the PHL secure messaging between adult KP patients and 263 PCPs was conducted^a with Institutional Review Board approval. There were three sources of information for this evaluation.

eEncounter Survey

Patients' perceptions of e-mail encounters with their PCP were collected using an e-mail encounter survey (eEncounter) developed for this study (Table 1). In this study an e-mail "encounter" began with a message from a patient to his or her PCP, and included any follow-up messages sent by the patient or the PCP as a result of that first message.^b

The final questionnaire was developed on the basis of a review of published literature,²⁻⁷ discussions with clinical staff, and a pilot test, which included two rounds of cognitive interviews with patients who had e-mailed their PCP.

An invitation to participate in an online questionnaire was e-mailed to a random sample of 2677 patients

Table 1. eEncounter survey measures
The key outcome measure was satisfaction with the e-mail exchange. The measures in the four subsections were:
<p>1. <i>Attributes of eEncounter</i></p> <ul style="list-style-type: none"> • Completeness of PCP's responses • Timeliness of PCP's responses • PCP's use of hard-to-understand medical terms • Courtesy of PCP's responses • Whether e-mail exchange yielded the results the member wanted • Amount of influence member had in decisions
<p>2. <i>Profile of eEncounter</i></p> <ul style="list-style-type: none"> • Primary and secondary reasons for e-mailing PCP • What member would have done if not possible to e-mail their PCP • Number of messages sent and received • Who sent e-mail to PCP • Preference if PCP is out of office
<p>3. <i>Demographic and Health Status Information</i></p> <ul style="list-style-type: none"> • Overall health status • Have chronic disease • Current number of prescriptions • Visits to PCP in prior 12 months • Age, gender, and education
<p>4. <i>Overall Opinion of KP</i> (Questions taken from the KPNW Medical Office Visit Survey)</p> <ul style="list-style-type: none"> • How likely to recommend KP to family or friends • Satisfaction with ability to get needed care from KP • Rating of PCP's knowledge of member's medical history



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Table 2. Content of analysis of e-mail encounters

Elements of *patient messages* to their primary care clinician:

- New versus existing problem
- Definite or diffuse requests or complex, open-ended questions
- Desired action: clinical assessment, clinical decision, or clinical action
- Update on their current condition (eg, blood sugar levels)

Elements of *PCP responses* to their patients:

- Responses involved nonclinical, low-clinical or high-clinical answers
- Responses addressed all or part of patients' questions and requests
- Patients received what they requested
- Tone and style of PCP responses
- Patient-centered behaviors

Table 3. Log template

The type of encounter: phone, e-mail, or visit
The length of time to complete each encounter including review of the medical record and placing orders
Whether the member was paneled to the clinician
Who initiated the encounter and the type of request
Level of staff involvement in preparing the encounter
The type of clinical decision: nonclinical, low-clinical intensity and high-clinical intensity
What the encounter would have been in an ideal practice
For PHL encounters, what the encounter would have been if PHL had not been available

who had e-mailed their PCP during the period of July 2005 through September 2005. Each sampled patient received an invitation within two weeks of the completed e-mail encounter with his or her PCP. A link to the online questionnaire was embedded in the invitation e-mail along with reference to a specific e-mail exchange: name of recipient's PCP and date of first e-mail message. The survey had a 64% response rate, with 1711 returned questionnaires.

Content Analysis of E-mail Encounters

The e-mail encounters of 476 randomly selected eEncounter Survey respondents were analyzed to better understand the elements of e-mail exchanges that explain the differences in patients' satisfaction. The encounters analyzed were those about which the patients were surveyed, and consisted of nearly 690 patient messages and 750 PCP messages. Patients reporting lower satisfaction

with their e-mail encounter were oversampled to support a comparison of lower- and higher-satisfied patients. The coding form used for the evaluation in the PHL 2003 Pilot¹ was refined for this study; coding was conducted by four Registered Nurses, from the KPNW Center for Health Research, who were specially trained to build inter-rater reliability (Table 2).

PCP-Recorded Encounters

To estimate the time it takes clinicians to complete e-mail and telephone encounters, 22 KPNW PCPs in Oregon agreed to keep logs of all their patient encounters, and the work activity related to these encounters, for a period of two to four days. The 11 Portland PCPs were active PHL users, with at least 20% of their panel registered for PHL and receiving at least three messages per day. The 11 Salem PCPs, who practiced in a medical office 40 miles from Portland, were infrequent PHL users. Each study group logged about

1200 patient encounters: patient- or PCP-initiated phone calls, e-mail messages, and office visits.

The log template (Table 3) developed for this study enabled PCPs to record, in sequential time increments, all activities of a PCP workday at the patient level, as well as batched clinical work and administrative work. Each participating PCP received one-on-one training in how to consistently log their activities.

This part of the evaluation is a case-study design and the time estimates should be considered illustrative, not definitive and generalizable. The results are based on a convenience sample of 22 PCPs. The lengths of time to complete encounters vary greatly by practice style, and there was an insufficient number of PCPs to control for practice style differences.

Results

PCP Users of PHL

In 2005, 263 KPNW adult PCPs in Portland and Salem, OR, and Southwest Washington, had PHL available for use. The majority of these PCPs (63%) were low-level adopters, with fewer than 15 e-mail encounters per month. Only 7% of PCPs were "high adopters"—at least 15% of their panel registered for PHL and they received at least 40 e-mail encounters per month. The remaining 30% of PCPs were "medium adopters"—at least 15% of their panel registered for PHL but they received only 15 to 40 e-mail encounters per month; or at least 40 e-mail encounters but less than 15% of their panel registered for PHL (Figure 1). It is interesting to note that PCPs who have historically scored higher on the ongoing, Art of Medicine survey (ie, office-visit patient satisfaction) were not more likely to use secure messaging.

The lengths of time to complete encounters vary greatly by practice style ...

