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Editors’ Comments

To Reach a High Level
Tom Janisse, MD, Editor-in-Chief

In September, at The Permanente Journal (TPJ) editorial team’s second strategic retreat, our invited guest was Dr. Morris Collen, a retired Permanente physician, in his mid-80’s, who worked with Dr. Sydney Garfield. Still very active, he is a member of a National Library of Medicine committee that approves new journals for inclusion in the library and MEDLINE.

In the early 1940’s, Dr. Garfield approached Dr. Collen and said, “Morrie, I want you to create a bulletin so that the physicians outside Permanente know what we do.” Dr. Collen became the first Editor-in-Chief of The Permanente Bulletin and authored a number of clinical articles. After several issues, an influential medical school dean said to Dr. Collen, “I used to think you Permanente physicians were a bunch of Communists, but since I have read about the work you are doing in The Permanente Bulletin, I am very impressed with the quality of medicine that you practice in Kaiser Permanente.”

As Dr. Collen addressed our editorial team, he expressed the same sentiment as had Sydney Garfield. “You need to publish The Permanente Journal so that physicians outside of Kaiser Permanente know what you do and how good you are. The Permanente Journal is a great vehicle for you to achieve that.”

Physicians outside Kaiser Permanente (KP) now read TPJ and are equally impressed. However, to achieve full national and international recognition, and for our articles to be cited in MEDLINE, TPJ needs approval by the National Library of Medicine. The primary criterion is the publication of scientific articles. Although we do that now, we must increase the number of articles in each issue that are clinical studies using research methodology to develop statistically significant data resulting in original findings.

The “Catch 22” for any new journal is that physician-researchers and authors routinely select a journal listed in MEDLINE—which defines the national medical literature. However, to gain approval for MEDLINE, a journal must attract those same authors. When MEDLINE approval is granted, articles published in that journal for the previous year are retrospectively listed, which means that Permanente physician authors who publish in TPJ in 1999 would be cited in MEDLINE upon approval in 2000, which is our goal.

Permanente has no shortage of highly productive publishing physicians, who place hundreds of clinical and research articles in major national journals each year. Several of those article abstracts are reprinted in each issue of TPJ. Other important Permanente sources for scientific articles include our Regions’ quality assurance and improvement studies, as well as Innovation Fund studies, and the Garfield Fund.

Although achieving MEDLINE status is certainly a worthy goal, TPJ publishes many important articles of high value for Permanente physicians, many of which define Permanente Medicine, such as: successful or best practices and health systems process innovations; crucial information on the external environment impacting Permanente; and articles demonstrating our social and humanitarian work.

TPJ already exhibits a unique format; raising this to the next level to achieve the stature of a major scientific journal aids the aspiration of Permanente to be the world leader in improving health.

Clinical Contributions and Original Research
Arthur L. Klatsky, MD, Associate Editor

The Clinical Contributions and Original Research sections are combined in this issue in order to feature a special research symposium, “The Gary Friedman Symposium” is devoted to papers derived from talks presented on May 11, 1998 at a celebration of a transition in the career of one of Kaiser Permanente’s most distinguished physicians. Gary Friedman has been with KP since 1968 and is an internationally known, outstanding physician-epidemiologist who is substantially responsible for developing one of the first and largest epidemiologic research programs in an HMO. More details about his impressive career are to be found in the biographical sketch in the Symposium (p. 38). The program included six scientific presentations, each of which emphasized Gary’s role as an initiator of scientific research and as a mentor of developing researchers. Five of the presenters have written articles for the Journal. In their totality, they present a varied, but only partial picture of the accomplishments of the KP Northern California Division of Research (DOR). These articles should not be considered comprehensive reviews of the topics since they are based upon relatively brief talks. Relevant anecdotal material was left in the manuscripts by several of the presenters. Dr. Stephen Sidney’s article, “The CARDIA study and the Development of Clinical Research at the Division of Research,” provides an account of some of the results of a major multicenter study of cardiovascular risk factors in young persons. KP was one of four field centers for this longitudinal clinical study. Already very productive, the CARDIA study promises to become a key effort in this area of research. The scholarly paper by Dr. Noel Weiss, “‘Sensitive’ and ‘specific’ epidemiologic studies: The Division of Research of the KP Medical Care Program,” provides information of con-
siderable scientific interest to all physicians. Dr. Weiss, another distinguished and productive physician-epidemiologist, is not a KP physician and thus provides an outside perspective of the value and quality of DOR research and of Dr. Friedman’s contribution. Dr. Joe Selby, who has succeeded Gary Friedman as Director of the DOR, has written “Screening for Colorectal Cancer: Research Contributions of The Permanente Medical Group.” This is an excellent summary of one of KP’s most shining series of research contributions, concerning the very practical and obviously important subject of how best to screen for colorectal cancer. Many persons have contributed to this effort, including Drs. Friedman and Selby. My contribution, “Illegal, Immoral, or Bad for the Heart?” is a personal account of development, under Gary Friedman’s mentorship, of a second career as a physician-epidemiologist, and the article presents some of the findings of this work. Dr. Friedman’s “Reflections” is also, in part, appropriately personal. The article includes some valuable reminders of the importance of preserving our records—“a national treasure.” Dr. Friedman also discusses some pitfalls of interpreting data, problems in accepting abstracted information, and the importance of investigator-initiated research in our type of medical system.

Another major portion of this issue’s Clinical Contributions, “Operating Room Benchmarking: The Kaiser Permanente Experience,” reports the experience of a National KP group of experts who comprehensively examined operating room practices, culture, and problems. Not surprisingly, the results have been controversial, and for this reason, several commentaries representing diverse views have been included. As there is also an editorial comment about this article, it is not necessary to say more here, except that the article, which was evaluated by the Juran Institute as an “exemplary” benchmarking project in scope and depth, should be of interest to physicians in all specialties since we are all caught up in examination of our methods. Change—or the prospect of change—is always initially difficult and painful.

Finally, we include in this issue a brief report by Drs. Jeffrey Pollen and Daniel Smiley entitled, “Antibiotic Prophylaxis and Needle Biopsy.” It is a nice example of the type of clinical study which Permanente physicians could and, I think, should do in substantial numbers. There must be many such data bases in the records of hundreds of physicians in all specialties. We would be more than happy to receive some of these as brief articles for consideration of publication.

Please write with comments, additions, corrections, disagreements, or personal observations about any Clinical Contributions article.
External Affairs
Scott Rasgon, MD, Associate Editor

The External Affairs section has a variety of articles with different perspectives on the state of affairs inside and outside our health care organization. Susan Ayres’ article, “The New, 1998 Brand Advertising Campaign,” speaks about us as a health care organization “in the hands of doctors.” This is an advertising campaign to differentiate us from our competition. The message is that we are not a medical business with medical decisions made by business personnel. In “Coming Clean,” Cynthia Lopez and Nancy Buell highlight the community service project in California to help people remove tattoos. Dr. Joel Hyatt writes in “Purchasers’ Demands for Care (Disease) Management” about our work on care management and how purchasers are looking for this type of care. Dr. Don Parsons comments on what might be happening on medical care legislation after the President’s troubles are resolved. I hope you find this selection of articles to be enjoyable and informative reading. ☮

Isaac Asimov

The most exciting phrase to hear in science, the one that heralds new discoveries, is not “Eureka!” (I found it!) but “That's funny ...”
Operating Room Benchmarking: The Kaiser Permanente Experience

In 1994, a Kaiser Permanente (KP) Interdivisional Task Force—comprising 30 surgeons, anesthesiologists, perioperative managers, and technical staff—completed a comprehensive, internal Operating Room (OR) Benchmarking Study. The study used 11 metrics in three categories—OR Productivity, OR Costs, and Satisfaction—and set operational targets, or benchmarks, for many of the metrics. The resulting Operating Room Best Practices (ORBP) report describes many business and clinical Best Practices that may be expected to produce substantial performance improvements. The 1994 study estimated potential organizational savings of $72.6 million. In a 1996 follow-up study, the KP-California Division demonstrated actual savings of $10.1 million for three of the metrics combined. By showing the clinical and economic benefits of collaboration among surgeons, anesthesia personnel, and other OR staff, our study has also led ORs throughout KP to use a multidisciplinary problem-solving approach instead of giving perioperative managers sole responsibility for improving OR efficiency.

Introduction

As an established and leading health maintenance organization in terms of reputation, longevity (50 years), and membership (more than nine million), the primary focus of Kaiser Permanente (KP) is our organization in terms of reputation, longevity (50 years), and membership (more than nine million). Our greatest challenge is to maintain a high-quality standard of care that fosters wellness, appropriately treats illness, and accomplishes both of these functions at a reasonable cost to health plan members. Consequently, acting neither in a crisis mode nor from any sense of urgency, KP in 1991 began to scrutinize its business and clinical practices to explore how we could improve the way we do things. This exploration reflected senior management’s anticipation of the competitive health care market which was developing.

Specifically, other health care organizations were offering lower rates, promised better access to ambulatory services, and appeared to design more flexibility into their health plans. Our leading edge was developing laboratory services, and appeared to design more flexibility into their health plans. The goal of the study was fourfold: to learn what makes a good operating room; to identify Best (Business) Practices; to identify potential cost savings; and to provide a model for KP interdivisional cooperation.

Methods

Scope of Study

The study examined hospital-based ORs (ie, main ORs and ambulatory surgical units [ASUs]); scheduling and preoperative processes used for surgical patients; anesthesia staffing practices; management of OR supplies; OR nursing staffing practices for direct caregivers (ie, persons who provide care to patients) and indirect caregivers (ie, managers, coordinators, housekeepers, clerical staff, other ancillary personnel); and utilization of OR time (ie, by nursing, anesthesia, and surgical staff).

The scope of the study did not include minor and special procedure rooms outside the OR “boundaries” or ORs within the labor and delivery units; staff practices in areas or departments other than described above (ie, scheduling office, housekeeping); reusable items (eg, instruments, capital equipment); staff who process surgical instruments, engage in general handling of materials, or who do not work in the OR.

Even though the scope of the study did not cover these departments or functional areas, relevant issues were discussed and anecdotaly documented in interviews and site visits of candidate high-performing facilities.

Participant Selection

A team of >30 surgeons, anesthesiologists, perioperative managers, and technical staff—supported by a consultant from the Juran Institute, a

“The 1994 study estimated potential organizational savings of $72.6 million. In a 1996 follow-up study, the KP-California Division demonstrated actual savings of $10.1 million for 3 of the metrics combined.”

“Benchmarks are operational targets that ... are determined from a combination of information in the literature, results of data analysis, professional expertise, and operational expertise.”

The Kaiser Permanente Experience

By Kay Stodd, MSN, RN, CNOR
Alex Ortiz, MS
Inez Tenzer, MS, RN, CNOR, CNAA

By Kay Stodd, MSN, RN, CNOR
Alex Ortiz, MS
Inez Tenzer, MS, RN, CNOR, CNAA
quality management consulting firm—was selected by an Executive Steering Committee of senior management to participate in the study. The three hospital-based KP Divisions (California, Northwest, and Hawaii) were selected for internal benchmarking. This methodology was chosen primarily because we wished to further investigate our own environment and because we anticipated difficulty in obtaining comparable data from non-KP organizations. From within these three KP Divisions, data were collected from 42 sites, including 30 main ORs and 12 ASUs.

**Study Metrics**

The team chose 11 metrics for comparison to evaluate OR productivity, cost, and satisfaction. To evaluate productivity, the team used four metrics: OR performance (effective use of surgical time), OR utilization (percentage of allocated OR time used), room turnaround time (time interval between one patient leaving and next patient entering the OR), and surgeon turnaround time (time interval between end of surgery for one patient and making an incision on the next patient).

To measure cost, the team used three metrics: cost of OR labor, cost of anesthesia labor, and cost of materials.

To measure satisfaction, the team used four metrics: patient satisfaction, OR staff satisfaction, physician satisfaction, and CRNA satisfaction.

**Formation of Benchmarking Teams**

Using a team of more than 30 members to conduct benchmarking was not a practical approach. Consequently, a Core Team was derived from the original Task Force to conduct the benchmark analysis and site visits and to generate recommendations. The Core Team included representatives from OR nursing disciplines, medicine, and anesthesiology, with support from technical staff.

**Equalizing Comparability of Facilities**

Each site studied had unique features with respect to types of patients (inpatients/outpatients), mix and severity of surgical cases, business schedule (24-hour versus daytime-only), physical layout of facility, and staffing composition (ie, variable use of support staff among facilities or among departments of the same hospital). Therefore, to equalize comparability of facilities in preparation for data collection, we designed analytical tools that would both screen variables and provide sufficient detail to detect differences in them. For example, selected positions (eg, OR registered nurse, surgical technician) were designated for comparison. In addition, a methodology was created for comparing OR effectiveness as well as for comparing each facility’s cost of surgical materials that also accounted for mix or acuity of procedures at that facility. A staff model and methodology were developed to compare diverse staff compositions and tasks.

Differences in labor costs (eg, geographic, union-related) were also considered when comparing operational costs. For example, the staffing analysis used full-time equivalents (FTEs) instead of payroll dollars, and the materials cost analysis used a standardized unit cost per procedure. In addition, main ORs and ASUs were compared and benchmarked separately because as different types of facilities (ie, inpatient versus outpatient), they differed in type and case-mix of patients, scheduling practices, facility layout, and hours of operations. To ensure that information was sufficiently uniform for comparison among all facilities, existing data bases were used for workload statistics (although some data had to be reentered in a standardized format).

**The Benchmarking Process**

Our benchmarking process generally matched traditional benchmarking processes and consisted of four phases: data collection and analysis; identifying Best Practices and any performance gaps; implementation; and...
recalibration (ie, monitoring and evaluation).

**Phase 1: Data collection**

In the first phase—data collection and analysis—we identified high-performing facilities, medical facility performance gaps and major contributors to these gaps; estimates of potential savings; emerging themes related to cost and productivity; and predictors of overall satisfaction.

To collect information about these operational processes, detailed survey questionnaires were designed. The survey data as well as information obtained from standard payroll and nonpayroll reports enabled us to identify candidate high-performing facilities. To ensure that these survey data were reliable despite the length and complexity of the survey tool, the technical staff held individual meetings with each major stakeholder in the OR (eg, the perioperative manager and chief or manager of anesthesiology).

To evaluate patient satisfaction, a questionnaire was given to each surgical patient during a specific timeframe before discharge. (The patient satisfaction survey was also designed to help us identify major predictors of surgical patients' overall satisfaction.) Patients were requested to complete the form and return it by mail in the stamped envelope provided. To evaluate satisfaction of the OR personnel, we mailed surveys to the anesthesiologists, surgeons, and nurse anesthetists at their home addresses; OR staff received their surveys at the workplace.

**Phase 2: Identifying Best Practices.**

The Business and Clinical Best Practices identified with each metric were defined as actual standards, policies, procedures, and practices found during initial data collection or, most frequently, during site visits.

Two-day site visits to 11 candidate high-performing facilities were conducted to validate the information received, to determine the practices that made the site a high performer, and to identify the Best Practices. Best Practices included processes that promote high performance as well as standards that are realistically achievable by other facilities.

During our survey of these high-performing facilities, we reviewed clinical outcomes to ensure that the Best Practices identified were not likely to have adverse impact on patients. (Best Practices were explored further if any resulting outcome fell outside the acceptable range.) This approach was taken so that clinical outcomes would be compared among all facilities and measured against industry standards instead of being statistically correlated with Best Practices.

During the site visits, clinical staff interviewed the managers and supervisors responsible for clinical outcomes would be compared among all facilities and measured against industry standards instead of being statistically correlated with Best Practices. Recalibration (ie, monitoring and evaluation).

**Phase 3: Implementation**

To enable OR stakeholders to successfully implement the Best Practices identified by our benchmarking project, we formulated a communication plan that addressed the logistics—ie, how, when, what, and with whom to communicate the results of the study.

To communicate with all concerned parties simultaneously while addressing the concerns of first-line managers (who might need the information to explain results to their managers), we used meetings, presentations, and publications as part of our communication strategy.

Specifically, information constantly flowed throughout the project to and from all perioperative managers, chiefs, and managers of the anesthesiology departments via our meetings with them during the initial survey. This information flow was achieved by soliciting input from these personnel, by conducting group meetings to discuss preliminary results, and by keeping personnel informed of results by mail. In addition, meetings with the Interdivisional OR Task Force were held about every six months to obtain input and feedback regarding progress.

After the results of the study were prepared, the Steering Committee was contacted to inform them of the findings, implications, and potential issues. The study report was distributed to all parties concerned: perioperative managers, directors of nursing, administrators, chiefs of surgical services, and chiefs of anesthesia. Results were also presented to the Medical Group administrators and hospital administrative personnel in each Division as well as at group presentations for the chiefs of surgical specialties as requested.

We also organized a teleconference with all 42 sites and invited key stakeholders, administrators, and se-
The program included an interactive question-and-answer session.

**Phase 4: Recalibration**

To ensure ongoing monitoring and evaluation of the effort, to share new Best Practices, and to encourage continued focus on the major issues of the project, we published a Best Practices Newsletter containing information from each of the facilities regarding their successes. (Ongoing individual Divisional work is also being conducted to expand and improve the original communication product.)

**Estimating Savings**

The 1994 study identified potential cost savings for five of the 11 metrics. In 1996, two years after completion of the initial report, a follow-up study was performed to measure how much could be saved with the goals of the original study modified for selected metrics. That follow-up study compared three of the five cost metrics in California facilities only. The metrics compared were OR Labor, OR Utilization, and OR Performance.

**Results**

**Benchmarks Identified by the Study**

Benchmarks were created for the areas shown in Figure 1. The benchmark for OR Utilization was set at 80% for ASUs and was set at 85% for main ORs. These targets were set in accordance with observed Best Practices to achieve optimal balance between efficient use of ORs and ability to provide the flexibility to add urgent cases. For main ORs, the benchmark for OR Performance (effective use of surgical time) was set at 5% below the mean length of procedure; for ASUs, the benchmark was set at 10% below the mean length of procedure.

To calculate the benchmark for OR Labor Cost, the cost for all ORs was compared with an “optimal” staffing model developed for different-sized ORs. Similarly, to calculate the benchmark for Anesthesia Labor Cost, the cost for all ORs was compared with an “optimal” staffing model developed for different-sized ORs. The benchmark for OR Material Cost was set to the 10th-lowest cost of materials observed among the 42 facilities studied. Also included in this target was the case-mix acuity at each facility.

**Best Practices Identified by the Study**

In the satisfaction category, Best Practices were identified as factors which have a positive influence on overall satisfaction for the group being studied. The results of the satisfaction survey identified these specific factors predicting member satisfaction.

Eight Best Practices contributed most toward positive change: OR productivity, labor, and materials; anesthesia labor; and satisfaction of patients, OR staff, physicians, and CRNAs. (For a complete list of these Best Practices, please contact the authors.)

**Best Practices in OR productivity (OR Utilization and OR Performance)** included use of all-day blocks of time, on-time start for first case of the day, physician serving as OR director, effective OR Committee, streamlined preoperative processes, overlapping turnaround processes, accurate procedure cards, scheduling guidelines, and routine block reallocation.

**Best Practices in OR labor** included use of two staff members per OR; RN-to-ORT ratio of 65:35 (now set at 60:40 throughout KP); use of 2.4 to 2.5 staff members per OR (in electively scheduled blocks); use of short shifts; staffing to demand; and use of part-time staff, per diem staff, or both.

**Best Practices in OR materials** included standardization of materials with compliance monitoring; move...
from surgeon preference cards to procedure cards; presence of an OR materials coordinator and an OR Cost Awareness Committee; use of "reusable" instead of "disposable" materials; and designation of supplies as "available" instead of "open."

Best Practices for anesthesia labor included assignment of anesthesiologists to OR as primary care provider for high-risk patients; Anesthesia Care Plan formulated by anesthesiologist with assistance of CRNA; CRNA participation in preoperative evaluation of all but high-risk patients and patients who require complex care; and appropriate CRNA education and credentials in regional anesthesia if opportunities are provided to practice in this area.

Anesthesia care received and confidence of patients with OR staff were predictors of high overall patient satisfaction. Quality of staff, quality of instrumentation, and level of responsibility in job predicted high overall OR staff satisfaction. Performance of OR nursing staff, physical characteristics of OR suite, and availability of equipment and supplies in the OR predicted high overall physician satisfaction. Quality of OR staff service, relationships and communication with other hospital staff, and quality of service provided by surgeons predicted high overall CRNA satisfaction.

Potential and Actual Organizational Savings Identified by the Study

For the 1994 operating year, overall potential savings of $72.6 million were identified for the organization. Grouped by study metric, potential savings (in millions) were identified for OR Materials ($21.7), OR Labor ($5.2), Anesthesia Labor ($10.9), OR Utilization ($14.5), and OR Performance ($20.3). All potential savings were thought to be achievable without causing any adverse clinical outcome (Figure 2).

In the 1996 follow-up study of three of the metrics—OR Labor, OR Utilization, and OR Performance—at California facilities, realistic potential savings were calculated as $18.7 million (ie, a figure equivalent to two-thirds of total theoretical potential savings, as explained in Discussion).

Of this $18.7 million in potential savings, the 1996 follow-up study showed that an actual savings of $10.1 million was realized (Figure 3). The major areas of savings were OR Utilization (which increased from 81% to 86%), OR Performance (which improved in main and ASU ORs), and RN-to-ORT ratio (which changed from 71% RNs to 67% NRs). Total savings identified by these three metrics were equivalent to 54% of the savings originally projected and were believed to constitute a major accomplishment, considering that no formal implementation project efforts were conducted after publication of the original study results.

Discussion

Our ORs had all been studied frequently in the past. Perioperative managers and physicians had various levels of skepticism and criticism of previous cost analyses studies, which were usually very broad in nature, included little input from key stakeholders, and were performed by Divisional support staff or external consultants. For this reason, we determined it necessary to allocate a substantial amount of time to maintaining direct contact with individual managers. We also determined it necessary to work with groups personally to build credibility, to gain confidence in our benchmarking process, and to obtain early “buy-in” for the results.

Partly as a consequence of this extensive contact, the project took nearly three years to complete. This duration was longer than originally intended, but it is vindicated considering that no formal implementation project efforts were conducted after publication of the original study results.
Practices associated changes in practice, only to identify the different from that their practice area for potential improvement, look up the Best Practices associated with the area, and develop an action plan. The Best Practices (ORBP) report. This report is a practical, "user-friendly" document, not merely theoretical or conceptual: To implement changes in practice, a manager needs only to identify the area for potential improvement, look up the Best Practices associated with the area, and develop an action plan. The Best Practices are concrete suggestions found in high-performing (Best Performer) facilities and are transferable to ORs and ASUs at most KP locations.

### Other Learnings

In addition to these major, positive learnings, results of the project taught us about allocating resources, setting project scope, reporting potential savings realistically, obtaining acceptance of the report, and integrating the data that were obtained in the course of conducting the project.

### Need for Allocating Resources

Although the need for project-specific personnel was identified early in the study, the issue was never pursued long or diligently enough to become a reality, and all members of the Task Force continued to maintain other full-time employment. In retrospect, we believe that the project's value must be identified at the onset and that resources (ie, people, time, and dollars) must be assigned accordingly. Had this project been approached from a more organized, project management perspective, it could have been completed in less time.

The project was expensive with regard to the people, time, and travel required. A budget was not prepared at the beginning of the project, and we do not know the actual cost to the organization to produce this study. For future projects of this magnitude, we would recommend that a formal budget be prepared so that cost-benefit decisions can be made.

### Need for Narrowed Scope

Our first challenge in designing the study was to define the scope of the project to include only the most essential areas, departments, and processes that would lend themselves to comparison. The original Task Force specifically attempted to narrow the scope to include ORs only, but we now believe that the project probably would have benefited from division into smaller segments. The complexity and interrelation of the metrics would have made this seg-
m entation difficult but might have resulted in quicker turnaround time. Main ORs could also have been studied separately from ASUs.

Considerations in Reporting Potential Savings

Although our study reported potential overall organizational savings of $72.6 million, the Core Team did not believe this amount could be actually attainable within a short time (ie, within three years). Indeed, the percentage of potential savings that was realistically achievable was difficult, if not impossible, to achieve; and obstacles to fully achieving these financial goals were clearly delineated in the ORBP report. These obstacles included facilities’ physical constraints to implementing Best Practices; short timeframe for cost data base; and the likelihood that some data supplied by managers and physician chiefs were estimates (ie, figures not actually observed).