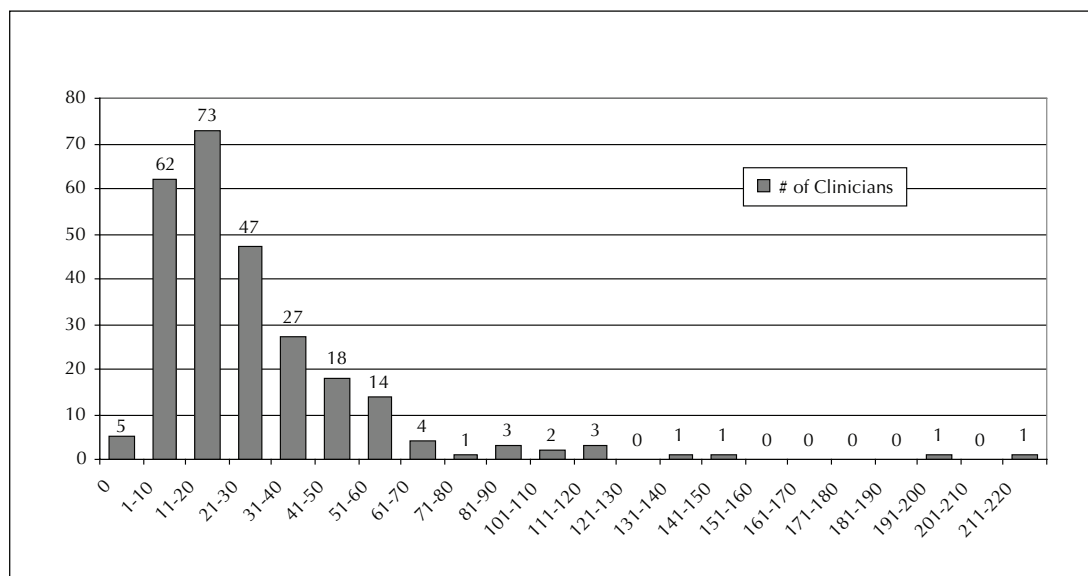


Figure 1. Use of Personal Health Link by PCPs.

Number of e-mail encounters in January 2006 by number of PCPs (total 263). Average of 27 encounters per PCP.

... there was no difference in the rate of messaging between men and women after adjusting for age and health ...

Patient Users of PHL

During the study period patients who were paneled with a PCP were eligible to register for PHL. As of September 30, 2005, there were 16,990 PHL users representing 5% of all 337,423 adult paneled patients in the KPNW Region. Older patients—women 45-64 years old, and men over 45 years—were more likely to register for PHL than other age groups; these age groups comprised 44% of paneled patients, but 62% of PHL users. Patients with chronic diseases were also more likely to register than other groups; for example, patients with diabetes represented 8.7% of paneled patients, but 13.6% of patients registered for PHL.

Women were somewhat more likely than men to register with PHL (5.6% vs 4.4%). However, there was no difference in the rate of messaging between men and women after adjusting for age and health status. Of those who were registered with PHL, 62% had sent at least one message to their PCP.

Profile of Patient-Initiated E-mail Encounters

Slightly more than two-thirds (68%) of e-mail encounters involved one member message and one clinician response. Another 20% of e-mail encounters consisted of two member messages and two or more PCP responses. Often the reason for multiple clinician responses is that the initial response was an out-of-office automatic reply. Less than 10% of e-mail encounters had three or more member messages.

Reasons Patients E-mailed PCPs

Slightly less than half (45%) of encounters began with a clear request—the patients knew what they wanted. However, 34% of the encounters began with diffuse, open-ended or complex questions. The vast majority (75%) of e-mail encounters were for ongoing medical problems or care plans, while nearly one quarter were concerning a new medical event, condition, or symptom.

When patients e-mailed their PCP

they typically reported more than one reason for the e-mail. Nearly one-third (31%) reported that they had two reasons for e-mailing their PCP and 38% reported three or more reasons. The five leading primary reasons for patients to e-mail their PCP were: report a change in a condition, 16%; discuss lab results, 14%; discuss a new condition, 12%; discuss changes in prescription dose, 11%; and discuss need for new prescription, 10%.^c

E-mail messages from patients were clinically relevant; 63% of patient-initiated e-mail encounters required clinical assessments or decisions. Another 24% of e-mail encounters were requests that required clinical actions (orders, tests results). Less than 5% of patients mentioned a nonmedical reason for e-mailing (Figure 2).

Member Satisfaction with PHL

Overall patients were extremely satisfied with e-mail exchanges they had with their PCP; the vast majority (85%) rated their encounters 8

or 9 on a 9-point satisfaction scale (70%-9; 15%-8). Satisfaction was positively associated with whether all of the patient's questions were *answered*, *completeness* of answers, *timeliness* of PCP response, whether the e-mail exchange yielded the *results* the patient wanted, *courtesy* of PCP response, and the amount of *influence* the patient wanted and had in decisions (all statistically significant at $p < 0.01$).

Satisfaction was *not* associated with the *specifics* of patients' requests, such as whether the member e-mailed about a new or ongoing problem, and whether the requests were *complex or open-ended*. Satisfaction was *not* associated with the following characteristics of PCP responses: clinical *intensity* of the assessments or actions, use of *slang* (eg, abbreviations commonly used in e-mails), grammar and *spelling errors*, or whether the exchange included an out-of-office *auto reply*.^d Almost none of the patients (2%) reported that their PCP used medical terms that they did not understand. Interestingly, PCPs' historic *Art of Medicine* scores are not a predictor of patients' satisfaction with their e-mail encounters. This suggests that the skill set required for a successful e-mail encounter is not the same skill set required for a successful in-person office visit.

PHL and Overall Satisfaction with KP

Patients less satisfied with their e-mail encounters were also less satisfied with KP in general. For example, only 34% of patients who were less satisfied with their e-mail encounter (gave a score of 6 or lower on a 9-point scale) indicated that they would definitely or very likely recommend KP to family or friends. Whereas 70% of members who were very satisfied with their

e-mail encounter (gave a score of 7, 8 or 9) indicated that they would definitely or very likely recommend KP. This evaluation was not designed to study the causal relationship between patients' overall satisfaction with KP and satisfaction with e-mail encounters. Over time one would expect that repeated positive experiences with e-mail encounters would increase patients' overall satisfaction with KP. On the other hand, one would expect that patients who were very satisfied with KP, and liked their PCPs, would be more likely to give high ratings to their PCPs' performance in e-mail encounters.