The decision to publish the total overall potential savings was made by the Task Force and was supported by the Steering Committee; however, publication of this dollar figure caused those who only read or heard the “bottom line” of the study to place unrealistic expectations on the managers who would be required to implement the cost reductions. Therefore, for purposes of the 1996 follow-up study, we reduced by a third the potential savings figure reported for the three metrics.

Need for Promoting Acceptance of Results

Most key stakeholders enthusiastically accepted the findings of this study, with one exception in one area. Extensive work was done during the project to overcome this problem and to resolve the issues, but in the end, all attempts were unsuccessful. In one KP Division, the problem has interfered with acceptance of the other 90% of the ORBP report. In retrospect, more stringent initial validation of process ownership and of study results by each key stakeholder would have great value. To achieve effective implementation, a project of this size needs active “champions” by peers in each area.

Need to Integrate Data

From the outset, we knew that data collection would present major problems. For the technical support staff, for example, integrating four different OR information systems into comparable data was very difficult. In addition, because Divisions defined like times differently, data for these times were reported inconsistently, and many inaccuracies in the data were discovered. More time spent during the initial phases of the project in identifying and resolving these issues would have saved us much time later in the study.

Organizational Effects of the Study

Several years have passed since publication of the results of this extensive benchmarking project in the Operating Room Best Practices (ORBP) report. Indeed, the key to the operational value of this study is its Best Practices information. We are very happy to report that most aspects of the study have been accepted and that the report is in various stages of implementation and recalibration throughout each KP Division and at individual KP facilities. The largest Division, California, has expanded and improved upon specific data points. Immense strides have been made in increasing the timely production of accurate comparative information for facilities to use in their day-to-day operations.

This study has changed the culture of our organization in how it looks at the OR. Before the advent of this project, most administrators believed that saving money and improving efficiency in the OR was the responsibility of individual perioperative managers. By emphasizing clinical and economic benefits of collaboration among surgeons, anesthesia personnel, and the OR staff, and by using the Task Force and Core Team as role models, the report has helped to make the multidisciplinary approach to problem solving in the OR the accepted norm.

In studying some “sacred cows” in OR practice, we have shown that some of these can be justifiably eliminated without eventuating any adverse clinical outcome. Each day, talented and innovative perioperative managers and physicians are discovering new ways to improve the cost-effectiveness and productivity in their ORs. We should continue our efforts in external benchmarking to add another dimension—especially outside the KP organization—to increasing the efficiency and cost-effectiveness of our ORs.

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Commentary

Hawaii Region

Albert Mariani, MD

Dr. Mariani did his training in Urology at the Mayo Clinic, after which he joined the Hawaii Permanente Medical Group in 1980. He was appointed Chief of Surgical Services in 1983 and has served in that capacity since. He has served on the Interregional New Technologies Committee since 1991 and authored the Hawaii Specialty Care Model which has been featured at national meetings.

The Operating Room Benchmarking Study was the largest effort to date by the KP Medical Care Program to understand that incredibly complex and very expensive health care environment known as the OR. The Task Force consisted of analysts, OR directors, hospital administrators, anesthesiologists, CRNAs, and surgeons. The Task Force members were experienced, knowledgeable, and dedicated to what turned out to be several multiday meetings over three years.

In the Hawaii Region, the OR metrics proved to be the most useful and have become the benchmarks whereby we measure our OR efficiency. I have found several “thumbnail” metrics useful in managing the surgery department and its approach to the OR. For example, a well-managed OR has 85% utilization; a minute of OR time costs about $13; an hour of OR time costs roughly the same as a day of hospitalization; the OR costs about twice as much as an ambulatory surgery unit, with short-stay cases being of intermediate cost.”

Albert Mariani, MD
talization. Careful definitions of OR Turnaround Times (Room Turnaround Time, Surgeon Turnaround Time) can be useful for quantifying what really is going on regarding turnaround. Unfortunately, we were unsuccessful in our efforts to collect this information in a public way to challenge discrepancies and thus to validate the data. The data have been collected but taking action on the data would be difficult without independent validation, which would require a focused study.

Finally, marked cost efficiencies can be achieved by assigning cases to the appropriate setting. The OR costs about twice as much as an ambulatory surgery unit (ASU), with short-stay cases being of intermediate cost. These OR metrics give us an instrument that measures performance by commonsense, widely accepted definitions that allow longitudinal comparisons over time. We have adopted the metrics of the Task Force to measure the efficiency of our OR.

There are some caveats. We should remember that this is a Best (Business) Practices study, which means that although quality of service was acknowledged to be an important determinant of organizational success, this study emphasized cost. Some evidence showed a trend toward a mild negative correlation between cost and satisfaction.

Despite Herculean efforts to standardize data, this task was impossible without on-site inspection. However, this standardization of on-site data would be prohibitively expensive if done for ongoing evaluation of OR services in every service market. Collecting comparable data in the same market over time would be more feasible because the same market uses the same information services infrastructure over time. Thus, not all intuitively good ideas could be quantified. Some were accepted in our Region simply because they made sense on the basis of extensive OR management experience. Uncovering new ideas was the most beneficial effect of the attempt to standardize the data.

While I am obviously biased and while there are few endeavors that depend upon teamwork as much as in the OR, there is a hierarchy of required satisfaction determined by personal risk and responsibility. That hierarchy looks something like this: patients > surgeons > anesthesiologists > CRNA > staff. This concept was not addressed in the report. At each meeting, never more than 3 of approximately 30 participants were surgeons, and only 1 of these surgeons attended all sessions. Some of the report’s recommendations must be read in this light. The report notes that the Permanente Medical Groups are managed by influence rather than authority. In my experience, influence based on correct data is far more powerful than authority for achieving desired results, and this report represents a substantial and meaningful effort to provide such data.

Southern California Region
Max Wirjo, MD
Coordinating Chief of Anesthesiology, SCPMG.

As we all remember, the ORBP Task Force initially created controversies and criticism—if not skepticism—from different directions when it was created. Even we had to settle our differences in the final days of finishing that document. Furthermore, looking at the criticisms carefully, I notice that they entirely differ from each other depending on the specialty and department that produced the criticism. On the basis of this experience alone, I concluded that the ORBP report is probably the best document or set of recommendations that we have ever created, and that we should be proud of that.

Even now, three years later, we can still look at the ORBP report and check whether our practices match its recommendations. The ORBP report is certainly specific to our practice and culture, but I think the report would apply and be useful to any health care organization that has a setup similar to ours.

My only disappointment has been that the ORBP document has been underutilized—that not enough commitment was given to implementing it. Even now, three years later, we can still look at the ORBP report and check whether our practices match its recommendations. The ORBP report is certainly specific to our practice and culture, but I think the report would apply and be useful to any health care organization that has a setup similar to ours.

My only disappointment has been that the ORBP document has been underutilized—that not enough commitment was given to implementing it. This could well be due either to the criticism heard at the time or to the lack of champions for the report’s recommendations, but I believe that time will show the ORBP report being used as a reference for OR Best Practices. Thanks for asking me to comment and reflect on this important document.

Northern California Region
Gene Golfus, MD
Medical Director of OR and Perioperative Services, Napa-Solano (Vallejo), California; and Co-chair, Regional Perioperative Management Group (RPMG).

A major recommendation of the final ORBP report was that each of our ORs should have a physician-director, as I am. The report also recommended that a group like the Regional Perioperative Management Group continue to work collaboratively between Kaiser Foundation Hospitals (KFH) and The Permanente Medical Group (TPMG) on OR issues. The RPMG is composed of the OR Directors within TPMG, the Perioperative Service Line Directors within KFH, and the OR Managers within KFH for the North’s 23 OR facilities. Although I was
"This report is a monumental achievement, and it offers central points that allowed me to begin to think about ORs. That being said, I paraphrase a famous author: It was the best of reports, it was the worst of reports."

Gene Golfus, MD

However, there are things in the report that, in retrospect, I do not think hold up as well. For example, the ever-rising bar of the ‘25th percentile’ Best Practice time was accepted by the senior leadership but is less than clear as an attainable goal—and may not be a desirable one.

Gene Golfus, MD

not a part of the original OR Benchmarking Study, I have been invited as a participant in the 1998 “OR Improvements Task Force,” a group put together by Kay Stodd involving the California Division, to look for guidelines for KP ORs.

Before I begin “picking” on this report, I would like to emphasize that I think Kay Stodd deserves a medal for it and for her continued work on ORs for this organization. I do not wish to be misunderstood; I am not criticizing Kay. To the contrary: this report is a monumental achievement, and it offers central points that allowed me to begin to think about ORs.

That being said, I paraphrase a famous author: It was the best of reports, it was the worst of reports.

Actually, the report was good; the way it has been interpreted and implemented is, well, less good. I think the ORBP study was a fantastic attempt to put together an organized look at a very complex area: the OR. Much is useful in the 1994 ORBP report as a stepping-stone to continued thinking about ORs, but many of the conclusions and uses of the report are misguided.

Moreover, much of the good has been lost and forgotten, and much of the error, revered. Many of the caveats were good, but no one remembers them.

The value in this report is largely as a beginning, and a stimulus for further progress in the OR. The ORBP report—and the facility profile that came from its work—had an impact on me and on the OR I work in. In 1991, the Vallejo OR was at 45% utilization, whereas today it is at 93% utilization. Much of that increase came from this report, which encouraged addition of an OR director and stimulated the OR manager, Sharon Fine, of KFH and myself to work as a collaborative team to improve OR utilization. The sections on professional satisfaction of surgeons, OR nursing, and anesthesia are also very good beginnings.

The report was correct in noting that an OR that is already achieving utilization beyond 85% may have difficulty adding urgent add-on cases. We are experiencing that situation now; the report was correct—we have overshot the mark.

However, there are things in the report that, in retrospect, I do not think hold up as well. For example, the ever-rising bar of the “25th percentile” Best Practice time was accepted by the senior leadership but is less than clear as an attainable goal—and may not be a desirable one.

The OR timeline is split into time intervals, and mean operative time for each interval is calculated for each OR. The time that is the fastest at the level of the 25th percentile (i.e., the upper fourth in time) is considered the “Best Practice.” The assumption then is that if each OR across the Region were to come to the best 25th percentile in each time slot through a case, then the Region could save $20 million. The amount of time your OR took “to set up the case” or “from cut to close” beyond the Best Practice 25th percentile would be seen as potential savings by multiplying “excess” minutes times dollars per minute.

This process had an impact on my CSA in that $3 million was removed from the OR’s budget as allocated for 1996 to determine the 1997 budget. This budgetary reduction was largely based on the report’s numbers and led to an unrealistic, unobtainable budget.

The ORBP report has also stimulated us to go back and realize that timelines—and the definitions we base those timelines on—are not the same across the Region. This discrepancy could affect the way time is recorded in each box, and it probably means we are not comparing like items.

The Executive Steering Committee of the RPMG compiled in April 1998 and is now implementing a new set of consolidated definitions and a timeline to be used by all ORs in our Region. These definitions will match national definitions agreed upon by AORN.
(American Operating Room Nurses) and AACD (American Association of Anesthesia Clinical Directors).

I will conclude with the point that the report is good but should not be taken as “gospel.” The report is a wonderful stimulus for further learning. We should not throw it away, but we should question and improve on its most valuable beginnings.

Northwest Region
Tom Janisse, MD
Former Chief of Anesthesia, Northwest Permanente; Member, Interregional ORBP Task Force member.

Change and Implementation
As a member of the OR Benchmarking Study Task Force, I experienced all phases of this complex process. It was an enormous undertaking when you consider that the strategy was to include all key stakeholders in four hospital regions and, through them, to include those people involved or affected in local departments as well as in their ORs. This process required many meetings, phone calls, and e-mail exchanges. And still, more the potential changes could affect each department or individual, or the more interest the Best Practices generated, the more comments arose that people did not feel sufficiently included. This was a major lesson for the group. Change that has major importance requires tremendous communication and inclusion and is likely never to be done well enough. And where change falls short, implementation falters or fails—the best ideas, the best discoveries, and the best efforts may be expended for nothing. Or so it appears, because new ideas and change also require readiness in the local group, and that readiness may arrive many months or years in the future.

Initial Comments
The following quotes exemplify sentiments initially expressed by our OR members and were to some extent echoed in the four KFH Regions:

“It gives only lip service to quality and service.”

“It is my concern that an administrator will look at this document and firmly establish initial guidelines without looking at the big picture, because the big picture isn’t totally presented.”

Operations Group
In KP-Northwest (KPNW), a study of regional OR practices (by a group called “Group 11”) had been underway in 1994 when the Interregional OR BP Benchmarking Study work began. We had reached several of the same conclusions before the Task Force did, and from the value of our learnings were able to add experiential credibility to ORBP recommendations. For example, a KPNW team—a surgeon, an anesthesiologist, and an OR manager; known as the “Surgical Operations Group”—was formed to manage the OR. The group studying KPNW ORs clearly recognized from past experience that no one person—surgeon, anesthesiologist, or nurse-manager—could adequately effect change in the OR or, more importantly, manage daily activities and resolve differences involving the three groups.

An “Open OR”
Another learning for KPNW—which maintains eight operating rooms at one site and 10 at its other site—was the importance of large OR suites having one OR available for urgent and emergent add-on cases each day. This need becomes more critical when the OR suite’s utilization exceeds 80% of capacity. Because so much effort goes into optimal scheduling of elective surgery, disrupting this scheduling with urgent cases by “bumping” elective cases wastes many people’s time, is highly frustrating for the OR team, greatly dissatisfies patients, and is very costly.

The concept of an “open OR”—either a half-day block or a whole-day block—proves valuable for creating a “just-in-time” method of adjusting for another area of complexity, i.e., the variable nature of surgical procedures, patients, equipment, and OR capacity. The OR Benchmarking Study Task Force tried to construct a model—or a dynamic equation—for evaluating and predicting this variability so that the schedule could be built and resources made available to routinely improve OR effectiveness. To construct this model, the Task Force researched four factors:

- The case adjustment factor, which uses relative value units (RVUs) to quantify magnitude of surgical case difficulty;
- The patient acuity index, which quantifies the critical nature of an illness or its medical complexity;
- The length of stay (LOS) for the case;
- The variable cost per unit of each OR.

In KP-Northwest, a study of regional OR practices (by a group called “Group 11”) had been underway in 1994 when the Interregional OR BP Benchmarking Study work began. We had reached several of the same conclusions before the Task Force did, and from the value of our learnings were able to add experiential credibility to ORBP recommendations. For example, a KPNW team—a surgeon, an anesthesiologist, and an OR manager; known as the “Surgical Operations Group”—was formed to manage the OR. The group studying KPNW ORs clearly recognized from past experience that no one person—surgeon, anesthesiologist, or nurse-manager—could adequately effect change in the OR or, more importantly, manage daily activities and resolve differences involving the three groups.
Clinical contributions

"It is obvious that we cannot reduce costs only by removing people. We can only drive down Anesthesia Labor costs by driving up anesthesiologist and CRNA productivity. This increased productivity is possible only in a high-performance system that requires high levels of competence and performance from anesthesiologist, CRNA, and technician staff. Progress toward superior, cost-effective care may require a substantial ongoing education and training process for all anesthesia staff." Tom Janisse, M D

"For me, this Best Practices effort has not only saved millions of dollars in well-defined ways across the four KFH Regions, but it has resulted in enhanced business and clinical practice for OR teams as well as significantly improved management of OR operations. Our organization is a leader because of it."

Tom Janisse, M D

- Evaluation of technology to determine how complicated the equipment was to operate, troubleshoot, or make available;
- OR capacity: the existence and availability of space to perform procedures.

Creating this formula was at first difficult to conceptualize and then became a daunting task to apply in practice, given the time and resources required as well as other priorities. In the end, if you had an "open OR" you could dynamically shift cases or reconfigure case lists that day to adjust for a critically ill patient, a prolonged surgical procedure, or unexpected delays caused by equipment malfunction. In practice, this procedure seemed to work well by supplementing the experience of the OR Team in anticipating these complexities and scheduling appropriately. If OR utilization was in the 60% - 70% range, then an open OR in effect existed. When OR utilization increased to an optimum 85% of capacity, then the open OR had to be incorporated into the schedule ahead of time. It took a great deal of persistence to achieve this, considering the apparent importance of cases vying for use of OR space.

Staffing Model

Complicating direct application of the anesthesia staffing model recommended in the Best Practices document was the fact that the benchmarking project looked just at the intraoperative area during an eight-hour day without presenting the "big picture" of anesthesia practice. To elucidate that "big picture," the report undertook major exploration of the "extraoperative" work done by anesthesia departments and made great efforts to build the results of that exploration into the staffing model. However, each local site has enough difference in procedures performed (eg, central lines, nerve blocks); in services offered or expected (eg, code response, acute pain service, sedation for cardioversion and MRI scans); and in the staffing for these services (eg, physicians only, physicians teamed with CRNAs) that wholesale application of the model was not easily possible. Today, the KPNW Region does use the recommended 1:3 anesthesiologist-to-CRNA staffing ratio. The ORBP document contains language that I drafted specifically for implementation of the staffing model. We felt this language was imperative for the model to operate well and for it to maintain high levels of quality and service. "It is obvious that we cannot reduce costs only by removing people. We can only drive down Anesthesia Labor costs by driving up anesthesiologist and CRNA productivity. This increased productivity is possible only in a high-performance system that requires high levels of competence and performance from anesthesiologist, CRNA, and technician staff." Progress toward superior, cost-effective care may require a substantial ongoing education and training process for all anesthesia staff." In large part, this reasoning accounts for why the Task Force recommended that Best Practices be implemented over a broad time line of 18 to 24 months and that each site look at its own OR practice in the larger context of its anesthesia department practice.

Procedure Time and Turnover Time

I would also comment on the effort to create savings by reducing either the OR Procedure Time or the OR Turnover Time. Although this reduction is important for creating high performance, the few saved minutes does not add up to cost savings unless these increments cumulatively create enough added capacity to allow an extra case to be done. One thing that helped summate increments was to give surgeons a whole-day block of OR time. Within eight hours, efficiencies can be accumulated to an extent not possible in a four-hour block. At times, ending one block and beginning another in the middle of the day creates an artificial construct with much shifting around of staff and equipment; and delays and bumping of cases easily result when blocks are overbooked or when a longer-than-usual morning clinic causes a block to start late.

Conclusion

For me, this Best Practices effort has not only saved millions of dollars in well-defined ways across the four KFH Regions, but it has resulted in enhanced business and clinical practice for OR teams as well as significantly improved management of OR operations. Our organization is a leader because of it. In KPNW alone, we have seen this in obvious and demonstrable ways. KP OR experts have taken these practices and their experience to other hospitals where we now admit our patients; and these OR experts have been instrumental in recommending and assisting the implementation of many of the practices there. In the final analysis, our members have benefited from our work. I would like to personally thank every person across our organization who spent time and energy, and offered knowledge and expertise, to the OR Benchmarking Study effort and to the resulting ORBP report.

Acknowledgment: The Medical Editing Department, Kaiser Foundation Research Institute, provided editorial assistance.
DAVID WATT, MD, MPA, is an Anesthesiologist with Northwest Permanente, PC. He was first exposed to the photographic process in college and continues to develop his interest in fine art photography.

"Mac's Hands" by David Watt, MD, MPA
The Lighter Side of Medicine

DR. GARFIELD - PERMANENTE PHYSICIAN

Yes, this guy actually said this a few months ago.
Yes, Dr. Garfield, school is going well.
Perhaps we can practice medicine together?
No, by the time I'm done with school, you'll probably be dead.

F.P.S. What specialty would this guy be good at?

BY JOE OLENIUK

LIFE ON THE SUNNYSIDE

DR. KLOZ TO THE BLOOD CLOTTING PANEL STAT 5 TODAY.
SURGICAL PREP RESIDENT MEETING IN ROOM.

ARENA NURSE IS UNAVAILABLE AFTER 2.

OPERATOR, THE PAGING IS SO LOUD I CAN'T HEAR MY PATIENT, CAN YOU DO SOMETHING?

ENGINEER, STAY OUT OF THE SURGICAL PREP.

S. BACHMUBER

JOHN MARK BRIGGS, educator, artist, and health plan member in San Jose, CA, sent us this cartoon. He writes, "I thought I would offer a true incident cartoon I drew after a 'Halloween Blood Testing' as a contribution to your 'Lighter Side' feature," signed "an appreciative care receiver."
On May 11, 1998, a well-attended affair was held at the University of California in Berkeley, entitled: Gary Friedman at the DOR: 30 Years (and Counting)—A Celebration of a Career.

The triggering event for the celebration was the end of Gary Friedman’s seven-year term as Director of the Kaiser Permanente Medical Care Program Division of Research (DOR) in Oakland. The program included six Scientific Presentations, each of which emphasized Gary’s role as an initiator of scientific research and as a mentor of developing researchers. They also serve as an admittedly incomplete catalog of the epidemiologic oeuvre of the DOR over the past few decades; for this reason and because of scientific interest in the presentations, it was decided that publication of manuscripts based upon these talks in The Permanente Journal would be of value. Five of the six presenters (including Gary) have submitted the manuscripts published here. Based upon somewhat informal talks, they should not be considered comprehensive, fully referenced reviews of the topics. Some anecdotal material relevant to the occasion was left in the manuscripts by several of the presenters. This deserved tribute to one of Kaiser Permanente’s (KP’s) most distinguished physicians (see biography) should interest and give pride to the Journal’s readers.

We hope it will also encourage others to submit original research articles to The Permanente Journal. The work of Gary and his colleagues is an excellent example of the important discoveries that can accrue when clinicians analyze their practices in a rigorous fashion and share their findings with others.

— Arthur L. Klatsky, MD, and Mary Durham, PhD, Associate Editors

Illegal, Immoral, or Bad for the Heart?
by Arthur L. Klatsky, MD

Introduction
It is a great pleasure and honor to be a speaker at this Symposium. In 1971, 10 years after I started cardiology practice with The Permanente Medical Group, Gary Friedman invited me to become a clinical associate in a National Heart Lung and Blood Institute application entitled “Predisposing Factors for Myocardial Infarction and Sudden Cardiac Death.” It proved to be an event which changed my life. His invitation led to an exciting and personally very fulfilling second career in epidemiology, for which Gary’s guidance, tolerance, and generosity are substantially responsible. He has been and remains a marvelous mentor.

First Alcohol-Coronary Heart Disease (CHD) Study
The essential and— at the time, novel— concept of the study was to use computer matching to find controls. Gary realized this possibility inherent in the existence of hundreds of thousands of multiphasic health checkup (MHC) records. This incredibly rich epidemiologic data base was created through the work of Dr. Morris Collen, who, among his many distinguished accomplishments, was the founder and first Director of the DOR. The matching execution was done by Abraham Segelaub, who retired after a long, active DOR career and died several years later.

Hundreds of items (history questions, health measurements, lab tests) were screened. Gary called the study a fishing expedition, but I think the hypothesis was that new predictors would be found. This hypothesis was amply fulfilled— Gary’s very productive study resulted in published articles about lung function, psychological traits, coffee, medical history questions, and the first report of the leukocyte count as a heart attack predictor. As we surveyed the data, an inverse relationship of coronary risk to alcohol drinking habits was one of the more striking findings. Gary very generously suggested that I write the first report of prospective data suggesting that nondrinkers were apparently at higher CHD risk. Thus, an article appeared in the Annals of Internal Medicine in 1974, reporting a significantly lower myocardial infarction (MI) risk among alcohol drinkers, compared to abstainers.

There were 464 patients with a first MI. All had a prior MHC exam. The computer selected a “risk control” group well matched to each case for demographics and seven established coronary risk factors; and an “ordinary control” group matched only for age, race, and sex. Thus it was possible to ascertain whether a predictor was associated with or independent of the established risk factors. The important smoking-drinking interaction was recognized. In retrospect, lack of control for smoking was probably a major reason why prior studies failed to recognize this inverse alcohol/MI relationship.
recognize this inverse alcohol/MI relationship. Results stratified by smoking habit were graphically presented (Fig. 1). Since this was the first published epidemiologic report of this finding and no mechanism was apparent, interpretation was cautious. Nine possible (mostly spurious) explanations were discussed, only one of which was a protective effect of alcohol.

Since then dozens of epidemiologic studies, including further Kaiser Permanente studies, have almost unanimously found that lighter drinkers are at lower coronary heart disease (CHD) risk than abstainers (both lifelong and former drinkers). Plausible mechanisms have been demonstrated, most notably that alcohol raises the coronary protective high-density lipoprotein cholesterol (HDL). Antithrombotic effects of alcohol may also be involved. Most scientists now accept this as a probable causal relationship. Benefit of lighter drinking for persons at coronary risk has found its way into U.S. and U.K. governmental advice to the public. Current debate is largely focused on possible additional benefits in specific beverages (wine, beer, liquor), and how best to advise the public. Due to extensive lay media reporting, much of the public is aware of this relationship. A 1995 publication commemorating the 25th anniversary of the National Institute of Alcohol and Alcohol Abuse cited the 1974 publication as one of 16 "seminal" articles in alcohol research.

This got us started in alcohol-health research, and led to a 20-year series of grants from the Medical Advisory Board of the Brewers Association of America and later from the Alcoholic Beverage Medical Research Foundation. These resulted in many reports. Over the years major roles were fulfilled by Abraham Siegelaub, Mary Anne Armstrong, and Harald Kipp.

Alcohol-Hypertension Association

One of the first reports from these studies was a 1977 NEJM article showing association of heavier drinking with hypertension. This cross-sectional analysis showed age adjusted mean systolic and diastolic pressure in three racial groups according to usual drinks/day (Fig. 2). Hypertension prevalence was approximately doubled in...
the heaviest drinkers. Direct cross-classifications showed independence from several potential confounders.

This was one of the first analyses of the alcohol-blood pressure relationship and remains one of the largest. By now dozens of cross-sectional and prospective epidemiologic studies, including additional Kaiser Permanente studies, have solidly established an empirical alcohol-hypertension link. These are supported by intervention studies showing blood pressure changes in several days to weeks with drinking or abstinence, with no convincing evidence that confounding is responsible. A mechanism has not been established although some data suggest a centrally mediated sympathetic nervous system action. The fact that explanations remain speculative is the only major deficiency in the case for causality.

Public Affairs Aspects

From the outset we had public affairs rewards and problems related to reporting benefits of light/moderate alcohol drinking. The major public health problems related to alcohol drinking are the adverse effects of heavier uncontrolled drinking. But it has always been widely apparent lighter drinking had few risks. No one expressed it better than Abraham Lincoln, who, more than 150 years ago, in a speech to a temperance society said:

"It is true that many were injured by intoxicating drink, but none seemed to think the injury arose from the use of a bad thing, but from the abuse of a good thing."

As Gary and I were flying to Atlantic City for the first public presentation of the alcohol-CHD data, we had a drink with dinner. Gary said to me, "we may have to be careful about drinking in public after our presentation, because we'll be accused of wanting to justify our bad habits."

Indeed we have been attacked over the years—not for our personal habits, but for possible bias related to our funding. The obvious harmful effects of alcohol make it difficult for many to accept the concept of possible benefit from lighter drinking. The attacks were bothersome, but Gary—as always—was a calming influence. The funding sources of the early studies became useful in rebuttal of suggestions of possible bias in our work. The apparent beneficial effect of lighter drinking in CHD was uncovered by work supported by the NIH, while the apparent harmful effect on blood pressure resulted from work indirectly supported by beverage industry funds. Of far greater importance in—I think—our success in maintenance of a reputation for honest reporting has been Gary's richly deserved reputation as an investigator of absolutely impeccable integrity.
Alcohol-Mortality Relationship

In returning to the alcohol CHD story, I want to briefly describe one additional report based upon the 1964-68 data base. This was a 10-year follow-up of four matched groups of 2015 persons. An excellent match was found for each person reporting 6+ drinks per day among nondrinkers, drinkers of <2 drinks/day, and a daily drinker of 3-5 drinks. The data, reported in the Annals of Internal Medicine in 1981, showed a J-shaped total mortality relation to alcohol, and a U-shaped curve for cardiovascular deaths. The nadir of the mortality curves were due mostly to lower CHD death rates in lighter drinkers; the increased risk of heavier drinkers was due to a variety of causes. By the time of this report, some data about HDL cholesterol and antiplatelet effects of alcohol had appeared; these possible mechanisms for the alcohol-CHD relationship were mentioned.

Alcohol Data In a 1978-1985 Cohort

A special alcohol research questionnaire was appended to the MHC examination from 1978 through 1985 at Oakland, and from 1978 through 1980 in San Francisco. Almost 129,000 persons satisfactorily completed this questionnaire. Lighter drinking was now subdivided into 3 groups and data were gathered about wine, liquor, and beer use. Nondrinkers received questions about past drinking, reasons for abstention or quitting, and maximum past amount for ex-drinkers. Alcohol questionnaire responses were reasonably comparable to data from a subset who also gave seven day recall information about alcohol in a study performed by Lorraine Midanik. We derived definitions of “preference” based upon usual number of days/week each beverage (wine, liquor, beer) was taken. A report of correlates of usual alcoholic beverage preference detailed major differences between the groups, indicating that the lifestyle habits of wine preferers were healthiest and those of liquor preferers least healthy.

The long range objective was study of relationships of drinking behavior to a variety of health measurements and outcomes. Prospective alcohol related reports included analyses of pancreatic, breast, prostate, and large-bowel cancer; total hospitalization days; changes in drinking; liver cirrhosis; cerebrovascular disease; supraventricular arrhythmias; total mortality; unnatural deaths; and, of course CHD. New cross-sectional analyses of the alcohol-hypertension relationship and the alcohol-smoking association were also published.

The first CHD study based upon the new data set found at higher drinking levels, independent of baseline CHD risk or symptoms. Choice of beverage had no major independent relationship in the entire group and at specific drinking levels.

The “Sick-Quitter” Hypothesis

In 1988 a major counter hypothesis was forcefully presented in a Lancet article—with editorial support and wide media publicity. It has been called the “sick-quitter hypothesis.” Briefly stated, it says that lighter drinking is not really protective against CHD, but that abstainers are at higher risk because of more baseline disease in this group. Previous studies, including our earlier ones, were cited as defective because they did not separate nondrinkers from ex-drinkers. This, of course, was not the case in our new data base. Gary pointed out that this controversy was a break for us, because it afforded a good opportunity for rebuttal by creating interest in new studies. Others obviously felt the same way, because a number of reports soon appeared which separated out ex-drinkers and controlled for baseline disease. These reports, in my opinion, have put the “sick-quitter” hypothesis firmly to rest. In 1990 we presented a prospective report of alcohol relation to 1002 cardiovascular deaths, with special emphasis upon ex-drinkers. Ex-drinkers and very infrequent drinkers were at risk similar to abstainers in adjusted analyses of all cardiovascular or CHD deaths. Ex-drinkers were at higher risk only for noncardiovascular causes, and quitting for medical reasons enhanced this risk. Reasons for quitting or baseline CHD risk had little relationship to CHD risk. These data were interpreted as suggesting that the lower risk of drinkers for CHD was not due to selective abstention by high risk persons.

The Role of Beverage Choice

Almost everyone is familiar with the concept of the “French Paradox,” which was widely popularized by 60 Minutes telecasts in 1991 and 1995. The “paradox” is the low CHD mortality in France despite a CHD risk profile similar to other Western countries. This hypothesis has been supported by several international comparison ecologic studies, going back to a 1979 report of an inverse relationship between national wine consumption and CHD mortality. More recently, it has been shown that France is an outlier on graphs of national saturated fat consumption and CHD mortality, unless corrected for wine intake.

Little is new under the sun. Actually, the first presentation pertinent to the “French Paradox” was in 1819 by Dr. Samuel Black, an Irish physician with a great interest in angina pectoris and of considerable perception with respect to epidemiologic aspects. His delightfully Francophile explanation of the disparity in CHD...
between Ireland and France, attributed the low French angina prevalence to "the French habits and modes of living, coinciding with the benignity of their climate and the peculiar character of their moral affections."

The recent studies, plus the discovery of antioxidant phenolic compounds in red wine, have led many to believe that alcohol is protective against CHD, but that red wine is more protective than other alcoholic beverages. Prospective population studies, on the other hand, show no consensus, and suggest that each beverage type is protective. This controversy led us to study this aspect. We first examined CHD mortality by studying risk for persons who took almost all of their alcohol in the form of one beverage type. These preference groups represented only a fraction of the CHD deaths, and there were major user differences between the groups. All beverage types were protective, but wine and beer preferrers were at lower risk than liquor preferrers—this difference was statistically significant only for wine preferrers. There was no difference in risk between persons who took red wine and those who took other types of wine.

We recently reported CHD hospitalization data with a much larger group of cases. As in all previous Kaiser Permanente studies, total alcohol intake was inversely related to CHD risk (Table 1). By assigning a proxy variable to use of wine, liquor or beer, we were able to utilize all beverage choice data. Again, each beverage type was protective, but beer use appeared most protective in men and wine (both red and white) in women (Tables 2 and 3). We concluded that the major benefit was from alcohol and that user differences and drinking patterns were most likely to be responsible for the beverage type disparities.

"Almost everyone is familiar with the concept of the 'French Paradox,' which was widely popularized by 60 Minutes telecasts in 1991 and 1995. The 'paradox' is the low CHD mortality in France despite a CHD risk profile similar to other Western countries."

---

Table 1. Adjusted RR CHD* by Total Alcohol

<table>
<thead>
<tr>
<th>Alcohol Use</th>
<th>Men RR (CI)</th>
<th>Women RR (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstainers#</td>
<td>1.0 (ref)</td>
<td>1.0 (ref)</td>
</tr>
<tr>
<td>Ex-drinkers</td>
<td>1.0 (0.8-1.2)</td>
<td>1.1 (0.8-1.5)</td>
</tr>
<tr>
<td>Infrequent**</td>
<td>0.9 (0.9-1.1)</td>
<td>1.0 (0.9-1.2)</td>
</tr>
<tr>
<td>usual drinks/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1</td>
<td>0.9 (0.8-1.1)</td>
<td>0.8 (0.7-1.0)*</td>
</tr>
<tr>
<td>1-2</td>
<td>0.8 (0.7-0.9)*</td>
<td>0.6 (0.5-0.8)*</td>
</tr>
<tr>
<td>&gt;3</td>
<td>0.7 (0.6-0.9)*</td>
<td>0.6 (0.4-0.9)*</td>
</tr>
</tbody>
</table>

* 3931 persons hosp for CHD (among ~129,000)
# lifelong (4125 men, 11,373 women)
** less than once/month
a=p<0.05; b=p<0.01; c=p<0.001

Table 2. Adjusted RR CHD by Total Wine, Liquor, Beer

<table>
<thead>
<tr>
<th>Group</th>
<th>Wine</th>
<th>Liquor</th>
<th>Beer</th>
</tr>
</thead>
<tbody>
<tr>
<td>total alcohol not controlled</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both sexes</td>
<td>0.8*</td>
<td>0.9*</td>
<td>0.7*</td>
</tr>
<tr>
<td>Men</td>
<td>0.9</td>
<td>0.9</td>
<td>0.7</td>
</tr>
<tr>
<td>Women</td>
<td>0.7*</td>
<td>0.9</td>
<td>0.7</td>
</tr>
<tr>
<td>total alcohol controlled</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both sexes</td>
<td>1.0</td>
<td>1.0</td>
<td>0.9</td>
</tr>
<tr>
<td>Men</td>
<td>1.0</td>
<td>1.0</td>
<td>0.8*</td>
</tr>
<tr>
<td>Women</td>
<td>0.9</td>
<td>1.3</td>
<td>1.0</td>
</tr>
</tbody>
</table>

*a proxy variable representing drinks/day of beverage type
a=p<0.05; b=p<0.01; c=p<0.001

Table 3. Adjusted RR CHD Among Persons* Taking 1-2 Drinks/Day

<table>
<thead>
<tr>
<th>Beverage Type</th>
<th>Group</th>
<th>Wine</th>
<th>Liquor</th>
<th>Beer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both sexes</td>
<td>1.0</td>
<td>1.0</td>
<td>0.7*</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>1.0</td>
<td>1.0</td>
<td>0.7*</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>0.7</td>
<td>1.0</td>
<td>0.5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of Wine</th>
<th>Red</th>
<th>White</th>
<th>R&amp;W</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both sexes</td>
<td>1.3</td>
<td>1.0</td>
<td>0.9</td>
<td>0.7</td>
</tr>
<tr>
<td>Men</td>
<td>1.3</td>
<td>1.1</td>
<td>0.9</td>
<td>1.0</td>
</tr>
<tr>
<td>Women</td>
<td>0.5</td>
<td>0.8</td>
<td>0.7</td>
<td>0.6</td>
</tr>
</tbody>
</table>

*a using proxy variable representing drinks/day of type
# n = 13,512 men reporting 1-2/day, 530 of whom were later hospitalized for CHD; and 9896 women reporting 1-2 drinks/day, 149 later hospitalized for CHD
a=p<0.05
that this view has become the prevailing current assessment of many workers in the field, but, as Yogi Berra’s much quoted wisdom goes, “it isn’t over until it’s over.”

Conclusion

We remain active in the alcohol-epidemiology field. The major current effort is a study of alcohol and stroke. Plans include further exploration of beverage choice and various health outcomes. I certainly hope that my association with Gary will continue for many years. It would be highly appropriate to have a drink to this wish, but I’ll have to be content with answering the query: “Is everything one enjoys illegal, immoral, or bad for the heart?” The answer is “not quite.”

References

The CARDIA Study and the Development of Clinical Research at the Division of Research
by Stephen Sidney, M.D., M.P.H.

One of Gary Friedman’s legacies to the Division of Research (DOR) was the development of a clinical research unit. Prior to 1984, the DOR (then known as Medical Methods Research) had been involved in few externally funded studies involving the clinical examination of research subjects, the most notable of which was a study of female twins, funded by NHLBI and headed by Gary. In December 1983, that changed with the funding of the Coronary Artery Risk Development in Young Adults (CARDIA) Study. Gary was the principal investigator and led the writing of a successful application for Kaiser Permanente (KP) to be one of the four field centers for this study. CARDIA was initially funded for a period of five years with a baseline and a two-year followup examination and with the primary aims: 1) to determine the distribution of coronary heart disease risk factors in a biracial cohort of men and women aged 18-30 years at entry; and 2) to identify habits and behaviors that are associated with both initial levels and later changes in these risk factors.

Our initial plan was to conduct the clinical examinations for this study in the multiphasic health checkup area of the Oakland KP Medical Center, but we soon realized that this facility would not be adequate. The problemsolving process led us to develop research clinic space in the old DOR building on Piedmont Avenue. In February 1985, clinic equipment and supplies began to arrive at the DOR in preparation for the baseline exam startup scheduled to take place in the late spring—a low-temperature freezer, centrifuge, pulmonary function and exercise treadmill testing equipment, needles, syringes, food models, etc. It was both an exciting and chaotic time for us.

At the baseline examination conducted for a year in 1985-86, 5115 participants were recruited into the 4 clinical centers (Birmingham, AL; Chicago, IL; Minneapolis, MN; and Oakland, CA) with 1426 recruited at Oakland, making it the largest center. The participants were 18-30 years of age, with relatively equal numbers of African Americans and whites, men and women, ages 18-24 and 25-30 years, and education <12 years and ≥12 years. The success of the study (high quality data and 91% cohort retention at the two-year follow-up) led to continued funding. Five examination cycles have been completed (baseline and 2-, 5-, 7-, and 10-year follow-up exams), and a 15-year follow-up examination is planned for the year 2000-01. Retention has remained very high for this relatively young and mobile cohort with nearly 80% of the cohort returning for the 10-year follow-up exam.

The longitudinal study of cardiovascular risk factors in the CARDIA Study group has yielded very interesting findings. A sampling of these findings is shown in Figs. 1 through 4. Fig. 1 shows the mean cumulative weight change over time, one of the more dramatic findings from the CARDIA Study. The mean 10-year weight change ranges from a 15.7-pound increase in white women to a 25.4-pound increase in African American women. Fig. 2 suggests one of the reasons for this marked weight gain. Physical activity score, reflecting the frequency and intensity of participation in 13 different kinds of activity during the past year, decreased substantially and fairly consistently over 10 years with a mean decrease of about 20% in men and 25% in women. Fig. 3 demonstrates relatively small 10-year changes in systolic blood pressure (SBP). All race/gender groups show a decrease in SBP between the baseline exam and the two-year follow-up, a...
The observation that LDL cholesterol is actually decreasing in women (and not increasing dramatically in men) in spite of large weight increases might seem surprising to some. One of the strengths of the CARDIA Study is that the longitudinal measurement of many factors that influence cardiovascular risk, and the aging of the younger part of the study cohort has allowed us to understand to a great degree how this perplexing situation has occurred. CARDIA is the first study to document directly the impact that secular trends are having on individual changes in LDL cholesterol level with age. Two concepts of group change need to be understood:

1) Cohort (or aging) change, which is change occurring in a measurement over time associated with aging of the study cohort; and

2) Secular change, which is the component of change occurring in a measurement over time that is not associated with aging, but is associated with overall societal trends.

In the CARDIA Study, Bild et al. examined seven-year secular trends by comparing older participants at the baseline CARDIA examination (ages 25-30 year, N=2788) with younger CARDIA participants who aged into the 25-30 year group at the seven-year follow-up exam (ie, those who were 18-23 years old at the baseline exam in 1985-86 became 25-30 years old at the seven-year follow-up exam in 1992-93, N=1395). Comparison of these two groups (those who were 25-30 years-old at baseline and those who were 25-30 years old at the seven-year follow-up) provides information on the secular influences that have caused changes in the characteristics of 25-30-year-olds at these two points in time. Table 1 shows the secular percentage changes in LDL cholesterol, body weight, and Keys score. The Keys score predicts cholesterol change based on changes in dietary fat and cholesterol and was measured from dietary data collected at both points in time. We see that a secular decrease in LDL cholesterol occurred during this time period, ranging from 5.2% to 8.9%, in the setting of a secular increase in body weight (ranging from 5.3% to 6.9%) and a secular decrease in Keys score (ranging from 9.5% to 15.2%). We conclude that the secular decrease in LDL cholesterol offsets the expected increase in LDL cholesterol with age and increasing weight and that this decrease was probably due to secular dietary changes that lowered lipids.

As the CARDIA Study prepares for a 15-year follow-up exam, the participants are still too young to experience many incident events of atherosclerotic cardiovascular disease. However, it has only recently become clear that the presence of subclinical cardiovas-
cular disease can be quantified noninvasively in a sub-
stantial proportion of the population in the age spec-
trum represented by the CARDIA Study population. For
example, coronary artery calcium can be quanti-
ified quickly and noninvasively by electron beam com-
piled tomography (EBCT) and has been found to corre-
spond to the quantity of coronary plaques and the
probability of significant disease as assessed by
angiography. The Oakland and Chicago centers par-
ticipated in a CARDIA EBCT substudy that was con-
ducted during 10-year follow-up exams. In the 443
CARDIA Study participants, coronary artery calcium
was detected in 40% of African American men, 46% of
white men, 37% of African American women, and 17%
of white women. The high prevalence of subclinical
CVD in this population of young adults is not surpris-
ing, reflecting the fact that atherosclerosis is a lifelong
process that is highly prevalent in this country. Plans
for the 15-year follow-up exam include the assess-
ment of atherosclerosis in the carotid artery of all study
participants using ultrasound imaging.

Gary remained the principal investigator of the CAR-
DIA Study until he was awarded an Outstanding Inves-
tigator Grant from the National Cancer Institute in 1991.
During his tenure as the Principal Investigator, he wrote
two papers based on the CARDIA data. The first was a
descriptive paper about the design of the CARDIA Study
with a report of the recruitment experience for the
baseline examination and some of the sociodemographic
and risk factor characteristics of the study cohort. The
second paper has a story to go along with it because
it represents part of a longer story about the
pioneering aspect of Gary’s work, of his being the "dis-
coverer" of epidemiologic findings that other research-
ers later replicated and verified. In this case, it is the
story of the leukocyte count (white blood cell count)
Journal of Medicine published a paper by Gary, Art
Klatsky, and Abe Siegelaub showing that leukocyte
count predicted the development of first acute myocar-
dial infarction.4 In an accompanying editorial, Dr. Henry
count predicted the development of first acute myocar-
dial and coronary artery disease. In 1974,
story of the leukocyte count (white blood cell count)
was later replicated and verified. In this case, it is the
the seed sown by Gary in the start up of the CARDIA
study has grown into the implementation of many clinical
research studies at the DOR, and the development of
a large clinical research facility. These studies account
for about 20 to 30 percent of the annual DOR
research budget. The growth of clinical research activity
has been particularly rapid during Gary’s tenure as
director, and is one the many legacies of his research
career at the DOR.

The high prevalence of subclinical CVD in this
population of young adults is not surprising,
reflecting the fact that atherosclerosis is a lifelong
process that is highly prevalent in this country.

The Kaiser group has gone fishing and caught an
interesting specimen, the leukocyte count.5

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A recent line of investigation suggests that
inflammation and evidence of past infection with one of several agents (Chlamydia
pneumoniae, cytomegalovirus, and herpes
simplex virus type-1 HSV-1) are
associated with increased risk of
atherosclerosis.7,10

“The Kaiser group has gone fishing
and caught an interesting
specimen, the leukocyte
count.”

“A recent line of investigation
suggests that inflammation and
evidence of past infection with
one of several agents (Chlamydia
pneumoniae, cytomegalovirus, and
herpes simplex virus type-1 HSV-1)
are associated with increased risk of
atherosclerosis.”

“Perhaps this might be the link between the leukocyte
count and cardiovascular disease risk, ie, that the leu-
cocyte count is, to some degree, a marker of inflamma-
tion, reflecting the fact that atherosclerosis is a lifelong
process that is highly prevalent in this country.”
“Sensitive” and “Specific” Epidemiologic Studies: The Division of Research of the Kaiser Permanente Medical Care Program

by Noel S. Weiss, MD, DrPH

As critics of epidemiologic research are all too eager to point out, this type of research can lack both “specificity”—it can erroneously observe an association—and “sensitivity”—it can fail to identify an association that truly is present. There are a number of strategies available to epidemiologists to increase the specificity and sensitivity of their investigations, the use of which generally makes the results they obtain more valuable. Nearly all of these have been employed commonly by Gary Friedman and his colleagues at the Division of Research (DOR), which is one of the reasons their work is valued so highly.

Minimization of Measurement Error

Inaccuracy in the assessment of either exposure or outcome status will lead to a biased result. The DOR has thought to minimize error by means of its careful data collection methods. In addition, when error is unavoidable it is recognized by the investigators, and the data are interpreted accordingly. For example, in his case-control study of risk factors for multiple myeloma, Gary Friedman examined medication use that occurred no more recently than a reference date set six months prior to the date of diagnosis among cases (and a corresponding point in time in controls). This was done in an effort to reduce the chance that an early manifestation of not-yet-diagnosed multiple myeloma led to taking a particular drug, and thus created a spurious association. In this study, an association was found with use of the analgesic, propoxyphene; 41.3% patients had taken this drug before the reference date vs. 33.6% of controls (odds ratio = 1.44). However, nearly the whole of the association was due to propoxyphene use in the two years prior to the reference date (odds ratio = 2.1); the odds ratio associated with propoxyphene use before that time was only 1.17. Gary Friedman duly warned his readers that such a pattern of odds ratios is unlikely to reflect a causal role of propoxyphene use on the risk of multiple myeloma. Rather, this pattern was more consistent with “reverse” causality, that is, disease giving rise to drug use. He realized that for this drug, the reference date simply had not been set far enough back in time prior to diagnosis.

Exposure Subclassification

Generally, not all users of a drug or other therapy that alters the incidence of a given outcome are at equal risk of that outcome. The risk may vary by dose, duration, or recency of the therapy, for example, and the DOR studies of the effects of therapy consistently have been characterized by their search for such heterogeneity. An important extension of this work occurred in the DOR evaluation of the efficacy of various screening modalities against mortality from colorectal cancer. Their case-control studies of sigmoidoscopy, fecal occult blood testing, and digital rectal exam took account of the fact that the duration of the screening benefit cannot exceed that period of time that a tumor is clinically occult and yet detectable by a given test. By examining differences between cases and controls in the receipt of screening in different periods of time extending backwards from the time of diagnosis, they could explore the possibility of a transient benefit associated with screening.