However, the content analysis of e-mail encounters provides some insights into this relationship. The content analysis found no substantive or significant differences between high- and low-satisfaction e-mail encounters, in either the member messages or PCP responses. Therefore, the ratings of e-mail encounters appear to be more a function of patients' perceptions of the e-mail encounters, than of observ-

able differences between encounters. Patients' perceptions of these encounters are possibly influenced by their prior experiences with their PCP and KP, and not just by what occurred during these encounters. Patient satisfaction scores may be subject to inertia—eg, it may take several positive, better than expected experiences before a patient who has been somewhat dissatisfied will give a PCP a higher rating.

Timeliness of PCP Responses

Patients sending secure messages to their PCP were told that they would receive a response from their PCP within two business days. Forty percent of patients reported receiving their PCP's responses within eight hours, and nearly 75% of patients reported receiving responses within 24 hours. Only 4% reported waiting over 48 hours. Nearly nine out of ten patients rate their PCP's response times as excellent if the responses come within 24 hours. Patients' ratings of PCPs' response times

Satisfaction was not associated with the specifics of patients' requests ...

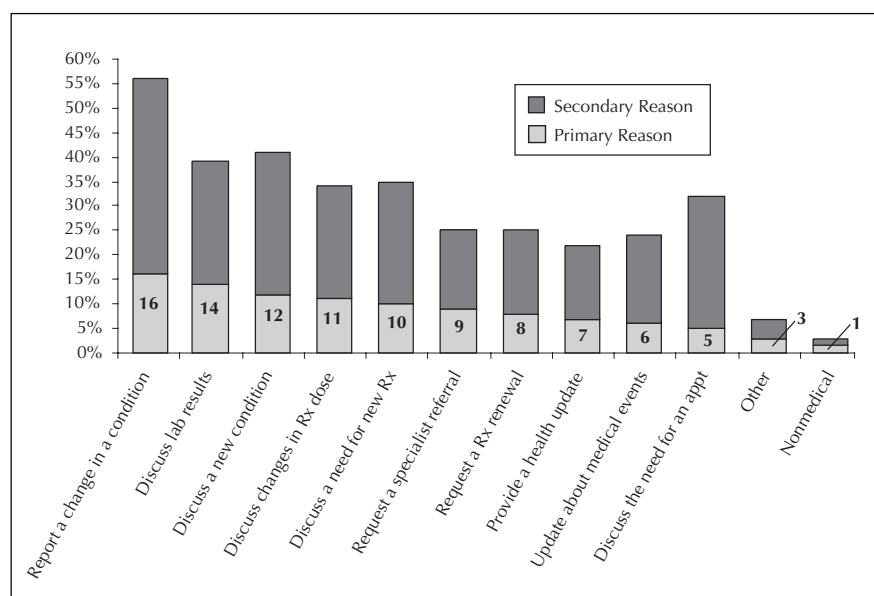


Figure 2. Reasons patients e-mailed their PCP.

Rx = prescriptions.

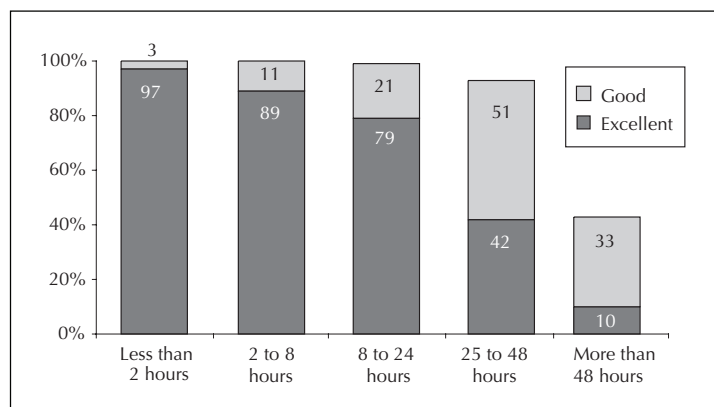


Figure 3. Timeliness of PCP response.

begin to fall sharply after 24 hours; although the vast majority of patients still rate response times as good or excellent if they receive their PCPs' responses within 48 hours (Figure 3).

Impact On PCP Workload Number of Messages Sent

On average, PHL users sent their PCP 0.35 messages per user per month, or approximately 4.2 messages per year. This represents about 2.9 e-mail encounters per PHL user per year—the average e-mail encounter with a PCP involves about 1.4 member messages. Although older patients were somewhat more likely to register for PHL, they tended to send fewer messages. PHL users age 35 years or less sent 0.42 messages per month; PHL users age 45 years or older sent 0.33 messages per month.

PHL Effect on Office Visits and Telephone Visits

One concern expressed regarding e-mail messaging is that it will lead to a large, and often inappropriate increase in the demand for care.^{6,8} This study found strong evidence that e-mail encounters reduced office visits and telephone calls to KP.

Patient Perspective

From the patient perspective, many thought using PHL did sub-

stitute for office visits. When asked what they would have done if e-mailing their PCP had not been available, 25% said they would have scheduled an appointment and 3% stated they would have walked in for unscheduled medical care. Although many of these calls for appointments might have been resolved on the phone by the doctor or an advice nurse, this high percentage reflects the high value patients have for secure messaging. In addition, 44% of patients said they would have called their PCP's office for advice and 18% stated they would have called the advice nurse.

Eleven percent of patients indicated they would not have contacted KP for care if e-mail had not been available. These patients' e-mails contained fewer questions and requests than other patients' e-mails, but their reasons for e-mailing were similar and clinically relevant. (Table 4)

PCP Perspective

PCPs who kept time logs of all patient encounters observed that the profile of patients' requests was very similar for e-mail encounters and patient-initiated phone calls. These PCPs indicated that nearly all low clinical intensity e-mails, and most of the higher clinical intensity e-mails, would have been

patient-initiated phone calls if PHL had not been available.

Utilization Data

A separate component of the 2005 PHL Evaluation compared primary care office visit rates and phone call rates by PHL users prior to and after registering for PHL, with those from a matched control group.⁹ This analysis found a 7-10% reduction in primary care office visits for PHL users (statistically significant at $p < 0.005$).^c This finding is based on patients who accessed any of the PHL features at least once, but not necessarily secure messaging.

In addition, PHL substituted for some of the scheduled telephone visits and other telephone calls documented in KP's electronic medical record system (KP HealthConnect). While the overall number of documented calls increased during the evaluation period (due to administrative changes at the call center), the documented calls for PHL users increased half as much as the control group—16% versus 30%. One limitation of this analysis is that only a fraction of phone calls to PCPs are documented in HealthConnect, although the clinically relevant calls are more likely to be documented.

Of note, PHL users are sicker than the general KPNW membership; the prediction of visit substitution amount needs to be adjusted according to the patient mix as well as the level of secure messaging use.

Efficiency: PHL Compared to Phone Calls

An important factor for determining the workload impacts of secure messaging is the relative efficiency of e-mail and phone encounters. This study found little difference in the average time for clinicians to complete an e-mail encounter and a simi-

This study found strong evidence that e-mail encounters reduced office visits and telephone calls ...

lar patient-initiated phone encounter. The estimates of how long it took PCPs to answer an e-mail encounter are based on time log data recorded by 22 PCPs—11 high-volume PHL users, and 11 infrequent PHL users. Total resolution of e-mail encounters took the PCPs an average of 5.7 minutes, including research and other work involved in the response. Total resolution of telephone encounters took the PCPs an average of 5.4 minutes. Because of the small number of PCPs in this case study and the wide variation in clinician practice styles, the average times reported here may not be predictive of overall PCPs. The particular value of this case study is the comparison of times to answer e-mail encounters and telephone encounters.^f

Factors Affecting Efficiency

Work time per e-mail encounter increases as clinical intensity increases: high clinical intensity encounters took over eight minutes to complete. Work time per telephone encounter showed a similar increase with clinical intensity. The work time per telephone encounter was also higher when the PCP directly talked with the patient, rather than relaying a message through a nurse or medical assistant. In this case study, there was no difference in the work time for e-mail encounters and the telephone encounters in which the PCP spoke directly with the patient.

Conclusions and Recommendations Use of Secure E-mail Messaging

During the first year that secure e-mail messaging was available to all PCPs in KPNW, the majority of PCPs were cautious about encouraging their patients to use e-mail messaging. At the end of the first year

of PHL's widespread availability, over 60% of PCPs had less than 15 e-mail encounters with patients per month, and only 5% of eligible patients (adult patients paneled with a PCP) were registered for PHL. This low level of adoption may in part be explained by the concerns of many PCPs that patients would overwhelm them with e-mails—many inappropriate—and without compensating declines in demand for office visit and telephone encounters. In addition, patient registration was also a barrier, as system design issues prevented PCPs from registering patients during an office visit.

Low use of PHL also reflects weak patient demand for e-mail encounters, in part from lack of awareness of this new service. Furthermore, many patients were discouraged from registering for PHL because of delays in the registration system. Patients wanting to e-mail their PCP for the first time must wait at least one week after registering online to receive a secure password, which is mailed to their home address.^g Frustrated, many patients call or come in for an office visit, without completing their online registration. Not surprising, patients most likely to register for PHL, and use secure e-mail messaging, had greater health care needs—older age, chronic conditions, and higher office visit utilization.

In contrast to PCP concerns, this study found that patients used e-mail messaging appropriately—seeking answers to clinically relevant questions. Nearly all patient-initiated e-mail encounters inquired about an ongoing medical problem or care plan, or a new medical problem. Less than 5% of e-mail encounters contained nonmedical requests or questions. On average PHL users sent 4.2 messages to their PCP per year—less than three e-mail encounters per year—the vast major-

Table 4: Patient description of potential action if e-mail encounter had not been available

Demand	Reason
44 %	Called PCP's office for advice
25 %	Scheduled an office visit
18 %	Called KP advice nurse
11 %	Would make no contact
3 %	Walk in for unscheduled medical care

Note: Percentages do not add up to 100% due to rounding.

ity not new demand. This study found strong evidence that patients who message through PHL reduced their primary care visit rate, and that PHL messages largely replaced phone calls. Furthermore PCPs could complete e-mail encounters in a time comparable to patient-initiated phone encounters. However, patients reported 11% of the encounters represented new demand—they would not have contacted KP otherwise.

What is the effect of secure e-mail messaging on PCPs' workload? Although this study found evidence that secure e-mail messaging *could* save PCPs' time, a definitive answer requires more information: 1) the precise extent that e-mail encounters substitute for office visits or telephone encounters, and 2) the actual time for PCPs to complete e-mail encounters versus comparable office visits or telephone encounters. Both of these depend on how PCPs work with their support staff to handle patients' calls, and which calls shift to e-mails. In particular, do patients' e-mails to their PCP cover the types of requests for which PCPs would call the patients directly, or the types of requests that the PCP would hand-off to their support staff?

Variation in PCP preferences and practice style, and confidence in their support staff, will determine the answers to these questions. Furthermore, secure e-mail messaging will have a changing impact over time on PCP workload, because of wider

Work time per e-mail encounter increases as clinical intensity increases ...

Patients were highly satisfied with the e-mail exchanges they had with their PCP. They were particularly satisfied that e-mail messaging allows them to conveniently communicate directly with their PCP.

adoption among patients and PCPs, and changes in how patients and PCPs use this new communication technology. For example, current users of secure e-mail messaging are sicker than the general population; so their current experiences may not accurately predict visit substitution for the general population. Finally, the answer will also depend on institutional parameters, such as the ease of telephone access to PCPs.

Secure E-mail Messaging and Patient Satisfaction

Patients were highly satisfied with the e-mail exchanges they had with their PCP. They were particularly satisfied that e-mail messaging allows them to conveniently communicate directly with their PCP. The most important factors associated with higher satisfaction are: all of their questions were *answered*; *completeness* of answers; *timeliness* of PCP responses; the e-mail exchange achieved the *results* the patient wanted; *courtesy* of responses; and the amount of *influence* they wanted and had in decisions.

Satisfaction was *not* associated with: the *specifics* of patients' requests—new versus ongoing problem; or whether *complex or open-ended* requests. Satisfaction was also *not* associated with the following characteristics of PCPs' responses: clinical *intensity* of the assessments or actions, use of *slang* (eg, abbreviations commonly used in e-mails), grammar and *spelling errors*, or whether the exchange included an out-of-office *auto reply*.

Interestingly, PCPs' scores on office visit patient satisfaction were not predictive of their patients' satisfaction with e-mail encounters. This suggests that the skill set required for a successful e-mail encounter is not the same skill set required for a successful office visit.