Disease Subclassification

Every disease has multiple causes, and often at least some of these causes can act separately from one another. Sometimes, a particular cause operates in a way that results in specific manifestations that differ to some extent from those produced by other causal factors for the same disease. For example, occupational exposure to chloromethyl ether appears to predispose only to one histologic type of lung cancer, small cell cancer, and not others. In their study of gastric cancer in relation to prior infection with Helicobacter pylori, DOR investigators acknowledged this possibility by subdividing cases according to anatomic location within the stomach. No association with H.pylori infection was observed for tumors of the gastroesophageal junction, in contrast to a 3.6-fold increased risk of other gastric cancers. Had they not disaggregated the case group, an overall relative risk would have been obtained that would not have reflected the size of the association with either cancer subsite.

Conclusion

Many of the questions that epidemiologic studies address require a great deal of careful handling in order to maximize the chances of finding an association when one is there and of not finding one when there truly is none present. Gary Friedman and his colleagues at the Division of Research have set an excellent example for the rest of us to follow in designing such sensitive and specific studies. Because
these studies have had such a large impact, the scientific community and other consumers of DOR research are hoping that both Gary and the DOR, together and separately, will continue to set this kind of example for a good while longer. ❖

References

Screening for Colorectal Cancer: Research Contributions of The Permanente Medical Group
by Joe Selby, M.D., M.P.H.

Screening for colorectal cancer has been a topic of exceptional interest to clinician researchers in The Permanente Medical Group since the early 1950s. Rigid sigmoidoscopy was employed in at least two medical centers at that time and became a part (albeit an optional part) of the multiphasic health checkup from its earliest days. The work of a number of investigators has added to and, in several cases, led development of public policy on screening for this common malignancy. Gary Friedman had a hand in many of these studies, as we shall see.

The Multiphasic Evaluation Study
This important study was an ambitious investigation,2,3 using randomized trial methods, to determine if periodic multiphasic testing could reduce mortality in healthy, middle-aged health plan members. Beginning in 1964, nearly 11,000 members aged 35-54 years were randomized to either a group study (N=5156) that was contacted annually by phone and urged to schedule a multiphasic health checkup annually, or to a control group (N=5557) who received no telephone calls but were free to schedule multiphasic checkups as they wished. Annual contact of intervention group subjects continued for ten years. The study was not intended or designed to test the efficacy of sigmoidoscopy. Rather, total mortality was the chief endpoint. The architects of the study, including Drs. Morris Collen and Gary Friedman, also designated a subgroup of causes of death as “potentially postponable deaths” and hypothesized that the reduction in mortality would be principally among these causes. Because sigmoidoscopy was an optional part of the multiphasic health checkup, death from colorectal cancer was included, along with deaths from cancers of the breast, uterus, cervix, prostate and kidney, from hypertension, hypertensive heart disease, and hemorrhagic cerebrovascular disease as potentially postponable deaths.

After 16 years of follow-up, mortality from potentially preventable causes was 30 percent lower in the study group, and approximately half of this reduction was due to fewer deaths from colorectal cancer (Table 1).4 Because colorectal cancer was not the focal point of the Multiphasic Evaluation Study, Friedman et al dedicated a relatively modest amount of space in their report to discussing details of the finding. They suggested that a specific trial of this question was needed to determine whether sigmoidoscopy indeed reduced mortality.

Despite these cautions, the Multiphasic Evaluation Study was embraced in the early 1980s by advocates of “evidence-based guidelines” as randomized trial evidence that sigmoidoscopy can lower mortality from colorectal cancer.5 The American Cancer Society, among others, used the study to endorse periodic (every three years) sigmoidoscopy.6 Concerned that the full story may not have been told, Dr. Friedman and I began a further set of analyses of the Multiphasic Evaluation Study in 1985.6 We reasoned that the full story may not have been told, Dr. Friedman and I began a further set of analyses of the Multiphasic Evaluation Study in 1985.6 We reasoned...
that if sigmoidoscopy were responsible for the lowered mortality from colorectal cancer, the mortality reduction should principally be for cancers of the rectum or distal colon (i.e., cancers within reach of the sigmoidoscope). We further suggested that sigmoidoscopy could lower mortality by either or both of two mechanisms. It could lower incidence of cancer (by detection and removal of adenomatous polyps), or it could improve the stage distribution of cancers. Finally, because the sigmoidoscopic examination was an optional part of the multiphasic, dependent upon scheduling by the patient and occurring at a separate later examination, we wanted to assure ourselves that there really was an excess of screening sigmoidoscopy in the study group.

After reviewing records of all incident cases of colorectal cancer and detailed chart abstraction forms from the entire cohort, we observed the following: 1) the mortality reduction in the study group was somewhat greater for cancers within reach of the sigmoidoscope than for cancers above reach of the sigmoidoscope (Table 2). Two-thirds of the reduction in mortality from distal colorectal cancers was due to lowered incidence; the remaining third appeared to be due to earlier detection with an improved stage distribution and lower case fatality rate. However, there was no difference between groups in removal of adenomas during the follow-up period. Thus, the incidence reduction cannot comfortably be attributed to sigmoidoscopy.

In further analyses, only a small fraction of the cancers were detected by screening in either group and the study group’s stage shift improvement was as great for cancers detected after onset of symptoms as for screen-detected cancers. Thus, it does not appear that screening sigmoidoscopy accounted for much of the stage shift either.

When we tallied the total number of sigmoidoscopies in each group, the study group had only a slight excess of sigmoidoscopies and this was contributed by a very small group of individuals (N=212 excess persons) who heeded the telephone urgings meticulously and had, on average, 3.3 sigmoidoscopic examinations in the ten-year period. This small excess of screening would be expected to prevent less than one fatal cancer.

In summarizing, we could say only that the Multiphasic Evaluation Study had not been designed or sized to test the efficacy of sigmoidoscopy and its results should not be used as evidence either for or against sigmoidoscopic screening.

The U.S. Preventive Services Task Force

Dr. Friedman joined the U.S. Preventive Services Task Force in 1985. Shortly thereafter, he was asked to prepare a paper evaluating the evidence supporting inclusion of sigmoidoscopy in the periodic examination of healthy adults. I joined him in this effort, reviewing the several descriptive studies that had reported the favorable stage distributions of cancers detected by screening sigmoidoscopy and jumped inappropriately to conclude that this earlier stage distribution was proof that screening sigmoidoscopy could save lives. We also re-

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Table 1. 16-Year Mortality in the Kaiser Permanente Multiphasic Evaluation Study

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Death Rates (per 1,000 for 16 years)</th>
<th>Chi-Square</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Study (N=5156)</td>
<td>Control (N=5957)</td>
</tr>
<tr>
<td>Potentially postponable causes</td>
<td>15.0</td>
<td>21.5</td>
</tr>
<tr>
<td>Cancer of colon &amp; rectum</td>
<td>2.3</td>
<td>5.2</td>
</tr>
<tr>
<td>Cancer of breast (women only)</td>
<td>4.1</td>
<td>4.3</td>
</tr>
<tr>
<td>Cancer of cervix and endometrium</td>
<td>1.0</td>
<td>0.9</td>
</tr>
<tr>
<td>Cancer of prostate (men only)</td>
<td>0.2</td>
<td>0.9</td>
</tr>
<tr>
<td>Cancer of kidney</td>
<td>0.2</td>
<td>0.7</td>
</tr>
<tr>
<td>Hypertension, hypertensive cardiovascular disease and hemorrhagic cerebrovascular disease with hypertension</td>
<td>4.7</td>
<td>7.2</td>
</tr>
<tr>
<td>Hemorrhagic cerebrovascular disease without hypertension</td>
<td>2.5</td>
<td>2.2</td>
</tr>
<tr>
<td>Other causes</td>
<td>98.9</td>
<td>94.7</td>
</tr>
<tr>
<td>All causes</td>
<td>113.9</td>
<td>116.1</td>
</tr>
</tbody>
</table>

*p<0.05

Table 2. Further analyses of colorectal cancer incidence and stage distribution, by anatomic location, from the Kaiser Permanente Multiphasic Evaluation Study

<table>
<thead>
<tr>
<th>Mortality (deaths per 1,000) with 18 yrs follow-up</th>
<th>Study</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancers within reach of sigmoidoscope</td>
<td>1.4</td>
<td>2.7*</td>
</tr>
<tr>
<td>Cancers above reach of sigmoidoscope</td>
<td>4.1</td>
<td>4.9</td>
</tr>
</tbody>
</table>

Cumulative incidence (cases per 1,000) with 18 yrs follow-up

| Cancers within reach of sigmoidoscope | 4.3   | 6.7* |
| Cancers above reach of sigmoidoscope   | 4.1   | 4.9  |

Case fatality rate (%)

| Cancers within reach of sigmoidoscope | 32    | 41    |
| Cancers above reach of sigmoidoscope  | 43    | 48    |

*p <0.10
viewed the Multiphasic Evaluation Study and concluded that there was not sufficient evidence to support inclusion of sigmoidoscopy in the periodic health examination. We suggested further that, since a randomized trial of sigmoidoscopy was unlikely in the near future, controlled observational studies had the greatest potential for providing some evidence on its efficacy.

A Case-control Study of Screening Sigmoidoscopy

In 1982, Morrison discussed the potential of case-control studies for evaluating the efficacy of screening tests.10 Noel Weiss carried the discussion and the theory further.11 Gary was familiar with these papers and recognized that Kaiser was ideally suited to conduct a case-control study of the efficacy of sigmoidoscopy. Our cancer registry identified large numbers of colorectal cancers, along with their anatomic location and subsequent vital status. Medical records allowed us to ascertain exposure to screening sigmoidoscopy along with a variety of covariates. Moreover, substantial screening with sigmoidoscopy had occurred over the past 20 years, so that exposure was sufficiently frequent that a benefit would be detectable with a reasonable sample of cases and controls if it existed.

Funded by the National Cancer Institute, the study was undertaken in 1989. The case definition was fatal colorectal cancer arising within reach of the rigid sigmoidoscope. Controls were drawn from the health plan membership, were matched on age and sex to cases, and had to outlive the case and not die of colorectal cancer. A total of 261 eligible cases were identified. These were matched to 868 controls. A large deficit of colorectal cancers, along with their anatomic location, was observed among cases during the ten years preceding diagnosis of the fatal cancer.12

The findings from this study were published in The New England Journal of Medicine in 199213 and reviewed by the U.S. Preventive Services Task Force in 1994. On the basis of this study, the Task Force recommendation for sigmoidoscopy was upgraded from “insufficient evidence” (Grade C) to “fair evidence” (Grade B), meaning that the Task Force now supported screening with sigmoidoscopy. On the strength of this change, coverage for sigmoidoscopy has now been added by HCFA for Medicare recipients and by many private insurers.

Table 3. Odds ratios (OR) for having at least one screening sigmoidoscopy in the ten years before case’s diagnosis

<table>
<thead>
<tr>
<th></th>
<th>Cases (N=261)</th>
<th>Controls (N=868)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR* (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All cases within reach of rigid sigmoidoscope:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 (9%)</td>
<td>104 (24%)</td>
<td>0.30 (0.15-0.46)</td>
<td>0.41 (0.25-0.69)</td>
<td></td>
</tr>
<tr>
<td>All cases above reach of rigid sigmoidoscope:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>54 (22%)</td>
<td>67 (27%)</td>
<td>0.80 (0.54-1.19)</td>
<td>0.96 (0.51-1.50)</td>
<td></td>
</tr>
</tbody>
</table>

*Adjusted for personal history of colorectal cancer or polyps, family history of colorectal cancer, number of periodic health checkups, and number of other colorectal cancer screening tests during the ten-year interval.

To determine whether this association might have been due to additional unmeasured self-selection factors, we studied an additional group of 268 patients who died of colorectal cancers arising above reach of the sigmoidoscope and a similar number of matched controls. For these cancers, sigmoidoscopy should offer no benefit. Any observed benefit would most likely be due to confounding by self-selection factors that made persons undergoing screening sigmoidoscopy less likely to develop or die from colorectal cancer. However, after adjusting for the same set of measured confounders, there was no residual benefit in this group (Table 3). The striking difference in benefit between cancers within reach and those above the reach of the sigmoidoscope strengthened the inference that sigmoidoscopy was truly beneficial.

Another important finding of the study was the observation that a person’s risk for developing fatal colorectal cancer remained extremely low for at least ten years following a negative sigmoidoscopy. This observation fits with what is known of the biology of colorectal cancer (ie, that cancer develops slowly from adenomatous polyps over a period of many years). However, it clashed with recommendations of the time that sigmoidoscopy should be performed every three years. A longer interval between screenings would make a sigmoidoscopy screening less costly as well as more acceptable to patients.

The CoCaP Program

The Permanente Medical Group took great pride in the recognition received by the case-control study. Having produced the evidence on efficacy, however, the Group was faced with a decision as to how it should respond to the study’s findings. Although a few medical centers had sigmoidoscopy screening programs in place, most did not and there were no sites at which active outreach sought to bring members in for screening. Upon the thoughtful urging of Dr. Albert Palitz, Chair of the Chiefs of Gastroenterol-
"A recent survey of Kaiser Permanente members found that more than 50 percent of age-eligible members now report having had a sigmoidoscopy within the past 5-10 years. This figure is much higher than levels reported nationally."

"A remarkable proportion of the best research on colorectal cancer screening over the past 20 years has come from Permanente Medical Group physicians."

Clinical contributions

"A recent survey of Kaiser Permanente members found that more than 50 percent of age-eligible members now report having had a sigmoidoscopy within the past 5-10 years. This figure is much higher than levels reported nationally."

"A remarkable proportion of the best research on colorectal cancer screening over the past 20 years has come from Permanente Medical Group physicians."

The CoCaP program (Colon Cancer Prevention), begun in January 1994, was the first sigmoidoscopy screening program in the country designed to serve an entire population. During its first four years, CoCaP screened approximately 60,000 members annually. A recent survey of Kaiser Permanente members found that more than 50 percent of age-eligible members now report having had a sigmoidoscopy within the past 5-10 years. This figure is much higher than levels reported nationally.

Data from the CoCaP screening examinations, along with pathology reports and follow-up colonoscopies, have been collected at DOR and entered into a large database for continued study of questions related to screening with sigmoidoscopy. Using this database, we have recently shown convincingly that neither the presence nor the size of tubular adenomas found at screening sigmoidoscopy predicts a greater likelihood of finding important adenomas in the proximal colon at follow-up colonoscopy. Rather, it is the presence of villous features in adenomas of any size that increases this risk.

We are also monitoring cancer incidence rates in the entire Kaiser Permanente membership. Given the degree of effectiveness shown in the case-control study, the CoCaP screening effort should eventually show up as a decline in the incidence of advanced colorectal cancers from the distal half of the colon and rectum. Just how long it will take to demonstrate this effect is uncertain. With complete cancer incidence data through 1996 (after three years of CoCaP), we do not yet see a significant decline in age-, sex-adjusted incidence of advanced stage cancers.

Studies of Alternative Screening Strategies (Fecal Occult Blood Testing)

Interest in colorectal cancer screening has not been confined to studies of sigmoidoscopy. Sigmoidoscopy, although effective, covers primarily the distal half of the colon and rectum, leaving approximately 40-50% of cancers undetected. Dr. James Allison, of the Division of Gastroenterology, Kaiser Foundation Hospital in Oakland, has conducted a series of important studies of an alternative screening strategy using tests for occult blood in the stool. These studies have done much to describe the performance characteristics of fecal occult blood tests in real world settings and to propose improvements based on these characteristics.

Dr. Seymour Grossman, also of Oakland's gastroenterology division, conducted one of the first studies to compare sigmoidoscopy findings with subsequent colonoscopy findings. Consistent with CoCaP data, he found that tubular adenomas, at least those of <1 cm in diameter, were not associated with increased risk for advanced proximal neoplasms at colonoscopy.

Summary

A remarkable proportion of the best research on colorectal cancer screening over the past 20 years has come from Permanente Medical Group physicians. This research has and continues to contribute to national policy in this area. It has also served to make Kaiser Permanente a leader in providing colorectal cancer screening. TPMG owes much to Dr. Gary Friedman, whose careful work produced many of the earlier contributions in this area and whose mentoring was responsible for much of what came later.

References

Reflections
by Gary D. Friedman, MD, MS

Summary
I am grateful to all who made possible this symposium, my rewarding career at KP, and the success of the Division of Research (DOR). In my 36-year career in epidemiology, I have seen many important developments in methodology, some of which I was slow to adopt.

One of the main reasons that KP in Northern California is one of the best settings in the world to conduct epidemiologic and health services research is our access to comprehensive, often long-term, medical records on millions of people. Although our newer computerized records are very valuable, our collection of manual charts going back over 50 years is a national treasure and must be preserved despite the storage and retrieval costs entailed. We must also guard against external threats to our access to our records for legitimate research resulting from overzealous protection of privacy. Other precious resources for research, such as the Kaiser-Orentreich frozen serum collection and tissue specimens in our pathology departments, also require care and preservation. While recognizing the value of all of our records we must be cautious about errors in data retrieved from either computer storage or medical charts.

Investigator-initiated, outside-funded research published in peer-reviewed journals must always be a primary activity of DOR. The keys to our success, both past and future, lie in our resources, objectivity, quality work completed and published, and helpfulness to others in KP.

Thanks and Acknowledgments
I feel truly honored by this symposium and thank Dr. Joe Selby, assisted by many in DOR (Diana Holt, Joey Macapinlac, Susan Mignano, Donna O’Connor, Scott Ryan, Alison Truman, Lyn Wender) and the invited speakers, all of whom made it possible. I also gratefully acknowledge all who made my career at the KP DOR so rewarding: my predecessors, Dr. Morris Collen, who persuaded me to join the department almost 30 years ago, who did so much to establish our precious data resources, and who set an example of hard work and productivity that is rarely equaled; and Dr. Ted Van Brunt, who maintained an atmosphere and fostered a culture that assured our continued success. I also appreciate the leaders of our organization who have recognized DOR’s value to KP and supported us, though we have been a little “offbeat.” I would mention especially, in The Permanente Medical Group, Drs. Cecil Cutting, Bruce Sams, Harry Caulfield, Jay Crosson and Philip Madvig; and on the Health Plan side, Jim Vohs, Clifford Keene, David Lawrence, Jim Lane, and the KFRI administrators, including Dick Nigro, Gil Lee, Glenda Marrow and Nancy King.

My Assistant Directors, Drs. Robert Hiatt and Joe Selby, have contributed much to the leadership of DOR, in part by covering for my inadequacies and making me look better than I was. I have been greatly stimulated by collaborating investigators in DOR and KP, of whom three of today’s speakers, Arthur Klatsky, Joe Selby and Stephen Sidney are prime examples. Young investigators have also been stimulating: mentoring them and watching them grow to be independent has been one of the most satisfying aspects of my career. I have received much help from DOR biostatisticians, originally Abe Siegelaub and Hans Ury and more recently the five excellent colleagues that we now have. (It is not well known that biostatisticians are ordained clerics, empowered to pronounce one’s analyses and statistical tests as kosher.) I have received indispensable computer programming by Donna Wells and Harald Kipp for many years. Similarly, I have relied on our excellent medical record analysts—led by P.H. Kidd, Carolyn Quan, and Donna O’Connor. Though Donna’s staff has grown along with the department, it is still lean, hardworking, and productive. Fortunately, there has been relatively little bureaucracy in DOR.

I am grateful to our outside collaborators who have brought good ideas and expertise to DOR: two of the speakers today, Julie Parsonnet and Noel Weiss are excellent examples, as is Leonard Syme here at the University of California. Finally, DOR and I owe a great deal to the overall KP organization. Although research is one of its important goals, it is not its main mission. KP has a wealth of talent that can participate in our research efforts and generally employees throughout KP have been willing to go the extra mile to help us.

Changes in Epidemiologic Methods and My Use of Them During My Career

My experience as a Commissioned Officer in the U.S. Public Health Service, first at the Heart Disease Epidemiology Study, Framingham, Massachusetts 1962-1966, ...
I have long viewed KP in Northern California as one of the best workshops in the world to do epidemiologic and health services research. KP is known for its computer-stored records, but much of DOR's research is based on abstracting manual records.

The Importance of Preserving Our Medical Records, A National Treasure

I have long viewed KP in Northern California as one of the best workshops in the world to do epidemiologic and health services research. An important reason is our collection of comprehensive medical records covering both inpatient and outpatient care of millions of people, often spanning long periods. KP is known for its computer-stored records, but much of DOR's research is based on abstracting manual records. Our staff now includes about 40 medical record analysts and the number has been increasing in recent years.

This collection began over 50 years ago and, obviously, many old records are no longer needed for the care of patients. The costs of storage of these records and retrieval for research are considerable and periodically questioned. Every few years I have been called upon to defend these old records from destruction and have zealously done so because I view them as a national treasure. The question has been raised again because of the merger of KP in Northern and Southern California into one division. The storage issue is especially urgent in Northern California because our long-term storage facility in Livermore will run out of space by the end of this year. KP in Southern California has more space available partly due, unfortunately, to their policy of destroying records of subscribers after they have left the Health Plan for seven years (except records of children and cancer patients).

Why I regard these records as a national treasure is well illustrated by one of the most influential studies ever done in DOR, the well-controlled study by Joe Selby and colleagues that showed that screening sigmoidoscopy prevents death from colorectal cancer. Because the ascertainment of cancer cases dated from 1971 and the review of the sigmoidoscopy experience of cases and controls went back ten years before the cases' diagnoses, we needed to include records of care in the early 1960s.

Primer of Epidemiology had a new chapter explaining multivariate analysis methods.

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There is no guarantee that our old records will prove so valuable in the future, but I think that the likeli-
hood is great. I know of no comparable medical record collection in a defined population in which long-term medical follow-up, or follow-back, is so feasible. The Mayo Clinic has a wonderful system, which goes back further—to the early 1900s, but the population of Rochester, Minnesota in which the Mayo group can do population-based studies is much smaller than ours and lacks the tremendous ethnic and socioeconomic diversity of our subscribers.

I have been meeting with persons in charge of medical record storage in KP's California Division, and they understand how important our records are, especially in view of KP's increasing promotion of research as a way to demonstrate its leadership in providing health care. We have been exploring ways to lower the cost of storing the little-used, older records and to support their preservation and retrieval through research-funding mechanisms.

External Threats to Research Using our Medical Records

There are external as well as internal threats to our access to medical records. With the growth of computer data banks of all sorts, the public is understandably concerned with the possibility of invasions of privacy—in the medical area, for example, with clerks at insurance companies seeing their medical records. This has led to proposals for sweeping privacy legislation that along with preventing abuses, would prevent researchers from looking at medical records without specific permission, not obtainable after a patient has died. As illustrated by the sigmoidoscopy study mentioned above, studying records of the deceased is essential if we are to find ways to prevent premature death.

Fortunately, recent proposals for legislation in California and at the federal level have been more reasonable, protecting confidentiality but allowing legitimate medical and public health research to go forward under the watchful eyes of Institutional Review Boards.

Other Priceless Resources

Besides medical records, the resources of our superb epidemiologic workshop include the 250,000-specimen frozen serum bank, now at the Orentreich Foundation for the Advancement of Science in New York, and the tissue specimens collected by our pathologists. We must guard against the loss, destruction, and inappropriate use of these biological specimens and be very careful to assure the complete and timely return of tissue to our pathology departments so that our pathologists will continue to assist us. The value of the serum bank has been well shown in several investigations, perhaps best exemplified by the studies in which Dr. Julie Parsonnet discovered that Helicobacter pylori infection predisposes to cancer of the stomach, both adenocarcinoma and lymphoma.

Some Cautions About our Valuable Computer-stored Records

Our computer-stored records are also a tremendous resource, mainly because information in them is so much more accessible than that in manual records. We have comprehensive hospital diagnoses stored since 1971 and outpatient diagnoses and pharmacy records since 1994, as well as records from pathology, laboratory tests, and imaging procedures. It should be noted that the computer recording of outpatient diagnoses and of prescriptions dispensed from the pharmacy was well developed and operating in KP's San Francisco facility in the late 1960s under the leadership of Drs. Collen and Van Brunt. The recently implemented Outpatient Summary Clinical Record (OSCR) and Pharmacy Information Management System (PIMS) have improved on the early clinic diagnosis and pharmacy systems, but, in many ways, were "reinventing the wheel."

I urge my colleagues to make good use of our computer-stored records. At the same time, recognize their limitations and maintain a healthy skepticism about what you find in them. Usually, a more full story can be found in the chart. In a postmarketing study of the antibiotic, clindamycin, we found two cases of diarrhea during three months of follow-up in the computer records. In the manual charts, we found ten. There were probably several reasons for the discrepancy, one of the most important being that the drug was prescribed frequently by otolaryngologists and there was no provision on their clinic diagnosis form for them to easily record the occurrence of diarrhea in their patients. In a study of the possible carcinogenic effects of lindane, applied topically for scabies or pediculosis, four of the skin cancer diagnoses turned out to be Kaposi's sarcoma in AIDS patients, which was not apparent in the computer records. Lifestyle factors could readily connect these infestations with AIDS. Another apparent lindane user who developed breast cancer had used her KP identification card to obtain the prescription for her husband. These errors were sufficient to reduce the apparent excess risk of cancer among lindane users to statistical insignificance.

So be careful. If you cannot review all the manual records of study subjects, at least review the critical ones or a random sample of all of the records for validation.

Chart Review is Subject to Error, Too.

I find it very difficult to review charts and am glad that we have so many capable medical record ana-
lysts in DOR. No matter how good analysts are, some errors in abstraction are inevitable. So a study involving chart review needs some rereading of charts to measure the error rate and to find out what errors are apt to occur, for training and quality improvement. Two excellent, experienced medical record analysts abstracted the data for our case-control study of bladder cancer screening by urinalysis.13 Initially and under supervision, both of them abstracted the same records for training. Then, one and six months after starting their independent work, both abstracted the same five charts to measure accuracy. In the one-month test there were 32 errors in 924 data items, or a 3.5% error rate. At six months, there were 40 errors in 1008 data items, yielding a 4.0% error rate. This is the magnitude of error one should expect from competent chart abstractors.

Be Especially Careful of Rare Findings or Events, Whatever the Data Source

I became acutely aware of the inaccuracy of rare occurrences in data when we became heavily involved in research on twins. Simple calculations showed that when twins were discordant for a characteristic, eg, one smoked cigarettes and the other did not as reported on a questionnaire, these apparently discordant pairs probably contained a substantial fraction of truly concordant pairs because of errors in the data. Twins are infrequently discordant for many characteristics, and the dilution by truly concordant twins becomes worse as discordance becomes less frequent. In describing this problem, I proposed that this partially explained why smoking-discordant twins seemed to differ less in disease occurrence than would be expected, given the known effects of smoking on health.14

My experience in searching for patients with rare diseases or findings in various data bases has confirmed this concern about accuracy. When you find only a few such patients, check their records carefully.

"Wouldn’t it be nice if DOR were totally supported internally and we were all on ‘hard’ instead of ‘soft’ money? Realistically, for this to occur we would have to devote all of our energies to responding to the needs of our management and to answering their pressing questions."

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Investigator-initiated Research in our Setting

Wouldn’t it be nice if DOR were totally supported internally and we were all on ‘hard” instead of “soft” money? Realistically, for this to occur we would have to devote all of our energies to responding to the needs of our management and to answering their pressing questions. If we did this well, our livelihoods would be secure and we would not have to worry about competing for grants or establishing good publication records to demonstrate productivity to peer reviewers. This might also be tempting to our parent organization; we would direct all of our energies to serve KP’s immediate needs as perceived by management in return for hard-money support.

Such a change would be most unfortunate,15 as is well illustrated by Joe Selby’s study of sigmoidoscopy.16 Previously, Joe had helped us on the U.S. Preventive Services Task Force (USPTF) to review the literature on whether screening by sigmoidoscopy prevents death from colorectal cancer. He and I concluded17 that there were no good, well-controlled studies that demonstrated the efficacy of this procedure, even though it was being recommended by prestigious authoritative bodies such as the American Cancer Society. The Task Force agreed, and its recommendation concerning the clinical application of screening sigmoidoscopy was neutral.18 Clearly, this procedure could detect cancer early and lead to the removal of premalignant polyps; but since it was unpleasant and costly, more evidence concerning its efficacy was needed.

Joe recognized that KP was an excellent setting for a case-control study of this question. Our records could reveal who died of colorectal cancer—the case subjects, and screening sigmoidoscopy had been offered at some of our medical centers and recorded in our records. He designed a case-control study in which the case subjects were compared with control subjects, the main focus being on their experience of sigmoidoscopy in the ten years before the cases’ diagnoses. Motivated by his personal interest and recognition of the need for such a study, Joe applied for a National Cancer Institute (NCI) grant. Peer review led to the application initially being turned down because Joe and I had not considered a methodologic problem known as healthy-screenee bias. We consulted with Noel Weiss, a leading expert in case-control studies of screening tests. As a result, an improved study design was resubmitted, and the study was approved and funded by NCI.

The study was completed and showed elegantly that screening sigmoidoscopies do prevent death from colorectal cancers within their reach. After additional peer review, the study was published in the prestigious New England Journal of Medicine16 and received considerable attention both nationally and within KP. Confirmed in a smaller investigation elsewhere,19 our findings led the USPTF to change its recommendation regarding screening sigmoidoscopy from neutral to favorable.20 The KP gastroenterologists were also impressed, and a systematic screening program for our subscribers,
known as Colorectal Cancer Prevention or CoCaP, was implemented.

This study was investigator-initiated, outside-funded, and published. What would have happened if DOR had been totally devoted to directed in-house research (assuming that someone of Joe Selby’s caliber would have been willing to work under such an arrangement)? First, the grant application was submitted in 1987, and the study was conducted from 1988 to 1991 at a cost of $457,000. I sincerely doubt that management at that time would have viewed this question of sufficient concern to devote almost a half million dollars to it. Second, with total internal support, we would probably not have benefited from external peer review of the study design, and the methodologic flaw would not have been detected. If anyone in KP had been aware of healthy-screenee bias, it should have been Joe and I, and we were not. Finally, if the study had not been published in a respected peer-reviewed journal, the findings would have been less impressive to our physicians and managers. If our leadership had instituted the CoCaP program on the basis of a purely internal unpublished study, it would probably have been met with skepticism and resistance, given the extra work, costs, and difficulties involved.

This example clearly shows several advantages of peer-reviewed published research and why it should always be a big part of our mission. This does not mean that DOR should become an ivory tower lacking organizational concerns. We must respect and respond to the interests and needs of KP. Not only would we not exist without its support, but we in DOR believe in KP, its principles and its social mission. We want to contribute to KP’s success in providing high quality care to its subscribers. Just as our work benefits the organization, the interaction with KP leaders and clinicians stimulates us to identify and investigate interesting questions.

The Keys to DOR’s Success, Past and Future

I think we have been very successful in using our rich research resources. DOR is internationally known in epidemiology and health services research and we are increasingly valued by KP. We achieved this success not by taking people out to lunch and schmoozing them, as some worried members of DOR have urged me to do. We achieved this success not just by starting projects but by finishing and publishing them, and by making sure that we maintain our objectivity. We achieved this success by being helpful whenever we can to our colleagues in KP.

The keys to DOR’s success, both past and future, are listed.

1. Resources
2. Objectivity
3. Quality work
4. Completion and publication
5. Helpfulness

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Gary D. Friedman, MD, MS: A Biography
by Arthur L. Klatsky, MD

Gary Friedman is an internationally known, outstanding physician-epidemiologist who has been with the Kaiser Permanente Medical Care Program (KPMCP) since 1968. Born in Cleveland, Ohio on March 8, 1934, he attended Antioch College and the University of Chicago (BS 1956) and received his MD at the University of Chicago in 1959. His internship and residency were served at the Harvard Medical Services, Boston City Hospital and at University Hospitals in Cleveland, Ohio. This was followed by obtaining an MS degree (biostatistics) from the Harvard School of Public Health in 1965 and American Board of Internal Medicine certification. He worked with the Framingham Heart Study (1962-66) and as Chief of the Epidemiology Unit, Heart Disease Control Program, U.S.P.H.S. in San Francisco before joining the KPMCP. At the KPMCP Division of Research (DOR), he served as Senior Epidemiologist (1968-76), Assistant Director (1976-91), Director (1991-98), and is now Senior Investigator.

Gary is substantially responsible for developing one of the first and largest epidemiological research programs in an HMO. His prodigious output of work has been in diverse areas of epidemiology, including cancer, cardiovascular disease, gallbladder disease, adverse drug reactions, twin research, effects of smoking and alcohol, and evaluation of screening tests. His textbook, Primer of Epidemiology, now in its Fourth Edition, is widely used by medical schools and health professionals (>80,000 copies sold) and has been translated into Spanish, Italian, and Chinese. He has authored more than 250 scientific papers or book chapters. He is one of the few epidemiologists to win a coveted seven-year, $4-million Outstanding Investigator Grant from the National Cancer Institute (1989-96; renewed from 1994-2001).

Among Gary’s epidemiologic “firsts” are the following:

• First to quantitate the risk of stroke in relation to atrial fibrillation (Circulation 1968; 38: 533-41).
• First to show the relationship of cigarette sale differences in U.S. states to risk of myocardial infarction (J Chron Dis 1967; 20: 769-79).
• First to conduct a large-scale survey of drugs to discern relationships to cancer (6 articles), resulting in a MERIT grant award from the National Cancer Institute.
• First to develop a twin research program in an HMO (5 articles).

His academic affiliations are:
Lecturer, University of California San Francisco and University of California Berkeley; Consulting Professor, Department of Health Research and Policy at Stanford University. Gary has been on the Editorial Boards of The American Journal of Epidemiology, HMO Practice, and the Journal of Medical Screening. Other community involvement includes or has included service on: Epidemiology and Disease Control Study Section, National Institutes of Health; U.S.-U.S.S.R. Working Group on Sudden Cardiac Death; U.S. Preventive Services Task Force; Scientific Review Panel on Toxic Air Contaminants, California Air Resources Board; Advisory Committee, Merck Foundation/Society for Epidemiological Research; and Senior Advisor, Expert Panel on Preventive Services. He is a member of numerous professional societies. He is President-Elect of the American Epidemiologic Society and on the Executive Committee of the Society for Epidemiological Research.

Gary is a devoted husband (married Ruth Schleien on 06/22/58), father (Emily, Justin, and Rick), and grandfather (Sophie and Nathaniel). His diverse interests include music and hiking. He has been a regular runner since age 27 and now runs 15-20 miles per week (bicycles regularly another day). Gifted with perfect pitch, he has played the piano since childhood and took up the oboe at age 54. He has played the oboe in numerous chamber music groups (was on Board of Directors, Chamber Musicians of Northern California) and is a performing member of the San Francisco Civic Symphony, the University of California San Francisco Orchestra, and the Bohemian Club Band.
Selected Publications By Gary D. Friedman, MD, MS
(of over 260)

Book:

Papers:
Friedman GD, Carroll PR, Cattolica EV, Hiatt RA. Can hematuria be a predictor as well as a symptom or sign of bladder cancer? Cancer Epidemiol Biomarkers Prev 1996;5:993-6.
Antibiotic Prophylaxis and Needle Biopsy

Introduction

Intensive screening for prostate cancer has led to a phenomenal increase in the number of biopsies done. To determine incidence of febrile reactions and to identify the most effective prophylaxis against fever after prostatic cancer biopsy, we reviewed the medical records of patients who had transrectal prostatic needle biopsy.

Method

We reviewed 172 consecutive records of patients who had transrectal prostatic needle biopsy during a three-month period in a health maintenance organization. We recorded the prophylactic regimens and incidence of febrile reaction, defined as temperature $>101^\circ$ F accompanied by shaking chills, with or without urinary infection symptoms.

Results

Patients had transrectal prostatic needle biopsy because of a clinical suspicion of prostate cancer or because of elevated serum levels of prostate-specific antigen. Procedures were done in the clinic without anesthesia or sedation and used an 18-gauge spring-loaded needle (Microvasive®, Boston Scientific Corporation, Watertown, Mass). Bowel preparation consisted of a phosphate enema given on the morning before biopsy. Some patients received an additional enema the night before biopsy.

The number of digitally directed and ultrasound-guided procedures were nearly equally distributed. A mean of three to four biopsies were taken (range, one to eight).

Prophylaxis

As preparation for biopsy, group A (102 patients) did not receive ciprofloxacin. Fourteen of these patients received a povidone-iodine enema, intramuscular administration of gentamicin, and oral administration of either trimethoprim (TMP) or trimethoprim-sulfamethoxazole (TMP-SMX) in single doses perioperatively. In 88 patients, the povidone-iodine enema was omitted. These patients received gentamicin alone preoperatively or gentamicin and either TMP or TMP-SMX in single doses. A small number of patients continued to receive TMP-SMX for three to five days.

In group B (45 patients), ciprofloxacin was added to the prophylactic regimen, postoperatively. Of these patients, 28 were given gentamicin preoperatively and ciprofloxacin, 500 mg every 12 hours for three days postoperatively. Seventeen patients received gentamicin, TMP, and metronidazole in single doses perioperatively and ciprofloxacin, 500 mg every 12 hours for two days postoperatively.

Group C (25 patients) started ciprofloxacin prophylaxis preoperatively. Ciprofloxacin, 500 mg, was given every 12 hours for three or four doses, starting the night before the biopsy. No other antibiotics were given.

Fever

Febrile reactions developed in 13 (7.6%) of the patients, usually within one to three days after biopsy (Table 1). There was no correlation of fever with number of biopsy cores. Fever developed in 11 (10.8%) of the group A patients and in two (4.5%) of the group B patients. Fever was not seen in group C patients, who started ciprofloxacin prophylaxis prior to biopsy.

Discussion

Urosepsis—usually caused by E. coli—is the most feared complication of transrectal needle biopsy of the prostate. Fever may be expected to develop in about 23% of patients who do not receive prophylactic antibiotics (range, 6% to 48%). Febrile reactions as low as 1.4% to 2.9% have been reported in patients who receive ultrasound-guided biopsy without the benefit of antibiotics. Nonetheless, most centers would recommend prophylactic antibiotics. Introduction of nonquinolone antibiotics can lower the frequency of febrile reactions to about 12% (range, 0 to 24%). Prophylaxis using quinolones can reduce febrile complications to about 3.2% (range, 0-3.9%). Ciprofloxacin diffuses readily into the prostate. After initially high serum levels, orally administered ciprofloxacin concentrates in the prostate during a 12- to 24-hour period. Maximal protection against febrile reactions can be realized when quinolone prophylaxis is begun one to 12 hours before transrectal biopsy is done. Although pre-treatment with antibiotics is largely responsible for the reduced complication rate, coverage must be continued for 12 hours to seven days after biopsy.

The value of ciprofloxacin prophylaxis was underscored by a recent report of 4439 biopsies. Of patients treated with 500 mg ciprofloxacin twice daily for eight doses (beginning with three doses before biopsy), febrile E. coli infections developed in 0.07%. Povidone-iodine solution administered rectally can reduce infectious complications, but its use was discontinued in our clinic after vasovagal reactions developed in some patients. Although our findings were not statistically significant, they support use of quinolones to prevent fever due to transrectal prostatic needle biopsy. Compared with other prophylactic regimens, ciprofloxacin prophylaxis substantially lowered the incidence of fever, especially when started preoperatively. Our current protocol calls for ciprofloxacin prophylaxis (500 mg every 12 hours for four doses) starting on the night before biopsy and

“Intensive screening for prostate cancer has led to a phenomenal increase in the number of biopsies done.”

“Urosepsis—usually caused by E. coli—is the most feared complication of transrectal needle biopsy of the prostate.”
The self-administration of phosphate enema on the morning of biopsy. Patients are encouraged to minimize consumption of liquids to maximize the concentration of antimicrobial agent in tissue and urine. This regimen has reduced the incidence of fever to <2%.

**Conclusion**

Ciprofloxacin given before and after transrectal prostatic needle biopsy may prevent febrile complications. Physicians who have not yet done so might consider a similar cost-effective policy.

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**Table 1. Results of antibiotic prophylaxis in 172 patients receiving transrectal needle biopsy of prostate**

<table>
<thead>
<tr>
<th>Group</th>
<th>No. patients</th>
<th>No. (%) febrile reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A (no ciprofloxacin)</td>
<td>102</td>
<td>11 (10.8)</td>
</tr>
<tr>
<td>Povidone-iodine enema</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Gentamicin, T M P (or T M P-SM X)</td>
<td>14</td>
<td>1 (7.1)</td>
</tr>
<tr>
<td>No povidone-iodine enema</td>
<td>88</td>
<td>10 (11.4)</td>
</tr>
<tr>
<td>• Gentamicin</td>
<td>11</td>
<td>3 (27.0)</td>
</tr>
<tr>
<td>• Gentamicin, T M P (or T M P-SM X)</td>
<td>77</td>
<td>7 (9.0)</td>
</tr>
<tr>
<td>Group B (ciprofloxacin added postoperatively)</td>
<td>45</td>
<td>2 (4.5)</td>
</tr>
<tr>
<td>• Gentamicin</td>
<td>28</td>
<td>1 (3.6)</td>
</tr>
<tr>
<td>• Gentamicin, T M P, metronidazole</td>
<td>17</td>
<td>1 (5.9)</td>
</tr>
<tr>
<td>Group C (ciprofloxacin only; started preoperatively)</td>
<td>25</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Total</td>
<td>172</td>
<td>13 (7.6)</td>
</tr>
</tbody>
</table>

T M P = trimethoprim; T M P-SM X = trimethoprim-sulfamethoxazole.

**References**

Life After an Acquisition

After months of planning, after countless people working countless hours, after solving for every conceivable problem, we thought we were prepared for the arrival of 12:01 am, February 1, 1997.

We weren’t.

When the switch was flipped and 100,000 members, six centers, 300 staff and physicians, 2500 network physicians, and two new products from the Humana Group Health Plan, Inc. became part of Kaiser Permanente (KP), we were not nearly as prepared as we needed to be.

Now, a year and a half later, we can look back and say what an incredible learning experience it was for us. At the time, however, it was a singularly frustrating, costly, exhausting, partnership-fracturing, nerve-shattering time. And although we are a healthier, smarter, larger company now, not a single one of us would welcome the opportunity to relive those days. Given our learnings, however, we look forward to expanding the Permanente Practice whenever possible.

I would like to share with you what we have learned from our experience.

Justify the Acquisition

Have sound reasons for the acquisition. Because when the going gets rough—and it will—you will need to remind the physicians and staff repeatedly of the business case for the expansion.

For the KP Mid-Atlantic Region, acquiring Humana brought a number of things that we needed to remain successful. From a business perspective, foremost was increased membership. We grew from 425,000 members to 525,000 members, and our market share increased from 15% to 20%. We expanded our delivery capabilities through an increase in the number of facilities (six additional medical centers) available to deliver care, through the types of products (network and Medicare Risk products) that we could offer to employer groups, and through the new choices (community-based physicians, additional affiliated hospitals) that we could provide to our members. In the process, we eliminated a competitor, prevented an opportunity for a new competitor to enter the market, and acquired members who were already accustomed to a group-practice delivery model.

From a mission perspective, the acquisition enabled us to continue advancing our goal of improving the health of our community. We knew both that our rich medical heritage would enable us to take better care of these people and that we had acquired Humana for a reasonable purchase price, thereby using our members’ health care dollars judiciously.

But as our medical centers became inundated with members, as our call center became overloaded with calls, and as we struggled to establish a foothold in our newly affiliated hospitals, our staff and physicians sometimes lost sight of why it was important for us to acquire Humana. Health Plan and Medical Group leadership were constantly questioned about our decision.

Even today, as we continue our recovery from this transition, we must remind ourselves of what the acquisition brought us.

Expect Surprises

As a for-profit, publicly traded company, Humana brought us a unique set of challenges. Because Humana existed in our market, antitrust regulations were quite specific about how far we could delve into the workings of Humana: specifically, we were limited in our ability to access data about Humana’s members, providers, employees, or financial performance prior to the acquisition. Consequently, we got more—and less—than what we bargained for in the acquisition.

For instance, we acquired fewer members than we projected, especially in Medicare Risk—and the overall health of these new members was much poorer than we anticipated. In addition, we assumed the responsibility of credentialing all physicians—even though we lacked the ability to contact them before the acquisition. Consequently, credentialing became a major problem for us, which became particularly apparent during our NCQA reaccreditation process.

Consider Revenue Carefully at the Due Diligence Stage

The rate contracts between Humana and some employer groups for Humana’s network-based health plan specified dramatically higher rates than those we were charging the same employers for our medical center-based health plan. The dual rates were not acceptable to employers, and most refused to pay the higher cost. In addition, the Medicare Risk sales force had been drastically reduced in the months before the acquisition, and this reduction affected membership. Because of these elements, revenue was markedly reduced, and we hadn’t factored this reduction into our revenue projections. Similarly, our multiyear strategy for rate differentiation didn’t hold. Had we focused on revenue more closely during the due diligence investigation, we might have faced a much more realistic financial picture and thus would have been better prepared.
Establish a Full-Time Team to Prepare for the Transition

You cannot handle an acquisition successfully unless the process is conducted by a team of people who are completely focused on it. In addition to hiring consultants with acquisition expertise, we created a cross-functional implementation team that included key stakeholders from the Health Plan and Medical Group that had sufficient authority to make things happen. The team had sponsorship at the highest levels of the Region, and its work took precedence over any other responsibilities its members might have had.

A major failing of ours was that we did not keep the implementation team fully staffed and supported for at least six months after the deal closed. Doing so would have been particularly helpful for addressing the infrastructural demands that the new products created in such areas as claims processing, development and management of the provider network, contracting, benefits administration, and even member services. Instead, our new infrastructure nearly collapsed before we began to use a unified approach to the integration of Humana.

Assume Nothing

In acquiring a separate health care entity, assume nothing—least of all that the acquisition target will continue doing business as usual from the time the Letter of Intent is signed and the deal is closed. Our new members came in so much sicker than we ever imagined. Overnight, we doubled the number of AIDS and end-stage renal disease (ESRD) patients and tripled the number of diabetic patients. In the ensuing months, prescriptions for diabetes medication increased by more than 85%, congestive heart failure became one of the top five admitting diagnoses, and our HEDIS childhood immunization measure fell by 8%.

Had we known then what we know now, we would have set minimum standards of care to be delivered with financial penalties for not meeting performance expectations.

Expect to Provide Aggressive Care to Many of Your New Members

Even with continuous care, you should expect that patterns of morbidity and disease among new members will differ from those of your existing membership. Our system of care provides for more integrated, comprehensive management of disease and requires time to assimilate a sudden influx of new patients, particularly those with AIDS, diabetes, and ESRD.

Woo Your New Members

Acquiring a competitor in an existing market means that you are acquiring many members who have chosen not to join your plan. They have formed an opinion of you, and the burden is on you to convince them that they were wrong to reject you in the past. Help them feel welcome, particularly if—as in our situation—you acquire medical centers and hire some of their physicians and staff. Many of our new members were being seen at their old medical center, but suddenly doing so was not as familiar as it had been. These members may have had the same physician, but everything else was new—from forms to computers to location of services within the same building. In many cases, patients had a new physician and new staff to get to know.

Remember Your Existing Members

The demands your acquired members place on you will affect your existing members. Our stated goal—to make the transition seamless for our new and current members—was one we were unable to fully achieve for many months. The impact on our level of service has certainly affected our membership renewal rate this year, a consideration that we did not include when calculating the opportunity cost of the acquisition.

Remember Your Existing Delivery System

Your core delivery system needs attention and investment, too. Diverting resources and people to support the acquisition can shift your focus from your core business. Almost 80% of our newly acquired members chose to receive their care from a Permanente physician, but we had not—and should have—hired a full complement of physicians (ie, before the deal was closed) who were ready for the large influx of patients. We learned that you cannot add physicians slowly when members are being added rapidly.

This situation also affected our hospital practice, because when we acquired Humana, we assumed a contract with a major hospital. We found ourselves caring for our sickest patients in a hospital that wasn’t set up to support the Permanente Practice of medicine. After the deal closed, we scrambled for many months to set up a system that was integrated with that of our other hospital partners.

Don’t Expect That Your Current Systems and Processes Can Handle the New Burden

Any systems that are already at capacity or that are not functioning well will collapse (at worst) or sputter (at best) with the sudden addition of more members, new products, and new delivery systems. Therefore, you should inspect your information systems and claims systems before an acquisition takes place. Neither our information systems nor our claims systems had sufficient capability to handle the new business.
or the increased load of members and physicians adequately. We depended on inadequate information systems that could not merge with those of the product we purchased. Claims processing is a nightmare we are still trying to awaken from.

In some respects, the inelasticity of the group model makes an acquisition more difficult. We immediately experienced a 1000% increase in calls to our appointment/advice lines and to member services. Our same-day access became a misnomer.