This evaluation reflects the experience of early-adopter patients (who were sicker than average patients), and of early-adopter PCPs. These findings are the best information available about the impact of secure e-mail messaging for KP patients, PCPs, and the KP care delivery system. However, these findings may not be predictive of future impacts, as secure e-mail messaging is used more broadly by patients, and as PCPs and support staff become more efficient and creative. Continuing to measure how much secure e-mail messaging substitutes for office visits and phone calls is crucial, as well as evaluating possible shift of work between PCPs and support staff. Finally, this evaluation was limited to adult primary care; similar evaluations should be considered as e-mail messaging spreads to pediatrics and specialty care departments. ♦

- ^a Although not part of this evaluation, 350 adult specialty physicians were added to PHL in 2005.
- ^b An e-mail encounter can also start with a message that a clinician sends to a patient. However, during this study period physician-initiated e-mail encounters were rare.
- ^c There was a high level of consistency in patients' self-reported reasons for e-mailing their PCP and the reasons documented in the content analysis.
- ^d The out-of-office auto reply informs patients that their PCP is away from the office until a specific date, and that the PCP will respond after s/he returns. The message also instructs patients to call their PCPs office if they need help before their PCP returns to the office.
- ^e Primary care visits include primary care daytime visits, urgent care visits, and visits to KPNW emergenciers.
- ^f During the evaluation, PCPs could not place orders from within a PHL encounter, increasing the time required to resolve the e-mail encounters when orders were required.
- ^g Focus groups with KPNW patients conducted by KP's National Market

Research Department found that many patients were unaware of the option to send secure e-mail messages to their doctors, and that many others were discouraged from registering for PHL (ie, MyChart) because of the long wait to receive their password.

Acknowledgments

We are grateful to Yvonne Zhou, PhD, and the many other KP staff members who served as sponsors, advisors, and colleagues during this evaluation. This work was partially funded by KP's Internet Services Group and Clinical Systems Planning and Consulting.

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A Next Step: Reviewer Feedback on Quality Improvement Publication Guidelines

By Tom Janisse, MD

Technology and Process Improvement

Dazzled by advances in surgical lasers, the anti-aging drug resveratrol, or Google's warp-speed search of the earth's information on their handheld computers, physicians and nurses may dismiss the significance of their recent diabetic and cardiac quality improvement (QI) work that arguably improves health care more than many technologic advances. Despite the intensity of designing and enacting QI studies to improve the processes, reliability, and safety of medical care, doctors and nurses have historically not captured or reported their data and findings with enough systematic rigor to turn your head from the brilliance of technology or the randomized, controlled, drug trials reported online and in the media even before print publication. Their work, however, is critical because embedding and integrating new knowledge into clinical practice through quality improvement work is ultimately the outcome that will improve the state of this country's health care.

Quality Improvement Guidelines

Because the Institute for Healthcare Improvement (IHI) has stimulated such a surge of QI work, and clinicians want to report their results in peer-reviewed journals, and because reviewers for leading medical journals are unfamiliar with the methodology and evaluation of QI studies, a set of guidelines was developed to guide editors and to ensure that QI article content is consistently complete, statistically sound, and high quality.

Frank Davidoff, MD (IHI), and Peter Batalden, PhD (Dartmouth Medical School), collaborated to create these new publication guidelines. Six-

teen items are included within their proposed format—Introduction, Methods, Results, and Discussion (“IMRaD”). Three examples of the sixteen items are: “Problem: Nature and severity of specific local dysfunction or failure; Analytic methods: Statistical and time series techniques used, and specific software; Outcomes: What effects the changes/improvements had on clinical and/or organizational and professional outcomes and processes including benefits, harms, unexpected results, problems, failures.” As an additional aid, the authors cite 67 “Examples of elements and criteria to be considered in reporting guideline items.”¹

These guidelines are part of an effort to improve the quality of health care through setting a standard that benefits: QI researchers performing studies and writing reports; journal editors reviewing manuscripts; and physicians, nurses, and project managers reading and evaluating the published results.

Reviewer Feedback

After attending Drs Davidoff and Batalden's IHI workshop in December 2005, I sent their article containing the publication guidelines to the 500 national reviewers of our Journal to inform, to educate, and to give them a tool. Representative feedback included:

- “This is the main focus of my current research/administrative activities; until now I have been struggling with how to publish the results of our work.”
- “I agree with the guidelines, have used them and find them most helpful.”
- “These guidelines have value in the setting of review of a quality improvement article, as well the structure of questions asked can guide the writing of the ar-

ticle, so it may be prudent to distribute these guidelines to the authors of papers.”

- “I think that the guidelines are enlightening and likely to be useful. Maybe a check-off form could be used, with the reviewer marking each of these guidelines as: met, possibly met, or not met, with specific comments added, as appropriate. I don't think the reviewers should be forced into a narrow format, as it could result in missing the forest for the trees.”
- “Adding a structured approach for reviewing quality assurance genre articles is a good idea.”
- “They are reasonable for QI types of articles, but a more stringent standard such as CONSORT should still apply for formal research studies.”

Outcome

The Permanente Journal has a particular interest in these guidelines because the editors, for a decade, have selected and published QI articles to enhance the development, communication, and dissemination of clinical practices that improve performance. The capstone is our annual publication of the Kaiser Permanente practices recognized as the Vohs Awards for Quality—comprehensive, clinical innovations demonstrating significant results in large populations. Publication guidelines can improve the quality of QI articles and the clinical practices they report. ♦

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Doctors and Patients Using an Electronic Health and Medical Record: Research Studies Offer Multiple Views of 21st Century Health Care

By Tom Janisse, MD

“I already know you better (after several e-mails) than the internist I was seeing since 1990,” wrote a new patient of Chuck Kilo, MD, MPH, at Portland’s Greenfield Health, who believes that the relationship between doctors and patients is built on continuous communication, requiring multiple modes and encounters.³ With the developing electronic capability that doctors and patients now have, to complement their traditional forms of interaction—the office visit, the hospital visit, the telephone—they can form quicker and deeper relationships than previously possible; and both can access data in a common electronic medical record. All of the Original Articles in this issue represent a research and applications view of various components of this developing integrated electronic capability.