Raid the Best Talent From the Acquisition Target

An acquisition provides an excellent opportunity to raise the skill and competency levels of your organization; don’t lose out by pretending that you know everything. For us, it was essential to bring to our organization people who knew how to sell Medicare Risk and how to manage a network of providers. In addition, we needed to hire a sufficient number of experienced physicians and managers.

Create Opportunities to Orient and Acculturate Staff and Providers

We all know it exists: the KP way of doing things. Often, however, new physicians and staff are expected to learn it through osmosis. A major growth in staff and physicians requires us to expend increased efforts to reach out to them. We did quite well at completing the transition of facilities—signs went up, computers were installed, equipment was made available, people were moved—but we didn’t do as well as we should have at orienting physicians and staff to a new culture. Having access to mentors, trainers, and more seasoned physician leaders would have given support on site, where it was needed.

Communicate, Communicate, Communicate!

Communicate continuously with new and old members and with new and old staff and physicians. The safest assumption is that no one has heard anything you’ve said before.

When the Deal is Closed, the Work is Just Beginning

Despite all the work we had done in the months leading up to the close, our most difficult challenges arose in the first five months after the deal was closed.

A Final Reaffirmation

Amid all the activities and concerns inherent in implementing an acquisition, you will find it helpful to remember this powerful reaffirmation: Permanente physicians practice great medicine.

While caring for sicker, more demanding patients, while learning how to manage care in a mixed model, while assimilating themselves into a new major hospital relationship, and while working through a fractured Health Plan partnership, the Mid-Atlantic Permanente Medical Group physicians showed every day what it means to be a Permanente physician. That reaffirmation gives me confidence that no matter what happens in the years ahead, Permanente will survive.

We can demonstrate to our members, to our communities, to the media, to legislators and regulators, and to the public that we know how to care for our patients. Ultimately, that demonstration will be the key to our success, because no matter what words you put around it—managed care, integrated care, indemnity care—health care is fundamentally what happens between patients and physicians.

Being a Permanente physician has always been about seeking ways to provide high-quality medical care to patients. Once it meant working in partnership with Kaiser Industries, evolving to a relationship with Kaiser Foundation Health Plan/Hospitals. What it means in the future is up to us to define. I know that we are ready for the challenge.

“That reaffirmation gives me confidence that no matter what happens in the years ahead, Permanente will survive.”

“We can demonstrate to our members, to our communities, to the media, to legislators and regulators, and to the public that we know how to care for our patients.”
Diabetes represents one of the most common and debilitating conditions seen among Kaiser Permanente (KP) members. Because care often involves multiple providers and because follow-up requires persistence by patients and clinicians alike, ideal outcomes are often difficult to achieve. Management of diabetes therefore offers an excellent opportunity to practice population management—a systems approach designed to ensure excellent care. Accordingly, through a broad KP collaboration, the Care Management Institute (CMI) developed a comprehensive approach to adult diabetes care: the Integrated Diabetes Care (IDC) Program. The IDC Program has three elements: an internally published report, Clinical Practice Guidelines for Adult Diabetes Care; a set of tools for applying population management and patient empowerment concepts; and an outcomes measurement component, ie, instruments for evaluating IDC Program impact and gathering feedback. In this article, we describe the IDC Program and the process by which it was developed. Included are specific examples of the tools and how they can be used at the population level and by individual clinicians in caring for patients.

Introduction

Toward the end of a busy morning session, Ms. Hopeful—a patient who is hypothetical but typical of many—appears in your office because of a week-long sore throat and a mildly productive cough. She also has diabetes (which you diagnosed seven years ago) and hypothyroidism. After taking the medical history and giving a physical examination, you diagnose a viral upper respiratory infection but also note that the patient has missed her last two appointments and has not been seen for her diabetes in more than a year.

You’re running late today and scheduled a lunchtime meeting with your Chief of Service. As you thumb through Ms. Hopeful’s thick medical chart for evidence of her last eye examination and relevant screening studies, you ask her about her diet and self-monitoring of blood glucose level. She tells you she thinks she is “doing okay” with her diet but could probably do better. She says she checks her finger stick results a couple of times a month and that they usually run 200 to 300 mg/dL, sometimes higher. She has not smoked in five years, she is proud to tell you.

By the end of her review, you still have not located tests through the quarterly diabetes reports for your patient’s blood glucose level. You are astonished to find Ms. Hopeful’s microalbumin level turned out to be elevated when last checked. This result—confirmed by repeat testing—is early evidence of end-stage organ damage. Ms. Hopeful is an excellent candidate for care management.

After completing a care management program, Ms. Hopeful says she feels more confident of her ability to participate in her own care and now understands why she must not miss any appointments. She returns to your care with all screening in order and with her medications fine-tuned. You know that your Chief is a stickler for punctuality. 
The Need for Coordinated Diabetes Care

The scenario described above shows how a diabetes care management program might improve the quality of life for an individual member, but that opportunity for improvement would apply to literally thousands of our members every day. The national prevalence of diabetes has been rising in recent decades. Among KP members, the prevalence of diabetes ranges from 3% to 6% across our 12 Regions, and data suggest that almost that many people in the general population have the disease without yet having been diagnosed.1

The consequences of diabetes are profound. Diabetes is responsible for increased rates of myocardial infarction, stroke, kidney disease, and limb amputation, among other serious ailments. Consequently, caring for the complications of diabetes leads to dramatically higher health care costs. A national study found that the cost of caring for the typical health plan member with diabetes was more than four times the cost of caring for nondiabetic members.2

Within KP, the cost differential was best measured in a Division of Research study led by Joseph Selby, MD, MPH, that compared cost of caring for KP Northern California diabetic patients with the cost of caring for a matched cohort of nondiabetic patients. The study found that the cost of caring for adult diabetic members was approximately two times the cost for nondiabetic patients, suggesting that better care may provide an opportunity for savings, i.e., by reducing the $20 million differential in cost of diabetes care in the KP Northern California Region.3

Studies have shown that careful diabetes population management is highly cost-effective.4,5,6

CMI’s Integrated Diabetes Care (IDC) Program

The Care Management Institute (CMI) emerged from the National Partnership Agreement forged between The Permanente Medical Groups (through The Permanente Federation) and Kaiser Foundation Health Plan. CMI’s vision is to develop a nationally consistent, evidence-based, process-efficient approach to delivery of health care that is customized to the individual member.

With the goal of systematically evaluating and improving care of our adult patients with diabetes, CMI released an Integrated Diabetes Care (IDC) Program in January 1998. Work is now underway in almost all KP Regions to implement a care management program for all members with diabetes. (Some KP Regions already have such a program in place and provided much of the expertise for the CMI IDC Program’s development.) CMI’s IDC Program grew out of KP’s Interregional Diabetes Effort, a national collaboration to develop, implement, and enhance disease management programs in diabetes care.

Combining the knowledge and experience of many KP physicians and health care professionals across the nation, the IDC Program provides tools for national, Programwide implementation of KP’s Clinical Practice Guideline for Adult Diabetes Care as well as evaluation of this implementation against a set of outcomes measures. The IDC Program also includes a curriculum for patient education and care redesign.

The core components of the IDC Program include Clinical Practice Guidelines for Adult Diabetes Care; use of tools that emphasize patient education and empowerment; and attention to monitoring and tracking outcomes for the population of diabetic patients.

As part of the IDC Program, CMI has produced two implementation manuals: The Integrated Diabetes Care IDC, Version 1.0 manual is intended to assist local KP areas in design, implementation, or enhancement of programs for adult diabetic patients; Living Well With Diabetes, Step by Step manual is an interactive patient education curriculum that promotes self-management and skill-building for people living with diabetes.

The IDC Program focuses on approaches that are either distinctive or emphasized in the current medical literature. Tools used as part of the IDC Program are designed to be as generalizable as possible, providing flexibility so that physicians and other health care professionals can adapt them to their own patients and unique care settings. Some tools may need to be customized for special patient populations. Although the IDC components and tools can be implemented separately, care management programs are most effective when they are fully integrated to provide a comprehensive approach to caring for the target population; implementing individual pieces alone appears to have far less impact. However, no formal outcomes data are available to compare the efficacy of implementing a whole program versus the efficacy of implementing only some component parts.

Process for Developing the IDC Program

To develop an informative, valid, and feasible operating plan, more than 70 experts in diabetes, adult behavior change, operations, and outcomes evaluation from across KP met in six workgroups for more than a year. The groups developed a comprehensive program of diabetes care that includes Clinical Practice Guidelines for Adult Diabetes Care, a model of care delivery, a curriculum for patient education, and outcomes measures (including technical specifications for administrative data as well as a survey template for collecting patient information). Materials will be reviewed and updated regularly.
Clinical Practice Guidelines of the IDC Program

Clinical Practice Guidelines for Adult Diabetes Care is the core of the IDC Program and consists of a series of algorithms and protocols to assist in screening, treating, and referring patients, depending on their specific circumstances. The guidelines are written in a concise instructive style designed to enable primary care physicians and other clinicians to use the IDC materials easily.

Presented (Figs. 1-3) are excerpts from the IDC Clinical Practice Guidelines for Adult Diabetes Care in three areas—glycemic control, renal screening, and podiatric screening—which are especially important in diabetes care. Clinical Practice Guidelines for Adult Diabetes Care can be found on KP Exchange, a secure Internet website for use by clinical and nonclinical employees of KP (who may register online at www.kpexchange.org).

Glycemic Control

Long-term control of blood glucose levels is the hallmark of effective diabetes care, and compelling evidence exists to show that this practice leads to lower complication rates. The IDC Clinical Practice Guidelines recommend assessment of long-term glycemic control by using a laboratory test such as for hemoglobin A1c levels. If another test is used, its results should be correlated to HbA\textsubscript{1c} test results.

<table>
<thead>
<tr>
<th>Goals for glycemic control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>If hemoglobin A1c is used to assess long-term glycemic control, the target goal is 1-2% greater than the upper limit of normal for the lab where the test was performed. Individual needs should determine the appropriate goal for any given patient. If an analogous test of glycemic control is used, the appropriate equivalent value should be used.</td>
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<thead>
<tr>
<th>Interval to monitor long-term glycemic control:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once goals for glycemic control have been attained, testing should be performed every 3-4 months for those requiring insulin, and every 6-12 months for patients not requiring insulin. The test should be performed more frequently if the glycemic control goals have not been met, if the patient’s diabetes medications are being altered, or if the therapeutic goal is to attain tight control.</td>
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</tbody>
</table>

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<thead>
<tr>
<th>Self-monitoring of blood glucose:</th>
</tr>
</thead>
<tbody>
<tr>
<td>All diabetic patients should be offered patient education on self-monitoring of blood glucose. This should be documented in the medical record. The goal of self-monitoring should be to maintain fasting blood glucose values of between 80 and 120 mg/dL, and to aim for a 2-hour post-prandial value of &lt;180 mg/dL, or as individualized to each patient’s situation. If preprandial values are &gt;150 mg/dL or post-prandial values are &gt;200 mg/dL, the physician and/or health care professional should reassess the need for tighter control. Patient success with self-management should be reviewed and reassessed at least annually. When appropriate, education in self-monitoring should be reoffered to patients.</td>
</tr>
</tbody>
</table>

Renal Screening

Diabetes patients are at risk for kidney damage that may ultimately require dialysis treatments. For patients who have tiny amounts of protein detected in their urine (ie, microalbuminuria), medication can delay or prevent deterioration of kidney function. Although the ideal interval for microalbumin testing is unclear, most groups (including the authors of KP’s IDC Guidelines and the American Diabetes Association) currently recommend annual screening for microalbuminuria. It is unnecessary to test for microalbumin in patients with more advanced stages of kidney impairment.

Podiatric Screening

Regular examination of the feet is an important component of diabetes care because it facilitates early detection of peripheral vascular disease and peripheral neuropathy. The American Diabetes Association requires that at least 74% of a clinician’s diabetic patients have a foot examination within a 12-month period in order to acquire points toward its provider recognition program.

Model of Care

The model of care is the infrastructure and process for managing and delivering patient care (Fig. 4). The IDC model of care is based on four key criteria: proven effectiveness; patient acceptance and satisfaction; facilitation of continual learning for diabetic health systems management.
The stratification method is based on critical synthesis of existing stratification methods within KP and on cost-effectiveness modeling.

Stratification of Patients

The stratification method is based on critical synthesis of existing stratification methods within KP and on cost-effectiveness modeling. The precise stratification for a given population is determined by several factors: size of the diabetic population, local KP leadership’s program objectives (eg, to demonstrate improved health outcomes in a brief period or improved Health Plan and Employer Data and Information Set [HEDIS] results), staffing expectations (especially for the care coordinator positions), and extent to which enabling technologies, such as care management software, can be used to serve larger numbers of patients.

At initial patient evaluation or when reviewing the local patient registry, the diabetic patient population must be segmented into groups most likely to benefit from different levels of intervention. The stratification methodology is intended to be coupled with other aspects of the IDC Program (ie, patient education, group visits, and programs for self-management of chronic disease) that provide direct service to patients. The stratification process relies on available KP data bases, allowing segmentation of the entire diabetic patient population without necessitating additional intake interviewing.

The stratification methodology in the IDC Program creates three tiers of patients with diabetes. The patients with the least severe disease are well controlled and usually have no evidence of end-stage organ damage. These patients will continue to receive most services in the usual way from their primary care physician or health care professional. Depending on available resources and maturity of the Program, some of these patients may also be targeted to receive additional educational programs to improve their diet and activity levels.

Patients with the most severe disease (about 15% of the diabetic patient population at any time*) have major multiple complications from diabetes, often requiring subspecialty services. Comorbidity caused by long-standing diabetes is often the major medical problem. These patients will continue to receive most specialized services in the usual way from their primary care physician or health care professional. Depending on available resources and maturity of the Program, some of these patients may also be targeted to receive additional educational programs to improve their diet and activity levels.

Between these two extremes is a sizable cohort of patients who have clinically significant diabetes care needs but whose care management can be handled well through a care coordination system. Typically, this cohort represents about 50% to 60% of diabetic patients (depending on age and severity of the cohort as well as on the criteria used for inclusion and exclusion). Markers for these patients include:

- Retinopathy;
- Microalbuminuria or early proteinuria;
- Angina;
- Neuropathy;
- Poorly controlled blood glucose values in relatively young patients;

*Population proportion estimates developed by diabetes outcomes researchers and program developers and validated against medical center level data in South San Francisco.

Patients without known renal disease should be screened annually, by first morning dipstick or equivalent measure, for microalbumin in the urine. Those patients (either Type 1 or 2, normotensive or hypertensive) who test positive for microalbumin on at least two occasions should be treated with an angiotensin-converting enzyme (ACE) inhibitor medication, unless contraindicated.

Visual inspection of the feet should be performed at all primary care visits. A full foot examination (including visual inspection for ulcers, cracks, calluses, and pressure points; palpation for pulses; and sensory testing—preferably with 10 g monofilament) should be performed at least annually or as clinically appropriate at each diabetes encounter. Findings should be documented in the medical record. Patients with exams that reveal one or more abnormalities should be referred if appropriate. Once a patient has demonstrated a foot abnormality they should receive a visual inspection of the feet every 3-4 months.
The exact mix of inclusion and exclusion criteria as well as duration of enrollment in a care management program should be determined, using different markers, in consultation with the local KP leadership through iterative review of the size of the three strata. Another criterion for assigning patients to care management is candidates’ readiness to make major lifestyle changes. To obtain such information, however, all candidates must be interviewed. Local KP leaders should decide whether to evaluate this parameter.

Commitment to a Team Approach

The model of care is a team approach in which specific responsibilities are assigned to different providers (eg, a care coordinator, diabetes educator, primary care physician, or eye-care specialist). Many team roles are likely to be new and unfamiliar to members of the team. Primary care physicians, in particular, will play more of an oversight and management role; direct patient contact is likely to be delegated to other team members. Because team members must clearly understand what is expected of them and must also understand the relationships within the team and with patients, team members’ roles are clarified and reinforced by position descriptions, support materials, and specially tailored training sessions.

The local KP leadership should determine how care can best be complemented through use of nonphysician clinicians who have diabetes-related clinical expertise. In addition, a key contact at the local level must be identified to explain care priorities and to provide patient registry data at timely intervals.

Evaluation of Care

All implementation should be evaluated to determine what is working and what really makes a difference. The CMI is learning about the IDC model of care by working with leaders at local sites to:

- Determine priorities for patient stratification;
- Evaluate ability of physicians and other health care professionals to interpret and use stratification reports;
- Assess how well the stratification method directs at-risk patients to care coordinators for an intensive level of care management;
- Measure impact on patients’ health status, self-confidence in managing their own disease, and satisfaction with care;
- Interpret whether stratification increases process efficiencies, ie, by reducing the need for physician visits and hospitalizations.

Fig. 4. The IDC model of care stratifies patients into three levels according to patient severity.

- Hypertension and hyperlipidemia with no history of cardiovascular or cerebrovascular disease.

The exact mix of inclusion and exclusion criteria as well as duration of enrollment in a care management program should be determined, using different markers, in consultation with the local KP leadership through iterative review of the size of the three strata. Another criterion for assigning patients to care management is candidates’ readiness to make major lifestyle changes. To obtain such information, however, all candidates must be interviewed. Local KP leaders should decide whether to evaluate this parameter.

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“Patients are encouraged to use the wallet-sized card to record their medical visits and laboratory test results.”

“Educational messages are tailored to each patient’s readiness for change and to each provider so that they are continually reinforced.”

Computer software for population management is a key tool for care coordination and is an important component of diabetes care management. Ideally, software should be able to quickly identify patients in trouble—for example, those who are not filling prescriptions or whose blood glucose levels are becoming dangerously high—and to remind care coordinators about scheduled follow-up care. The software should also be able to broadcast messages by e-mail, phone, fax, or paper to other team members (and, in future, to patients). Current approaches can deliver some of these services. The KP National Clinical Information System currently under development is expected to provide these services in the future.

In the absence of computer software, other tools can lend assistance for care management. For example, CMI has developed a template for a paper version of “speed charting” for patients with diabetes (Fig. 5). The Speed-Charting Template allows clinicians to easily check and record pertinent clinical data at routine scheduled visits.

A Personal Diabetes Record (Fig. 6) is another paper-based way to monitor the health status and treatment history of diabetic patients in the absence of computer software. Patients are encouraged to use the wallet-sized card to record their medical visits and laboratory test results. They take the wallet card with them when they visit their physician or other member of the Diabetes Care Team, using it to discuss aspects of their care. The card unfolds to reveal panels which include space for listing areas for discussion, for noting goals, and for recording medications, medical visits, laboratory test results, and phone numbers. In this way, the wallet card helps members to monitor and control their own health.

**Patient Education**

Another key component of the IDC Program is integrated patient education. Based on the KP Northwest Region’s Step-by-Step Program and the KP Northern California Region’s Living Well with Diabetes Program, the patient education component encourages Health Plan members with diabetes to participate in groups. The groups give members an opportunity to talk with others who face similar problems and to increase the number of educational encounters they have with KP.

To change the traditional, didactic method of diabetes education, patients are asked to set and pursue specific, attainable goals and to develop individual self-management skills. Educational messages are tailored to each patient’s readiness for change and to each provider so that they are continually reinforced.

The IDC Program includes several patient education tools to help members take charge of their health. Templates from the Diabetes Action Plan (Fig. 7) enable patients to note their personal behavior change goals, a copy of which can be made part of the medical record for regular review.

Tip Sheets (Fig. 8) containing helpful self-care information for members with diabetes also are included as part of a patient education section.
The IDC Patient Education Workgroup adopted this tip sheet from the American Diabetes Association (ADA) materials. An important recommendation (not included in the ADA handout) is the need to counsel patients about the use of metformin during sick days.

**Diabetes Outcomes Report and Patient Survey**

Condition-specific outcomes measures and targets provide the basis for all care management products. Outcomes measures are based on several factors: credibility as established in the biomedical literature in English; ability of providers to affect the outcomes; feasibility of measurement; and external demand for information.

Especially when embedded in a population management system, outcomes measures can help identify exemplary practices and point to areas for improvement. The 1997 KP National CMI Adult Diabetes Outcomes Report used administrative data to provide information on processes of care, utilization, and clinical outcomes of interest for more than 200,000 KP members with diabetes. The report represents major work by representatives from across KP to identify patient groups consistently and to measure outcomes equivalently.

This reporting process is expected to be repeated regularly and will be valuable for tracking trends over time.

After collecting administrative data, CMI surveyed members with diabetes to collect data available only from patients (eg, self-perceived health) or which cannot be reliably measured from other data sources (eg, foot examinations by physicians). The patient data survey summarizes measures of medical care interventions, self-care attitudes and behaviors, satisfaction with medical care, and patient perceptions of health status. CMI collected data from 7123 respondents and summarized its findings in the report, 1997 KP National CMI Survey of Adults with Diabetes, which is available on the KP Exchange website (www.kpexchange.org).

**Concluding Overview**

The Integrated Diabetes Care Program provides an opportunity to improve health status and outcomes for thousands of KP members while assisting KP physicians and other health care professionals. The IDC Program offers an integrated, coordinated approach to managing a chronically ill patient population. The Program provides tools and templates to help physicians manage their deskwork and gives opportunities to focus on care, instead of cure.

Although content development is important, implementation efforts are the core of CMI's work. An implementation network across KP is using the IDC program as it works with clinicians at the local level.
to assist them in improving outcomes for members with diabetes. 

The Care Management Institute would like to thank the following KP individuals for participating in development of the Integrated Diabetes Care Program:

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KP staff can access the Integrated Diabetes Care Program directly on the KP Clinical Practice Exchange website (register at http://www.kpexchange.org).<ref>

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References
Commentary: The Care Management Institute's Integrated Diabetes Care Program

In the ongoing wave of discontent about health care in the USA, two themes surface repeatedly in the political rhetoric and over-simplified soundbites from the media. The first is that consumers should have the freedom to go anywhere and choose anyone (specialists, alternative therapies, etc.) whenever they feel they need help. The second is that the phrase “managed care” is increasingly used as a pejorative euphemism for “bad care,” with all managed care organizations (MCOs) being lumped together as heartless money-grubbing demons which exist to make money for their shareholders by denying critical services to their hapless enrollees. There is certainly some justification for the concerns being raised, and there is plenty of room for improvement in the US health care system. But for those of us who work for organizations like Kaiser Permanente (KP), who dedicate our efforts to improving the health and quality of life for our enrolled members, this misrepresentation of managed care is hard to take. I would like to see two different themes receive increasing prominence in the near future. The first of these is that the biggest concern for the US health care system ought to be how to deal effectively with the ever-growing problem of chronic disease. And the second is that NOT all MCOs are the same. The article by Rachelle Mirkin, Neil Solomon, MD, and Helen Pettay in this issue of The Permanente Journal is a wonderful example of how organizations like ours can deal with chronic disease in ways that simultaneously will improve health outcomes, patient satisfaction, quality of life, AND reduce overall costs. I believe that this kind of work will set us apart from our competitors and should be promoted and expanded throughout our system.

Individuals with a chronic condition like diabetes dominating their lives need much more than cheap, easy access to a variety of services and specialists whenever they think they need help. They need to be empowered to take a central role in a health care team to utilize a coordinated set of services and supports that will promote better health outcomes and improved quality of life for them, long before they feel that they NEED to seek out someone because of a “problem.” In other words, they need “well-managed care.” The Care Management Institute's Integrated Diabetes Care Program grew out of KP's Interregional Diabetes Effort and has taken the knowledge and experience of many KP health care professionals across the nation. The goal was to develop a nationally consistent, evidence-based, process-efficient, and population-based approach to diabetes care that is customized to the individual member with diabetes. The keys to this approach are to first identify all diabetic patients by using consistent methods so that comparisons among different groups around the country are valid. Second, the key elements of good diabetes care need to be agreed on and defined. All these elements of care can then be tracked for all diabetic members on an ongoing basis (ideally using sophisticated electronic registries). Third, evidence-based guidelines for improving diabetes care need to be developed and become embedded in the health care system to ensure that they are followed. Fourth, patients need to be stratified so that the appropriate level of care and support can be customized to meet each diabetic patient's needs. All patients should have a clear, collaboratively developed Action Plan that is communicated to all team members. Last, the success of this integrated effort needs to be continuously evaluated throughout the KP system and be modified as needed to foster continuous improvement.

As described in the article, although not all these elements are being actively employed in all KP Regions of the country, the Care Management Institute has the goal of facilitating rapid dissemination of the relevant skills and resources to where they are needed. And in Regions where most or all of the components have been implemented (such as in KP's Northwest Region, or Group Health Cooperative of Puget Sound), the improvement in patient satisfaction and health outcomes has been clearly shown.

Another criticism which is often leveled against this kind of integrated approach to managing care is that it takes away from the individual freedom of both the patient and the provider to do what they think is best. I believe that this is a myth. There is plenty of evidence in the literature that the uncoordinated traditional approach to managing chronic illness like diabetes has resulted in abysmal outcomes, unhappy patients, and inefficient and expensive care.

A coordinated and integrated program like the one described here, which gives timely reminders about what services are recommended along with a range of options for supporting good decision-making and behavior change, can actually increase the sense of well-being and freedom for the patient and the other members of the health care team.

This work should be applauded and should be expanded to all regions of our organization as well as to other chronic conditions. Not only will it result in healthier, happier enrolled members, it is likely to reduce our overall costs of care, all of which will improve our competitiveness and make it clear to anyone who cares to dip below the superficial surface of rhetoric and soundbites that some MCOs are VERY much better than others.
KPNW’s Safety Net for Preventive Services: The Challenge of Reaching the Unscreened

In 1991, a Middle Management Development Project (MMDP) proposed that Kaiser Permanente Northwest (KPNW) strengthen its prevention program by creating a Safety Net. The proposal called for the prevention Safety Net to ensure that members at greatest risk, e.g., the unscreened, would receive services known to be effective in decreasing the risk of morbidity and mortality.

In 1994, a Prevention Steering Committee selected breast and cervical cancer screening as initial Safety Net interventions as these were known to be cost-effective and to have predictable screening intervals. A dual strategy was developed: unscreened members would receive an outreach letter; in addition, those who had clinical encounters would receive a verbal reminder from their clinician that they were overdue for screening.

Data suggest that the Safety Net has contributed to improved screening performance. Moreover, preliminary data from KPNW’s Tumor Registry suggest that we are finding a greater incidence of invasive cervical cancers that may have gone undetected without the Safety Net initiative. KPNW believes the Safety Net has enhanced preventive services for the Region. The Safety Net should prove to be a potent strategy for other preventive and population-based screening services.

Introduction

In 1991, when this quote appeared in an internal Kaiser Permanente (KP) publication, Spectrum, little or no concentrated effort by KPNW existed to coordinate a centralized prevention program. Instead, prevention was left to the departments—and more often to individual physicians within those departments. So although the concept of preventive care was implicit in the organization’s philosophy, KPNW had few resources for ensuring a coordinated prevention program.

But also in 1991, a Middle Management Development Project (MMDP) Team proposed to KPNW senior management a system to identify and deliver screening and other preventive services to members at highest risk. This proposal coincided with mounting expectations that in 1993 we would be required to report regional performance on certain Program outcomes such as breast and cervical cancer screening rates. The convergence of these events led to the Region’s Prevention Steering Committee deciding to sponsor and thereby strengthen centralized prevention services through the Safety Net.

In the ensuing years, 1994-1997, KPNW’s Safety Net has evolved as a centralized function to support clinician delivery of prevention services. The Safety Net has fulfilled much from its original objectives and has:

- Assured that effective prevention services are delivered to as many members as appropriate,
- Delivered effective prevention services cost-effectively by focusing outreach and education efforts on women not receiving prevention services on their own,
- Created a partnership between member and health plan to maintain women’s health,
- Protected health plan from medicolegal risk by initiating and documenting outreach efforts to women not coming for prevention services on their own,
- Created a system to synthesize outreach needs for members by standardizing and improving messages delivered.

It remains for the Safety Net to extend to outreach relating to specific medical follow-up by gaining increased organizational support for other prevention and population-based services.

Development of the Safety Net Initiative

Applying a concept that would go far beyond a centralized outreach program, the KPNW Safety Net was initially proposed to ensure that members at risk would receive prevention services known to be effective in decreasing the risk of morbidity and mortality to within a certain desirable interval. Very few screening interventions met current Safety Net eligibility criteria—that

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By Nancy H. Stevens, PhD
is: a) were likely to be cost-effective; and b) had predictable screening intervals. In fact, only breast and cervical cancer screening, immunizations, and smoking cessation could meet the criteria. From among these screening interventions, breast and cervical cancer screening were selected as the first Safety Net interventions because of their known benefit, the ability of existing clinical programs to deliver services, and the existence of systems to support data analysis for both breast and cervical cancer screening.

**Establishing Safety Net Parameters**

Safety Net intervals are longer than is normally recommended for intervals between screenings. Still, these intervals generally fall within ranges acknowledged as safe for screening tests. For example, if KPNW were to adopt a typical Safety Net interval, “it might extend its recommended screening interval for cervical cancer from two to five years, as existing data indicate that after a negative result, the risk of developing invasive cancer within the next five years is highly unlikely.”1 With the longer interval, KPNW still has two—perhaps three—opportunities to screen women who do not seek screening during the known latency period between development of early dysplastic changes and onset of CIS (carcinoma in situ). In addition, the organization can realize substantial cost savings.

Existing guidelines for both breast and cervical cancer screening defined the parameters of desirable clinical service and maximum Safety Net intervals.

**Guideline summary for breast cancer screening**

Regular mammographic screening should be considered for all women 40 years of age and older. No definitive studies either prove or disprove that screening mammography in women ages 40-49 and over age 70 results in significant decrease in mortality from breast cancer. A woman should decide the frequency with which she has mammography screening on the basis of her individual risk for cancer by considering factors such as personal or family history.2

Safety Net Parameters—women ages
52-69 years who have not had a screening mammogram within the past two years.

**Guideline summary for cervical cancer screening**

Pap smears should be repeated annually until the patient has three annual negative smears. Thereafter, recommended screening intervals extend to two to three years. All women between the ages of 20 and 70 years who have an intact uterus should be screened at least every three years.3

Safety Net Parameters—women ages
21-69 years who have not had a Pap smear within the past three years.

Initially, clinicians expressed concern about two aspects of the Safety Net planning. First, the concept of a maximum interval between screenings was unfamiliar; previous strategies to improve screening services had been to shorten, rather than to lengthen, the recommended interval cycle. More frequent screenings, it was assumed, could improve probability of early detection. But shortening the interval cycle is a much more costly approach to preventive care and all but ignores the screening needs of members who do not access the health care system.

Second, concern was expressed that the criteria for inclusion in the Safety Net did not include other behavioral, familial, or personal risk factors. But this concern overlooked a modest but crucial principle: the greatest risk factor for a condition that has an effective screening test is failure to be screened.

The Prevention Steering Committee addressed these concerns from an epidemiologic perspective and was able to maintain its original focus for the Safety Net.

**Developing an Outreach Strategy**

The aim of the outreach effort is to ensure that as many as are willing can receive services within the prescribed Safety Net intervals. For KPNW to reach members who were not inclined to seek clinical services in a given year (about 35% of members), an outreach component would be essential. Outreach was defined as a direct contact by KPNW to members—

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“If a prevention service is clearly effective at preventing death and disability, a managed care system is both ethically and pragmatically required to deliver the service to as many of its members (of appropriate characteristics) as is justifiable within economic bounds. A common approach to this problem involves a campaign to maximize the receipt of service, and the shortening of the recommended cycle of delivery of the service in order to maximize the opportunities for delivering it. This approach is both highly inefficient (that is, expensive) and not very effective at reaching the underserved.”

Tom Vogt, MD, MPH
Prevention Steering Committee, 1994

“The greatest risk factor for a condition that has an effective screening test is failure to be screened.”

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either by letter or phone call—to encourage those
within the Safety Net to obtain screening for breast or
cervical cancer. Interest in improving access and par-
ticipation in cancer screening programs was growing
at about this time,4,5 and three KP research studies6-8
were assessing the impact of outreach efforts to en-
courage women to be screened for breast and cervi-
cal cancer at recommended intervals. Their prelimi-
nary findings showed that about one fourth of sub-
jects responded favorably to one or more contacts
(21-37% of women overdue for mammograms; 20-34% of
women overdue for Pap smears). Somkin et al rec-
ommended the “use of patient reminder letters as a
first step in a mammography or Pap smear screening
outreach program.”7,9

Developing an Inreach Strategy

The term “inreach” here means communication with
the member at the time of a clinical visit to let her know
that she is overdue for preventive screening. The thrust
of inreach is to deliver the needed services, either im-
mediately or shortly thereafter at another appointment
scheduled at the patient’s convenience. Somkin’s stud-
ies7,9 had shown that a combined outreach and inreach
strategy was more effective than any single strategy.
Recipients of a reminder letter and a chart note reminder
were more likely to obtain the recommended screen-
ing in the following six months than women who re-
ceived only the reminder letter. The weakness in the
inreach strategy appeared to be that alerts and triggers
to the clinician are only effective for women who seek
appointments. With evidence from the
three research studies showing that even
a single direct contact with patients
helped elicit desired behavior and that
two contacts were more effective still,
KPNW determined to develop a strat-
egy that would employ both outreach
and inreach components.

Exclusions

Vogt’s8 study findings, although simi-
lar to those of the Somkin studies7,9 in
that both revealed the importance of
outreach messages and multiple con-
tacts, uncovered another important, if
unexpected, finding. Direct contact
with women in the Safety Net provided
all-important exclusion information—
that is, reasons why a woman would
not, or could not, be screened. KPNW
determined to document exclusion in-
formation as a component of its
screening strategy.

Infrastructure to Implement the
Safety Net

KPNW had most of the necessary
clinical and technical support for a
Safety Net function. Medical Econom-
ics could provide analytic support; In-
formation Services, access to data sys-
tems; Tumor Registry, a home for the
Safety Net data; and primary care cli-
nicians, the necessary clinical services.
What the organization lacked, how-
ever—at least at the onset—was the
personnel to mount a telephone out-
reach program. So, although tele-
phone contact was preferred, KPNW
opted for patient reminder letters. Letters are sent to women the first year they appear in the Safety Net but not thereafter, as Vogt et al had demonstrated only incremental improvement in screening behaviors from multiple letters.

Developing the capacity to identify women in the Safety Net at the time of a clinical encounter was problematic at first because KPNW lacked the necessary clinical information systems to support this need. But in October 1996, shortly after the Safety Net initiative was developed, a “prevention” screen was introduced into the KPNW Results Reporting System that could electronically summarize the screening history of members (Fig. 1).

By mid-year 1996, KPNW had introduced inreach in all primary care offices. When breast and cervical cancer screening history was absent from the Results Reporting System (indicating no internal record of an examination), clinical assistants were expected to ask prescribed questions related to the patient’s history and to note exclusions.

Characteristics of Women in the Safety Net

Once the Safety Net had been in place for a few years, we began to notice some distinct characteristics of unscreened women and to detect some changes in screening performance within the Region. We began to appreciate the unique qualities of women who, for whatever reason, have remained unscreened in spite of national and local efforts to emphasize the importance of screening and early detection of cancer. Although the characteristics of unscreened women are now being regularly reported in the literature,10-12 we have the opportunity to both substantiate research findings and offer new insights from an applied, managed care setting.

Women examined in the Safety Net are drawn from a pool of members who have met local guideline specifications for gender and age as well as criteria for continuous enrollment in the Kaiser Foundation Health Plan. After all eligible women are identified, those with documented permanent exclusions are eliminated from the pool, leaving a group of unscreened women who will be recipients of outreach and inreach efforts for the duration of that year.

In 1997, women in the Safety Net made up 23% of all our KPNW members eligible for breast cancer screening and 22% of women eligible for cervical screening services.

Women with No Clinical Encounters

One characteristic we found in most women in the Safety Net is their infrequent pattern of primary care visits. This pattern is particularly true for women in the cervical cancer Safety Net.

A significant portion of women in the Safety Net had no clinical visit during the previous year (52% for cervical cancer screening; 40% for breast cancer screening). This portion is far greater than that reported for the entire KPNW population (35%). These data support previous findings that women who do not get screened do not have regular health care visits.13 The fact that nearly half of women at risk have not sought an appointment within a year suggests that some women perceive barriers to seeking primary care services, particularly women who remain unscreened for multiple years. This subpopulation, whom contact reminders—no matter how numerous and no matter how conveyed—do not convince, poses a unique challenge, and we must consider different strategies to better understand and reach this population.

Women who Remain Unscreened after Clinical Encounters

One group we have closely watched are women with a primary care visit who do not get screened. These women either slip through our inreach efforts or defer the invitation to be screened. Our data systems do not allow us to determine the precise reasons screening does not occur during the course of a clinical encounter, but our exclusion data do offer us some explanation about why women don’t get screened (Table 1). However, we are unable to determine whether the decrease in cervical cancer screening for women with clinical encounters is due to improved intervention efforts or to better documentation of permanent exclusions among these women.

<table>
<thead>
<tr>
<th>Year</th>
<th>Breast Ca Screening</th>
<th>Cervical Ca Screening</th>
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<tbody>
<tr>
<td>1996</td>
<td>2,317 (28%)</td>
<td>5,325 (37%)</td>
</tr>
<tr>
<td>1997</td>
<td>2,202 (26%)</td>
<td>3,316 (23%)</td>
</tr>
</tbody>
</table>

Women Affiliated with a Primary Care Clinician

More than two thirds (68%) of all our KPNW members report an affiliation with a specific primary care clinician. Women in the cervical cancer Safety Net are less likely to affiliate (60%) than the member population, although the percentage varies greatly among medical offices—from as low as 46% to as high as 84%. For reasons we do not understand, the percentage of affiliated women within the breast cancer Safety Net (70%) more closely matches the affiliation rate in the member population.

Women with Longevity in the Safety Net

We have found that this year, 1998, the largest proportion of women in the Safety Net have been there since the list was first generated in 1995.
Breast Ca Cervical Ca Screening Screening

First year in Safety Net 2,527 (40%) 4,513 (37%)  
Second year 1,011 (16%) 2,561 (21%)  
Third year 2,780 (44%) 5,123 (42%)  
Total 6,318 (100%) 12,197 (100%) 

The fact that we have a subset of women who are chronically unscreened in spite of our attempts to reach them is somewhat discouraging but an important factor to acknowledge as we continue to improve Safety Net efforts. A quick examination of these women by age and visit history shows little differentiation by number of years in the Safety Net. Insight into the "chronically unscreened" is not provided by the research literature. Given our ability to retrieve archived data on these women, we hope to segment unscreened women by the length of time they have remained unscreened and learn more in order to better understand them.

Impact of the Safety Net

The most important goal of this initiative was to improve delivery of breast and cervical cancer screening services. As outreach was implemented in early 1996 and inreach implemented later that year, we did not anticipate seeing any impact on performance until the end of 1997 at the earliest.

Screening Rates in the Safety Net

The screening rates for women in the Safety Net have been monitored for the two years of implementation. The figures below indicate that the screening rates of women in the Safety Net remained steady in 1996 and 1997. These screening figures are not unlike the screening ranges documented in the previously cited research studies. They also support Somkin's finding that increased screening rates after interventions are generally lower for cervical cancer than for breast cancer when similar techniques are used.

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<tr>
<td>1996</td>
<td>2,793 (34%)</td>
<td>3,058 (21%)</td>
</tr>
<tr>
<td>1997</td>
<td>2,733 (32%)</td>
<td>2,754 (19%)</td>
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The minor changes between 1996 and 1997 may be statistical variation or may reflect a true decrease in the screening rate. This population may be becoming harder to convince that screening is important as a greater proportion of women in the Safety Net have now been there for multiple years, and we have improved our ability to detect permanent exclusions and avoid misclassification of appropriateness for screening.

Regional Screening Performance

Even before the Safety Net was introduced, KPNW was collecting HEDIS (Health Plan Employer Data and Information Set) data for both breast and cervical cancer screening. In 1996, we began to measure performance according to KPNW's own local specifications, thus broadening the screening specifications for breast and cervical cancer to include all women to age 69 years (Table 2). (HEDIS screening data were originally limited to commercially enrolled women up to age 65 years.)

As the regional performance measures show, the Safety Net appears to contribute to improved screening performance in 1997-98. Some believe that improvements may derive from more systematic documentation of exclusions, particularly for Pap smear testing, rather than from an increase in screening the previously unscreened.

Early Detection of Cancer

The Safety Net must not only improve screening rates but must also detect cancer at a curable stage, particularly among women who may be at increased risk. The data compare the results of cancer screening in the Safety Net population to figures from the KPNW population as a whole, using incidence figures from the KPNW Tumor Registry for 1997.
Breast Cancer

In 1997, 24,826 (77.8%) KPNW women between the ages of 52 and 69 years were screened for breast cancer. Of these, 2733 were in the Safety Net. That same year, 184 analytic cases of breast cancer were diagnosed in these KPNW women, 33 of whom were among women in the Safety Net. When we adjust the rates of cancer per 100,000, we find that the breast cancer rate is similar to that in the KPNW member population (Table 3). The difference in cancer rates between the two populations is minor and may be due to the few cancers found in the Safety Net as well as to the screening efforts that have continued in the KPNW Program for many years.13

Cervical Cancer

In 1997, 53,620 women between the ages of 21 and 69 years were screened for cervical cancer; of these, 2754 were in the Safety Net. In the same year, 14 cases of cervical cancer were diagnosed in women in the Safety Net, half of them in situ and half invasive (three localized, three regional, and one distant). The age-adjusted rates show the rate of invasive cancers was more than ten times the rate in the KPNW member population, although the in situ cancers did not show a similar elevated rate (Table 4). We cannot be certain why the rate of invasive cervical cancer is high in the previously unscreened women, particularly without a comparable increase in in situ disease. Our findings indicate that risk factors for the development of cervical cancer include earlier onset of sexual partners, more partners, other sexually transmitted diseases, cigarette smoking, and lower socioeconomic class. Some or all of these factors may also keep women from attending screening. The cancer rates should be regarded as preliminary because they are based on relatively small numbers and on only one year’s data. They must be interpreted cautiously and be followed over time.

Discussion

Learnings associated with this project go beyond the quantitative data we’ve discovered about

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<tr>
<th>Table 2. Screening Performance for HEDIS and Regional (KPNW)</th>
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<td>1995</td>
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<td>1996</td>
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<tr>
<td>1997</td>
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<td>1998 Jan-June</td>
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* hybrid methodology, ie, measurement by chart review.

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<thead>
<tr>
<th>Table 3. Breast cancer detection rates, 1997</th>
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<tr>
<td>Safety Net</td>
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<td>Population</td>
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<td>Screened</td>
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<th>Analytic Cancers:</th>
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<td>In situ</td>
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<td>Invasive</td>
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<td>Age-Adjusted Rates per 100,000:</td>
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<td>In situ</td>
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<th>Table 4. Cervical cancer detection rates, 1997</th>
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<td>Safety Net</td>
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<tr>
<td>Population</td>
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<tr>
<td>Screened</td>
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<th>Analytic Cancers:</th>
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<td>Invasive</td>
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<tr>
<td>Age-Adjusted Rates per 100,000:</td>
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<td>In situ</td>
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<td>Invasive</td>
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unscreened members and our ability to influence their screening behaviors. Like most other large-scale projects, the Safety Net has given us a number of organizational challenges and unanticipated learnings. These experiences have influenced ongoing design of the Safety Net.

Several of the Program goals set out in 1994 have been achieved. The Safety Net has delivered on its goal to improve effective prevention services, at appropriate intervals, to as many members as possible. The Safety Net also affords protection to KPNW from medicolegal risks by initiating and documenting outreach efforts to those at risk. One unanticipated and notable achievement has been our ability to monitor cancer outcomes among women in the Safety Net.

However, the Safety Net has been only partially successful thus far in delivering prevention services in as systematic and cost-effective a way as possible. And we have encountered several systemic issues that require our continued attention and negotiation with other KFHP and medical departments. Some of these include:

**Exclusions**

Exclusions for performance measurement are generally specified by HEDIS or another sponsoring organization. There is, however, no such internally agreed upon use of exclusions for the Safety Net, and ideas about the best way to treat Safety Net exclusions continue to generate considerable debate among clinicians.

KPNW has taken the position that women with permanent exclusions—bilateral mastectomy, hysterectomy, membership lapse, permanent medical limitations, or terminal illness—are ineligible for the Safety Net—even if those exclusions are not recognized in HEDIS performance measurement. In contrast, temporary exclusions—refusal by women to undergo tests, evidence that tests were performed outside KPNW, existence of a temporary medical condition—do not eliminate a woman from the Safety Net list.

**Access for Women in the Safety Net**

In spite of our efforts to facilitate appointment-making for women who respond to the outreach letter, we have been frustrated in our slow progress to assure their quick access to screening. We have only partially succeeded in finding a consistent, reliable method of identifying these women when they request clinical appointments. We must continue to work to eliminate any barriers to these women when they call in or arrive for appointments.

**Overscreening**

One discovery of the Safety Net was the extent to which we were screening women who had documented hysterectomy. Although regional guidelines state that women do not need Pap smear screening if they have had a hysterectomy for benign conditions, we found that in one of our local markets, more than half the women with documented hysterectomy also had had a Pap smear within the past three years. This finding raised questions about whether we are overexcluding or overscreening women. Women excluded from screening have expressed confusion about their need for regular gynecologic examinations. As a result, we are modifying our communication to women, distinguishing better between cervical cancer screening and other screening examinations.

**Uncoordinated Outreach**

A continuing challenge has been KPNW’s efforts to coordinate its outreach contacts. Currently, a patient who is in both the Safety Net and the Diabetes Registry, for instance, may receive separate reminder calls or letters instead of one. Not only is this an inefficient use of resources, but it also alienates members, who perceive that the right hand knows little or nothing about what the left hand is doing.

**Complexity of Unscreened Population**

Until recently, we have considered unscreened women as a single entity and the strategy for promoting breast and/or cervical cancer screening as the same. However, we may not be able to continue this assumption because fewer of these women (<10%) require both services, and women needing only cervical cancer screening are emerging as distinct in several ways. Besides the fact they are a much larger cross-section of our membership, they are more likely to be excluded from future screening, are less likely to be affiliated with a primary care physician, have fewer clinical encounters with the health care system, and seem less likely to respond to our attempts to encourage screening. The growing public awareness of breast cancer and media appeal for women to get mammograms is one possible explanation. Another may be that cervical cancer is not perceived to be as much of a threat. All these factors must be considered as we examine our continued participation in Safety Net activities.

**Conclusion**

Our preliminary findings give us a new appreciation for the complexity of influencing screening behaviors, particularly among women who are continually resistant to our outreach and inreach efforts through the Safety Net. Reasons for this resistance, probably due to a diversity of demographic, psychosocial, and organizational factors, will need to be better understood in the future if we are to identify...
new strategies to reach unscreened members. Our experience has influenced not only design and implementation of this single Safety Net initiative but the organizational systems that support KPNW’s clinical service delivery. We are encouraged by the potential of the Safety Net as a potent strategy to better understand the processes and outcomes of preventive as well as other population-based screening services...and all before the year 2000! ❖

Acknowledgments: The author acknowledges members of the MMDP Team #8 from KPNW, August 1991, who formulated the initial goals and planned early development of the Safety Net: Tom Vogt, MD, MPH; David Moiel, MD; Steve Gordon, MD; Mary Anne Hannibal; Jamie Forsythe; David Stokey.

Several people made major contributions to further development and implementation of the Safety Net initiative: Deborah Harris; Beverly A. Battaglia; Andy Glass, MD; Béle Sesh; Danielle Engels.

### Safety Net Timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tr>
<td>1991</td>
<td>Middle Management Development Team proposes “Safety Net: A Centralized Risk Registry for Prevention and Early Detection Outreach” to senior managers</td>
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<tr>
<td>1994</td>
<td>Safety Net Initiative adopted by Prevention Steering Committee</td>
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<tr>
<td>1995</td>
<td>Infrastructure developed; First Safety Net list generated; Outreach pilot tested</td>
</tr>
<tr>
<td>1996</td>
<td>Outreach initiated for all women needing “Mamms” and “Paps”; Inreach initiated (mid-year)</td>
</tr>
<tr>
<td>1997</td>
<td>First full year implemented; First outcomes documented</td>
</tr>
<tr>
<td>1998</td>
<td>Safety Net implementation maintained</td>
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### References


### CMI Endorsed Successful Practice: Cervical Cancer Screening Program

The Care Management Institute (CMI) has recently endorsed the Northwest Region’s Cervical Cancer Screening Program, “Safety Net,” as a successful practice. CMI established the Successful Practices Program as a means to identify highly effective and innovative programs within Kaiser and to help facilitate the program’s transfer and adoption to other sites. CMI evaluates the quality of the program, ensures the approach is supported by evidence, assesses potential problems, highlights key program requirements and success factors, and summarizes the program in a succinct, actionable format. Endorsement of a successful practice refers to the process CMI uses to determine the program’s merit. Endorsed successful practices are subsequently disseminated via CMI’s implementation network to encourage rapid adoption and sustained implementation throughout Kaiser Permanente.
Recognizing that excellence in clinician-patient communication can improve the medical care of patients and provide strategic benefits to a health care organization, KP’s Interregional Clinician-Patient Communication Leadership Group regularly assembles some of the best leadership and communication expertise from across KP to enhance the day-to-day communication skills of our clinicians. This article describes the importance of excellent clinician-patient communication, and the membership, goals, and activities of this interdisciplinary group.