Patients can now contact their physician by secure e-mail online—a new physician-patient e-communication—which resulted in Kaiser Permanente patients sending more than one million electronic messages to their physicians in 2006. E-communication will develop along the same continuum as have personal visits: from simple e-data to e-mail exchange to e-encounter to e-correspondence to e-conversation. The question becomes: How easily can doctors translate their patient-satisfying, personal office visit behaviors into a satisfying e-visit? Can doctors write a subjective, personal piece of e-correspondence? (MyChart—*A New Mode of Care Delivery: 2005 Personal Health Link Research Report*, page 14; see Figure 1 #1.)

With the electronic medical record available in the exam room, “it” could disrupt the personal visit. The effect that “it” has on patients depends on the doctor, though its intrusion can be positive, and, through involvement and by improved understanding, can enhance communication and relationship between patient and doctor. (*Implementing the Electronic Medical Record in the Exam Room: The Effect on Physician-Patient Communi-*

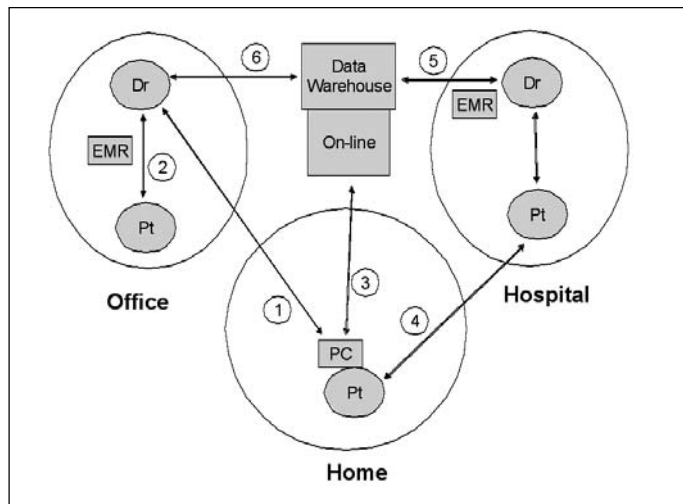


Figure 1. Research Studies: Realms of Health and Medical Care.
Pt = patient, Dr = doctor, PC = personal computer, EMR = electronic medical record.

cation and Patient Satisfaction, page 21; see Figure 1 #2.)

Online features accessible to patients at home include interactive, health e-programs, such as weight management, with positive outcomes of healthy behavior change. With a health e-program as part of the treatment plan, connection between patient and doctor builds without additional office visits. (*Obesity in the Kaiser Permanente Patient Population and Positive Outcomes of Online Weight-Management Programs*, page 25; see Figure 1 #3.)

As patients transition from home to the medical delivery system and back home, doctors and patients will be able to rely on an electronic reconciliation system to ensure that current outpatient medications continue when s/he becomes an inpatient, and inpatient medication changes continue when s/he becomes an outpatient again. (*Decreasing Medication Discrepancies*



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Between Outpatient and Inpatient Care Through the Use of Computerized Pharmacy Data, page 31; see Figure 1 #4.)

Surgical Intensive Care Unit glycemic control after Bariatric Surgery, reported from the Henry Ford Health System, exemplifies use of multiple hospital database and analytical systems that aid cycles of quality improvement work to advance clinical outcomes in the inpatient setting. (*Perioperative Tight Glycemic Control: The Challenge of Bariatric Surgery Patients and the Fear of Hypoglycemic Events*, page 36; see Figure 1 #5.)

Patients can benefit from doctors matching their health assessments with their documented medical histories through using a data warehouse to access information essential for understanding how adverse childhood events can result in unhealthy adult behaviors. (*Adverse Childhood Experiences and Smoking Persistence in Adults with Smoking-Related Symptoms and Illness*, page 5; see Figure 1 #6.)

This connection of electronic components becomes a web of electronic capability—a whole system of integrated data, information, programs, and communication—to enhance traditional in-person care, offering people a more complete health care experience.

By developing an eHealth Service, physician leaders define a new realm of health and medical care that is interactive, convenient, low cost, and personal. With its addition, medical and nursing care is now practiced in a whole-system context, without singular dependence on the office visit and the doctor as the only way to assess and treat a condition, or to improve health. Use of this electronic capability will transform medical care. ❖

^a Principles of Clinical Medicine Presentation: “Creating Relationship in Primary Care,” at Oregon Health and Science University, 2007 Jan.

Change

Change is hard because people overestimate
the value of what they have—
and underestimate the value of what
they may gain by giving that up.

— Flight of the Buffalo: Soaring to Excellence,
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Ralph C Stayer*, Warner Books: 1994.

Critical Appraisal of Clinical Studies: An Example from Computed Tomography Screening for Lung Cancer

By Nicholas P Emptage, MAE
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Introduction

Every physician is familiar with the impact that findings from studies published in scientific journals can have on medical practice, especially when the findings are amplified by popular press coverage and direct-to-consumer advertising. New studies are continually published in prominent journals, often proposing significant and costly changes in clinical practice. This situation has the potential to adversely affect the quality, delivery, and cost of care, especially if the proposed changes are not supported by the study's data. Reports about the results of a single study do not portray the many considerations inherent in a decision to recommend or not recommend an intervention in the context of a large health care organization like Kaiser Permanente (KP).

Moreover, in many cases, published articles do not discuss or acknowledge the weaknesses of the research, and the reader must devote a considerable amount of time to identifying them. This creates a problem for the busy physician, who often lacks the time for systematic evaluation of the methodologic rigor and reliability of a study's findings.

The Southern California Permanente Medical Group's Technology Assessment and Guidelines (TAG) Unit critically appraises studies published in peer-reviewed medical journals and provides evidence summaries to assist senior leaders and physicians in applying study findings to clinical practice. In the following sections, we provide a recent example of the TAG Unit's critical appraisal of a highly publicized study, highlighting key steps involved in the critical appraisal process.

Critical Appraisal: The I-ELCAP Study

In its October 26, 2006, issue, the *New England Journal of Medicine* published the results of the International Early Lung Cancer Action Program (I-ELCAP) study, a large clinical research study examining annual computed tomography (CT) screening for lung cancer in asymptomatic persons. Though the authors concluded that the screening program could save lives, and suggested that this justified screening asymptomatic populations, they offered no discussion of the shortcomings of the study. This report was accompanied by a favorable com-

mentary containing no critique of the study's limitations,¹ and it garnered positive popular media coverage in outlets including the *New York Times*, CNN, and the *CBS Evening News*. Nevertheless, closer examination shows that the I-ELCAP study had significant limitations. Important harms of the study intervention were ignored. A careful review did not support the contention that screening for lung cancer with helical CT is clinically beneficial or that the benefits outweigh its potential harms and costs.

Critical appraisals of published studies address three questions:

1. Are the study's results valid?
2. What are the results?
3. Will the results help in caring for my patient?

We discuss here the steps of critical appraisal in more detail and use the I-ELCAP study as an example of the way in which this process can identify important flaws in a given report.

Are the Study's Results Valid?

Assessing the validity of a study's results involves addressing three issues. First, *does the study ask a*

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... does the paper clearly define the population of interest, the nature of the intervention, the standard of care to which the intervention is being compared, and the clinical outcomes of interest?

clearly focused clinical question?

That is, does the paper clearly define the population of interest, the nature of the intervention, the stan-

dard of care to which the intervention is being compared, and the clinical outcomes of interest? If these are not obvious, it can be difficult to determine which patients the results apply to, the nature of the change in practice that the article proposes, and whether the intervention produces effects that both physician and patient consider important.

The clinical question researched in the I-ELCAP study² of CT screening for lung cancer

is only partly defined. Although the outcomes of interest—early detection of lung carcinomas and lung cancer mortality—are obvious and the intervention is clearly described, the article is less clear with regard to the population of interest and the standard of care. The study population was not recruited through a standardized protocol. Rather, it included anyone deemed by physicians at the participating sites to be at above-average risk for lung cancer. Nearly 12% of the sample were individuals who had never smoked nor been exposed to lung carcinogens in the workplace; these persons were included on the basis of an unspecified level of secondhand smoke exposure. It is impossible to know whether they were subjected to enough secondhand smoke to give them a lung cancer risk profile similar to that of a smoker. It is also not obvious what was considered the standard of care in the I-ELCAP study. Although it is common for screening studies to compare inter-

vention programs with “no screening,” the lack of a comparison group in this study leaves the standard entirely implicit.

Second, is the study’s design appropriate to the clinical question?

Depending on the nature of the treatment or test, some study designs may be more appropriate to the question than others. The randomized controlled trial, in which a study subject sample is randomly divided into treatment and control groups and the clinical outcomes for each group are evaluated prospectively, is the gold standard for studies of screening programs and medical therapies.^{3,4} Cohort studies, in which a single group of study subjects is studied either prospectively or at a single point in time, are better suited to assessments of diagnostic or prognostic tools³ and are less valid when applied to screening or treatment interventions.⁵ Screening evaluations conducted without a control group may overestimate the effectiveness of the program relative to standard care by ignoring the benefits of standard care. Other designs, such as nonrandomized comparative studies, retrospective studies, case series, or case reports, are rarely appropriate for studying any clinical question.⁵ However, a detailed discussion of threats to validity arising within particular study designs is beyond the scope of this article.

The I-ELCAP study illustrates the importance of this point. The nature of the intervention (a population screening program) called for a randomized controlled trial design, but the study was in fact a case series. Study subjects were recruited over time; however, because the intervention was an ongoing annual screening program, the number of CT examinations they received clearly varied, and it is impossible

to tell from the data presented how the number of examinations per study subject is distributed within the sample. With different study subjects receiving different “doses” of the intervention, it thus becomes impossible to interpret the average effect of screening in the study. In particular, it is unclear how to interpret the ten-year survival curves the report presents; if the proportion of study subjects with ten years of data was relatively small, the survival rates would be very sensitive to the statistical model chosen to estimate them.

The lack of a control group also poses problems. Without a comparison group drawn from the same population, it is impossible to determine whether early detection through CT screening is superior to any other practice, including no screening. Survival data in a control group of unscreened persons would allow us to determine the lead time, or the interval of time between early detection of the disease and its clinical presentation. If individuals in whom stage I lung cancer was diagnosed would have survived for any length of time in the absence of screening, the mortality benefit of CT screening would have been overstated. Interpreting this interval as life saved because of screening is known as lead-time bias. The lack of a comparable control group also raises the question of overdiagnosis; without survival data from control subjects, it cannot be known how many of the lung cancers detected in I-ELCAP would have progressed to an advanced stage.

The types of cancers detected in the baseline and annual screening components of the I-ELCAP study only underscore this concern. Of the cancers diagnosed at baseline, only 9 cancers (3%) were small cell can-

cer, 263 (70%) were adenocarcinoma, and 45 (22%) were squamous cell cancer. Small cell and squamous cell cancers are almost always due to smoking. Data from nationally representative samples of lung cancer cases generally show that 20% of lung cancers are small cell, 40% are adenocarcinoma, and 30% are squamous cell. The prognosis for adenocarcinoma is better even at stage I than the prognoses for other cell types, especially small cell.⁶ The I-ELCAP study data suggest that baseline screening might have detected the slow-growing tumors that would have presented much later.

A third question is *whether the study was conducted in a methodologically sound way*. This point concerns the conduct of the study and whether additional biases apart from those introduced by the design might have emerged. A discussion of the numerous sources of bias, including sample selection and measurement biases, is beyond the scope of this article. In randomized controlled trials of screening programs or therapies, it is important to know whether the randomization was done properly, whether the study groups were comparable at baseline, whether investigators were blinded to group assignments, whether contamination occurred (ie, intervention or control subjects not complying with study assignment), and whether intent-to-treat analyses were performed. In any prospective study, it is important to check whether significant attrition occurred, as a high dropout rate can greatly skew results.

In the case of the I-ELCAP study,² these concerns are somewhat overshadowed by those raised by the lack of a randomized design. It does not appear that the study suffered from substantial attrition over time.

Diagnostic workups in the study were not defined by a strict protocol (protocols were recommended to participating physicians, but the decisions were left to the physician and the patient). This might have led to variation in how a true-positive case was determined.

What Are the Results?

Apart from simply describing the study's findings, the results component of critical appraisal requires the reader to address the *size of the treatment effect* and the *precision of the treatment-effect estimate* in the case of screening or therapy evaluations. The treatment effect is often expressed as the average difference between groups on some objective outcome measure (eg, SF-36 Health Survey score) or as a relative risk or odds ratio when the outcome is dichotomous (eg, mortality). In cohort studies without a comparison group, the treatment effect is frequently estimated by the difference between baseline and follow-up measures of the outcome, though such estimates are vulnerable to bias. The standard errors or confidence intervals around these estimates are the most common measures of precision.

The results of the I-ELCAP study² were as follows. At the baseline screening, 4186 of 31,567 study subjects (13%) were found by CT to have nodules qualifying as positive test results; of these, 405 (10%) were found to have lung cancer. An additional five study subjects (0.015%) with negative results at the baseline CT were given a diagnosis of lung cancer at the first annual CT screening, diagnoses that were thus classified as "interim." At the subsequent annual CT screenings (delivered 27,456 times), 1460 study subjects showed new noncalcified nodules that qualified as significant results;

of these, 74 study subjects (5%) were given a diagnosis of lung cancer. Of the 484 diagnoses of lung cancer, 412 involved clinical stage I disease. Among all patients with lung cancer, the estimated ten-year survival rate was 88%; among those who underwent resection within one month of diagnosis, estimated ten-year survival was 92%. Implied by these figures (but not stated by the study authors) is that the false-positive rate at the baseline screening was 90%—and 95% during the annual screens. Most importantly, without a control group, it is impossible to estimate the size or precision of the effect of screening for lung cancer. The design of the I-ELCAP study makes it impossible to estimate lead time in the sample, which was likely substantial, and again, the different "doses" of CT screening received by different study subjects make it impossible to determine how much screening actually produces the estimated benefit.

Will the Results Help in Caring for My Patient?

Answering the question of whether study results help in caring for one's patients requires careful consideration of three points. First, *were the study's patients similar to my patient?* That is, would my patient have met the study's inclusion criteria, and if not, is the treatment likely to be similarly effective in my patient? This question is especially salient when we are contemplating new indications for a medical therapy. In the I-ELCAP study,² it is unclear whether the sample was representative of high-risk patients generally; inso-

... would my patient have met the study's inclusion criteria, and if not, is the treatment likely to be similarly effective in my patient?

far as nonsmokers exposed to secondhand smoke were recruited into the trial, it is likely that the risk profiles of the study's subjects were heterogeneous. The I-ELCAP study found a lower proportion of noncalcified nodules (13%) than did four other chest CT studies evaluated by our group (range, 23% to 51%), suggesting that it recruited a lower-risk population than these similar studies did. Thus, the progression of disease in the presence of CT screening in the I-ELCAP study might not be comparable to disease progression in any other at-risk population, including a population of smokers.

The second point for consideration is *whether all clinically important outcomes were considered*. That is, did the study evaluate all outcomes that both the physician and the patient are likely to view as important? Although the I-ELCAP study did provide data on rates of early lung cancers detected and lung cancer mortality, it did not address the question of morbidity or mortality related to diagnostic workup or cancer treatment, which are of interest in this population.

Finally, physicians should consider *whether the likely treatment benefits are worth the potential harms and costs*. Frequently, these considerations are blunted by the enthusiasm that new technologies engender. Investigators in studies such as I-ELCAP are often reluctant to acknowledge or discuss these concerns in the context of interventions that they strongly believe to be beneficial. The I-ELCAP investigators did not report any data on or discuss morbidity related to diagnostic procedures or treatment, and they explicitly considered treatment-related deaths to

have been caused by lung cancer. Insofar as prior research has demonstrated that few pulmonary nodules prove to be cancerous, and because few positive test results in the trial led to diagnoses of lung cancer, it is reasonable to wonder whether the expected benefit to patients is offset by the difficulties and risks of procedures such as thoracotomy. The study report also did not discuss the carcinogenic risk associated with diagnostic imaging procedures. Data from the National Academy of Sciences' Seventh report on health risks from exposure to low levels of ionizing radiation⁷ suggest that radiation would cause 11 to 22 cases of cancer in 10,000 persons undergoing one spiral CT. This risk would be greatly increased by a strategy of annual screening via CT, which would include many additional CT and positron-emission tomography examinations performed in diagnostic follow-ups of positive screening results. Were patients given annual CT screening for all 13 years of the I-ELCAP study, they would have absorbed an estimated total effective dose of 130 to 260 mSv, which would be associated with approximately 150 to 300 cases of cancer for every 10,000 persons screened. This is particularly critical for the nonsmoking study subjects in the I-ELCAP sample, who might have been at minimal risk for lung cancer; for them, radiation from screening CTs might have posed a significant and unnecessary health hazard.

In addition to direct harms, Eddy⁵ and other advocates of evidence-based critical appraisal have argued that there are indirect harms to patients when resources are spent on unnecessary or ineffective forms of care at the expense of other services. In light of such indirect harms, the balance of benefits to costs is an

important consideration. The authors of I-ELCAP² argued that the utility and cost-effectiveness of population mammography supported lung cancer screening in asymptomatic persons. A more appropriate comparison would involve other health care interventions aimed at reducing lung cancer mortality, including patient counseling and behavioral or pharmacologic interventions aimed at smoking cessation. Moreover, the authors cite an upper-bound cost of \$200 for low-dose CT as suggestive of the intervention's cost-effectiveness. Although the I-ELCAP study data do not provide enough information for a valid cost-effectiveness analysis, the data imply that the study spent nearly \$13 million on screening and diagnostic CTs. The costs of biopsies, positron-emission tomography scans, surgeries, and early-stage treatments were also not considered.

Summary

Using the example of a recent, high-profile study of population CT screening for lung cancer, we discussed the various considerations that constitute a critical appraisal of a clinical trial. These steps include assessments of the study's validity, the magnitude and implications of its results, and its relevance for patient care. The appraisal process may appear long or tedious, but it is important to remember that the interpretation of emerging research can have enormous clinical and operational implications. In other words, in light of the stakes, we need to be sure that we understand what a given piece of research is telling us. As our critique of the I-ELCAP study report makes clear, even high-profile studies reported in prominent journals can have im-

... did the study evaluate all outcomes that both the physician and the patient are likely to view as important?

portant weaknesses that may not be obvious on a cursory read of an article. Clearly, few physicians have time to critically evaluate all the research coming out in their field. The Technology Assessment and Guidelines Unit located in Southern California is available to assist KP physicians in reviewing the evidence for existing and emerging medical technologies. ❖

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Perfection

You know you've achieved perfection in design
not when you have nothing more to add,
but when you have nothing more to take away.

— *Antoine de Saint-Exupéry, 1900-1944, pioneer aviator, poet and novelist*