Introduction

Once a month, Kaiser Permanente clinicians, educators, and researchers from across six time zones meet by phone to talk about clinician-patient communication. We grapple with such questions as:

- Our primary care departments are switching to team-based care. What communication skills will be needed by the clinicians to explain changes in their role, make smooth referrals, and use the telephone as an alternative to in-person visits?
- As health care outcomes, quality, utilization, and patient satisfaction are more closely monitored, many clinicians are becoming concerned about their increasing professional and financial accountability for their practices. How can improved communication skills make a difference?
- Available time for medical visits seems to be decreasing. What specific skills could help clinicians manage time pressures?
- Some clinicians have good technical skills but do not relate well to patients. What resources are available for these clinicians?
- We need clinicians with excellent patient communication skills. How can KP recruit more clinicians with superior “people skills?”

These types of issues are addressed by our Interregional Clinician-Patient Communication Leadership Group during monthly conference calls. Our multidisciplinary group represents every Permanente Medical Group in the organization (Table 1). Because we are geographically scattered, we function primarily as a “virtual” group. Our group works under the leadership of Terry Stein, MD, Director of Clinician-Patient Communication in TPMG in Northern California, with sponsorship provided by Jill Steinbruegge, MD, Associate Executive Director of Physician Development of The Permanente Federation.

Impetus for the Group’s Formation

The need for convening this group became clear to Dr. Stein after the CME workshop, Thriving in a Busy Practice, was introduced to KP clinicians in North Carolina, Colorado, the Northwest, Texas, the Northeast, and Hawaii: she realized that coordinating efforts and sharing ideas about clinician-patient communication across the Program could be productive, cost-saving, and fun. In fact, when the group met for the first time in November 1996, we were impressed that our needs were remarkably similar.

Acknowledging that excellence in clinician-patient communication can improve the medical care of our patients “one conversation at a time” and provide strategic benefits to KP, we created a mission statement to show how our interregional group is prepared to leverage the leadership and expertise from across the Program to enhance the communication skills of our clinicians:

The mission of the Interregional Clinician-Patient Communication Leadership Group is to ensure that excellence in clinician-patient communication becomes a distinguishing feature of care delivery throughout Kaiser Permanente, is accepted as a critical aspect of clinical practice, and is recognized as a major contributor to organizational success.

Patients Don’t Care How Much You Know Until They Know How Much You Care

George Engel said that “the interview is the most powerful, sensitive, and versatile instrument available to the physician ...!” Despite the emphasis on new technologies and new medications, the medical interview with the patient remains one of the most
important tools available to health practitioners. “Before anything else, a good doctor must be a good communicator.”

The interview is also our most common clinical procedure: a physician conducts more than 150,000 medical interviews during a practice lifetime. Clinician-patient communication is a critical element of Permanente Medicine and reflects our values as caring people.

However, despite the acknowledged importance of good communication with patients, many clinicians believe that their communication skills can be improved. For example, in a 1997 national survey, 61% of 230 primary care physicians agreed that they were not well prepared by medical school or residency for the challenges of physician-patient communication.

The increasing sophistication of consumers means that skills such as attentive listening and collaborative decision-making between clinician and patient are becoming even more essential. As stated recently by Richard Barnaby, KFHP/H California Division President, “Our challenge is to continue to treat each patient as an individual by listening and caring. We’re doing it well, but the bar of expectations keeps rising.”

### What Difference Does Good Communication Make?

A growing body of literature shows that the way clinicians relate to patients has a major influence on patient behavior and health, clinician and patient satisfaction, and the number of malpractice actions. Multiple research studies have shown this impact on critical aspects of care such as diagnostic accuracy, adherence, and health outcomes. For example, when clinicians communicate effectively, patients are more likely to convey their main concern, to adhere to prescribed medication regimens, and to follow instructions. Communication also influences clinician and patient satisfaction as well as health systems management.
Myth #1

The problem isn’t my communication skills. The problem is that I don’t have enough time to spend with my patients.

Time pressures can be enormous and truly can impede the best intentions to communicate well. There simply needs to be enough time with each patient to sit down, to focus and listen attentively, and to discuss diagnosis and treatment.

Well-honed communication skills are even more important for interacting with patients, because time constraints make every second count. Skills such as setting patients at ease rapidly, eliciting patients’ concerns at the outset, and using empathy won’t add time to the day, but these skills will help visits go more smoothly and can enhance patient and physician satisfaction.1

How much time do “patient-centered” listening skills take? On average, less than one extra minute, according to one study.2

The quality of the interaction can affect patients’ perceptions of time. In a classic study by Barbara Korsch, MD,3 patients who were satisfied after a visit tended to overestimate the time the doctor had actually spent.

The problem isn’t my communication skills. The problem is that I don’t have enough time to spend with my patients.

In contrast, patients who were dissatisfied complained that the doctor had seemed in a hurry, even when visits were long.

patients. On the business side, effective communication is linked to our competitive strategy and our continuing success as a health care provider.

One of the most important research findings has been that clinicians' subjective experience of practicing medicine can be enhanced by learning better communication skills. Research on two interventions offered in KP-Northern California assessed clinicians' perceptions of patient interactions after the clinicians received specialized communication training. In the first study, three months after participating in the one-day CME Workshop Thriving in a Busy Practice, clinicians from more than 20 programs (n = 911) reported having fewer frustrating patient visits (p < .05). In the second study, several months after participating in the five-day Communication Skills Intensive Program, clinicians described more enjoyment when seeing patients, despite the ongoing time constraints. After attending the Communication Skills Intensive Program in 1997, Mira Kaplan, MD, Chief of Allergy at the KP Medical Center in Oakland, reported: "I've found that I'm able to express more of who I am with my patients and not be as removed as I thought I had to be. I get more satisfaction out of the visits now. Thanks to all the practicing we did in the course, when I encounter a difficult patient, I say to myself, 'I've seen this before,' and I know that I'm going to be able to get through it."

Another KP study underscored the importance of training and feedback as a means of giving clinicians insight into the level of their communication skills. In a study of 261 diabetic patients and their 44 personal physicians, questionnaires were distributed immediately after office visits. A direct correlation was seen between how patients perceived the communication and patients' overall satisfaction, but patients and physicians did not agree on the quality of communication that had just taken place. These findings suggest that although patient satisfaction is linked to their perceptions about quality of communication, physicians may require training or feedback to help them determine how well they are relating to their patients.

Patient satisfaction has also been shown to increase when clinicians receive feedback on their communication skills. Al Mehl, MD, from the KP-Colorado Region, tracked Art of Medicine scores for ten physicians who participated in an individual feedback process in which actual visits with patients were observed and specific suggestions for improvement were provided. In each case, scores improved during the next six months (Mehl A, personal communication, August 1998). Similarly, for the Communication Skills Intensive Program in KP-Northern California, during which clinicians receive detailed feedback on patient interviewing, members' survey scores were significantly better (p < .01) in the six months after taking the course than in the six months before taking the course (Stein T, unpublished data).

Improving communication skills may result in fewer patients voluntarily terminating their membership because of dissatisfaction. In exit interviews with members who voluntarily left the Kaiser Foundation Health Plan (KFHP), dissatisfaction with their personal physician was cited by nearly one in four members (Hughes E, August 1998, personal communication).

Expert clinician-patient communication may also provide a distinct competitive advantage for KP. If managed care organizations in time achieve parity on premium costs and documented quality measurements, some experts believe that the factor differentiating these organizations may be the level of service perceived by purchasers.

Finally, honing communication skills can be important for KP's public image. Amid the prevalent consumer fear that close ties with physicians are being lost in this era of managed health care, community

Myth #2

If I just give the patients what they want (tests, drugs, referrals, work excuses), then I'll score better on satisfaction surveys.

Logical enough! But research shows a more complicated picture.

One study found that if physicians asked for patients' requests and then listened attentively, patients were more likely to be satisfied regardless of whether their requests were granted. Another study looked at patients who expected medical tests to be ordered during an upcoming visit. Their satisfaction as reported after the visit correlated not with whether tests were actually ordered but with the extent of their physician's humanistic qualities.

These studies suggest that the interaction between physician and patients regarding patients' requests can have greater impact on satisfaction than simply saying "yes."

3. Colorado Permanente Medical Group, Boulder, Colorado
4. The Permanente Medical Group, Oakland, California
5. Director, Risk Management, Kaiser Permanente Walnut Center, Pasadena, California

"... the real push to improve physician communication will probably come from patients who are fed up with 'doctors who won't listen' and managed care organizations that view patient satisfaction and physician satisfaction as good business. Isn't it time that the profession embraces as worthy of its best talent and energy, the core clinical skill of dialogue?"

F. Daniel Duffy, MD, American Board of Internal Medicine.
Examples of Permanente Educational Workshops and Programs

**Video Visits:** A set of one-hour interactive programs designed to stimulate group discussions about communication with challenging patients. The set includes eight video vignettes, a facilitator guide, and a participant workbook.

**Thriving in a Busy Practice, Part 2:** A one-day workshop focusing on medical interviewing skills, nonverbal communication, and dealing with conflict. The workshop includes interactive discussions and small group practice sessions with actors, short lectures, and demonstrations.

**Appointment With Success:** A one-day workshop focusing on the medical interview process and some challenging clinician-patient interactions. This program uses actors to simulate individual cases so that physicians can practice new strategies.

**Director Observation Tutorial:** A focus on the communication skills of individual physicians. A physician’s interaction with patients in the examination room is observed by a consulting physician for half a day. Feedback on the observed behavior is reviewed in a subsequent consultation.

**Video Coaching:** A half-day program to refine the communication skills of individual physicians. A physician’s interaction with an actor-patient is videotaped, and the interaction is subsequently reviewed and discussed with a trained interaction coach.

**Communication Skills Intensive:** A five-day residential program with four-month follow-up. The content focuses on specific communication behaviors, including videotaped practice with actors, and on how personal and family history can affect interpersonal style.

**Thriving In a Busy Practice, Part 3:** Communicating for Health Behavior Change: A one-day workshop that presents a collaborative approach for discussing with patients their lifestyle and adherence issues according to patients’ readiness to change.

*For more information about these and other programs, contact your representative from your Medical Group [See Table 1]*
We are becoming increasingly aware of new types of clinicians, other health care practitioners, and health care delivery teams that have different communication needs and challenges. Some examples are the hospital-based specialist and the health care teams emerging from primary care redesign efforts. These practitioners will constitute new audiences for our efforts to improve clinician-patient communication skills in our Program.

In addition, we intend to help identify and implement the best methods of recruiting and retaining clinicians who have superior communication skills. Our group will work with medical group leaders to find strategies for attracting and retaining clinicians who are highly motivated and skilled in effective communication.

Finally, because customized care requires effective communication, we will be a resource to the organization as it implements the new KP Promise.

**Conclusion**

These are challenging and exciting times for Kaiser Permanente. As we move into the next millennium, we must return to the core skill of our medical practice and focus on enhancing communication with patients, one conversation at a time, in order to attain a high level of excellence throughout KP. By improving the medical care we give, increasing our work satisfaction, and enhancing our community image, this focus on effective communication can provide us with a major competitive advantage. The Interregional Clinician-Patient Communication Leadership Group strives to be a valuable resource to our organization by 1) highlighting the impact of communication skills on medical care and on our major business imperatives, 2) designing effective communication interventions, 3) coordinating implementation of these interventions across the Program, and 4) addressing future communication needs. In these ways, we hope to realize our vision of excellence in clinician-patient communication.

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**References**


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**Quotes from the National Quality and Learning Conference, November 1997**

“Ultimately, the two dimensions of quality—the technical, medical kind that we’re used to focusing on and the human experiential kind that’s in some ways even harder to deal with—must be brought together.”

Francis J. Crosson, M.D., Executive Director, The Permanente Federation

“We’re going to get tugged and pushed in all sorts of directions, and we always have to ask ourselves, ‘Does the way we’re doing it enable us to provide superior medicine to individuals in a supporting, caring, even loving way?’ That’s what we’re about: That’s our challenge together—to hold ourselves to that standard.”

David Lawrence, M.D., Chairman and CEO, Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals

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“As we move into the next millennium, we must return to the core skill of our medical practice and focus on enhancing communication with patients, one conversation at a time, in order to attain a high level of excellence throughout KP.”

TERRY LASKIEWICZ, M.D., is a Board-certified internist and has worked in the internal medicine and trauma clinic for Northwest Permanente (NWP) since 1988. She has been drawing and painting for eight years, and continues to explore the internal emotional landscape as well as the balance of beauty and conflict in the physical world. The painting shown above is untitled. To see another piece of her work, please turn to page 91.
The Permanente Knowledge Connection: A National Strategy for Clinician Use of Web Technology
Report of The Web Integration Council - Clinical Subcommittee

Introduction
Kaiser Permanente (KP) has a wealth of intellectual capital unmatched by any other health care system. During the recent past, Regions have been capturing this information—cataloging best practices and guidelines on web sites, building electronic data bases, and designing online decision support tools—at a bullish rate that may have outpaced the stock market. But the knowledge is located in regional pockets; finding a way to make this knowledge quickly and easily accessible to clinicians across the Program has been troublesome. In late 1997, the Web Integration Council was formed to explore how to make use of emerging Internet technology and bring consistency to web efforts throughout KP nationally. A Clinical Subcommittee, formed within the Web Integration Council, was charged with the task of developing a unifying strategy that could mine this intellectual wealth and leverage it in a way that would promote the practice of Permanente Medicine and, in turn, support the Kaiser Permanente Promise, focal point of the National Brand strategy. The Clinical Subcommittee produced a position paper and a corresponding business case for its proposal. In August of 1998, the Web Integration Council accepted this proposal and funded the project, to be known as the Permanente Knowledge Connection (PKC).

PKC will be a website accessible to any KP clinician with an Internet connection. The benefits include:

- **A single doorway for accessing all clinical information:** No more confusion will exist about whose site to go to or where to find what is needed. There is now a single location to access everything.
- **Relevant and current information:** No more doubt will arise about what is the most recent guideline or the latest word on congestive heart failure treatment. The website filters out the unnecessary and provides the information clinicians need.
- **Navigation tools:** A national search engine allows access to KP National and Regional clinical resources, including clinical practice guidelines, patient education pamphlets and tipsheets, best practices, key learnings, funding sources, and outcomes studies. The navigation tools also enable distinction between KP national and regional information so clinicians can see at which level each resource has been approved.
- **National online resources:** Not only will there be access to MEDLINE, The Physicians Desk Reference, The Merck Manual, and other top Internet resources, but also to online journals, medical news, medical textbooks, discussion groups, and work groups.
- **National online continuing medical education (CME) testing:** Clinicians can earn credits at home, on the road, or from other sites, while at the same time learning about KP National clinical guidelines for congestive heart failure, coronary artery disease, asthma, diabetes, and depression. Other computer-based training will follow such as evidence-based medicine tools.

**KP Intranet employee resources:** Phone directories, KP Stat, Kaiser Foundation Health Plan/Hospitals (KFHP/H) and Permanente Medical Group news and communications will be included.

In addition, this position paper outlines increasingly sophisticated functions that will be developed for later versions of PKC. These more advanced versions will make it possible to push information to users so that clinicians can be notified easily of changes in practice and new findings. PKC will eventually link with National Clinical Information Systems to obtain information from patient records, access formularies, view benefits, virtually link with National Clinical Information Systems Program Offices. E-mail: peter.juhn@kp.org

**Web Integration Team:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Location/Group</th>
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<tbody>
<tr>
<td>Paul V. Biron</td>
<td>Southern California Region</td>
</tr>
<tr>
<td>Homer Chin, MD</td>
<td>Northwest Permanente, PC</td>
</tr>
<tr>
<td>Bob Dolin, MD</td>
<td>Southern California Permanente Medical Group, National Clinical Information Systems</td>
</tr>
<tr>
<td>Ed Dyer</td>
<td>Care Management Institute</td>
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<tr>
<td>Tom Janisse, MD</td>
<td>Care Management Institute</td>
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<tr>
<td>Peter Juhn, MD (co-chair)</td>
<td>Ohio Permanente Medical Group, Inc., National Clinical Information Systems</td>
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<tr>
<td>Allan Khoury, MD</td>
<td>Kaiser Permanente Information Technology</td>
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<tr>
<td>Ric Leopold</td>
<td>Kaiser Permanente</td>
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<tr>
<td>David Levy, MD</td>
<td>The Permanente Medical Group, National Clinical Information Systems</td>
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<tr>
<td>Henry Neidermeier</td>
<td>Kaiser Permanente Information Technology</td>
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<tr>
<td>George Peredy, MD (co-chair)</td>
<td>The Permanente Medical Group, National Clinical Information Systems</td>
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<tr>
<td>John Vogt, MD</td>
<td>Permanente Medical Association of Texas</td>
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(pictured) PETER JUHN, M.D., is the Executive Director of Kaiser Permanente’s Care Management Institute at the Program Offices. E-mail: peter.juhn@kp.org

GEO R G E PEREDY, M.D., joined the Emergency Medicine Department, Santa Clara, California, in 1989. He has been a principal developer of several Clinical Information Systems (CIS) for KP. He is currently Director of TPMG CIS and a Director of National CIS.
Clinical Intranet Strategy

The number of sites on the Internet created by or directed at clinicians has recently exploded. This explosion indicates extreme interest by health care community members in using the Internet to increase knowledge and communicate with each other. Also clear is the opportunity for KP to take a proactive, organized approach to how we utilize this powerful tool.

The recommended approach is to create PKC as a KP National Clinical intranet populated by local components. A set of core KP national requirements will be met with additional functionality left to the discretion of regional Medical Groups and Local Market Areas (LMAs). A LMA lacking sites will be provided technical assistance for developing a site consistent with these KP national standards.

A review of the various applications and content either present or under development on local intranets within KP reveals an impressive array of information, both static and interactive. In addition, information about similar content (ie, clinical practice guidelines, human resource policies, telephone directories, management reports, formularies, data base queries, transaction processing applications, etc) is evolving at exponential rates, utilizing multiple forms of technology, languages, and software.

Consequently, multiple initiatives are underway to produce the same kind of information. These efforts result in unnecessary duplication of effort and unnecessary consumption of vital resources.

A process for leveraging development of content and functionality across KP nationally is highly desirable. The goals of this process are to:

1. Identify best practices in the production of various types of information.
2. Facilitate and underwrite the production costs and deployment of such information from best practice sites to other sites in the PKC environment in an efficient and expedited way.
3. Develop consistency in web information development practices and enhance developer skill sets through KP national-level training support to shorten development timelines.
4. Underwrite and facilitate innovation through deliberate support of research and development of new types of information and communication capability at selected sites around the corporate enterprise.
5. Explicitly measure and report cost-benefit of such development using consistent measurement tools to justify further robust investment in web technology.

Implementation of a central clearinghouse for web content development funded at the National level will facilitate these goals. Participants will be development champions from various websites around the enterprise. Project demonstrations, code, software capabilities, training modules, and identified future information requirements will be part of this clearinghouse activity.

Because national-regional-LMA-and facility-level content will coexist on the PKC, a hierarchy for classifying content is needed. Documents or other forms of clinical web content will carry this hierarchical classification scheme as part of the meta-data (attached generic description of document components) associated with the content itself. (See Appendix I for more information on the hierarchy classification scheme.)

This strategy both creates national consistency and leverages development done at a local level. Further, nationwide sharing of content will reduce practice variation and facilitate spread of innovation. The connectivity also creates the ability to quickly disseminate information to Permanente clinicians nationwide.

Content and Functionality

Recommended Content

The Clinical Subcommittee identified and prioritized a set of 30 content elements, rating them on a scale of 1 (highest priority) to 3 (lowest priority). The following list includes items that have been designated as highest priority because they are considered requirements of an effective intranet/Internet for clinicians and will have a National component to their development.

Clinical Content

- Clinical practice guidelines: both evidence-based and consensus-based guidelines that have been approved by a KP Divisional or National process. These include practice, process, and benefit guidelines.
- Clinical protocols: specific steps that KP staff take in interacting with a patient. Protocols may draw from all types of guidelines (practice, process, and benefit). An example of an appropriate set of protocols for PKC would be National Call Center nursing protocols.
- Case management protocols: for example, outlining for nurse practitioners care for patients post-discharge and before the first clinical appointment.
- Patient education materials: for example, description of exercises for alleviation of back pain.
**Interactivity**

- "Webside" consults: The use of electronic mail to enable physicians to advise each other in interactive online consultation. A desirable feature for consult capability would be the expectation for a prescribed response. For example, a physician may expect 24-hour response, or even 1-hour response. Another option would be to include chat functionality so that providers could have real-time, informal electronic exchanges. (See Appendix II for greater detail.)
- Interdepartmental clinician communication, or discussion groups: online threaded discussions allowing clinicians to communicate ideas with colleagues in other departments and facilities.

**Information**

- Utilization information: access to utilization information at facility, department, and provider levels with the ability to graphically compare this information across comparable entities.
- Medical textbooks: access to selected online textbooks that are easily navigable and searchable and that rely upon graphical and other multimedia learning tools.
- Medical news: technology that accesses both intranet and Internet wire news services and provides clinicians with current, relevant news specific to their individual needs. This element could be integrated with a personalized homepage.
- Phone books and organization directories: information, including department and facility name, e-mail and fax number, for all KP employees and clinicians.

**Applications**

- Population management applications: software to enable case managers to track and manage a patient population, ie, through data collection, decision support, notification.
- Web development applications: online, facilitated website development and hosting that provides clinicians and other site developers with tools and recommendations for creating their own websites or for placing content on the intranet. New content and sites are integrated with dynamic indexing and searching to update the intranet data base.

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**Recommended Technical Functionality**

The list of recommended content gives rise to specific technical functions that are required to access and use content.

**Navigability**

- Finding the most relevant information can be greatly enhanced by taking advantage of evolving search and retrieval technology. Some of the most efficient document retrieval techniques rely on the use of the attached meta-data describing key aspects of that document, such as AUTHOR, TITLE, DATE-OF-CREATION, KEYWORDS, ORIGINATING-DIVISION, LEVEL-OF-APPROVAL (see Appendix I), and DOCUMENT-TYPE. The values for many of these meta-data items can be constrained to a list of predetermined choices, thus enabling more focused document creation and enhanced retrieval. (See Appendix III for more detail on the document retrieval strategy.)

**Web Development Applications**

- Online authoring tools, templates, and recommendations should be available to assist clinicians with developing and submitting their own intranet content. Submitted content should be quickly and automatically incorporated into the intranet database, particularly with respect to meta-data tags and searching and to dynamic indexing. An approval process will determine which submitted content receives Nationally Approved status.

**Links to Outside Resources**

- Clinical resources will be made available through licensing arrangements with outside vendors. In many cases, allowing access to vendors through the conventional Internet may be advisable rather than mirroring them on the KP Intranet. The Physicians Desk Reference, The Merck Manual, MEDLINE searching, and journal abstracts from the National Library of Medicine and other reputable publishers are a few examples of content owned by other organizations. A security scheme will maintain the protected intranet environment without unnecessarily limiting access to the breadth of online resources.
Dial-in Capability
- Many clinicians still do not have access to online materials from their offices. Further, clinicians with computer access may not have time to use online resources due to time constraints of a clinical schedule. Access to intranet materials should be made available, through secure dial-in, to clinicians at home or when traveling. The security scheme, called an extranet, will maintain a protected intranet environment but still provide access from outside the office.

Discussion Functions
- Clinicians will have access to threaded, topical discussion groups where they can ask questions, exchange information, and obtain feedback from their colleagues. A means to consult with colleagues and specialists also should be developed, as well as the ability to communicate online with a patient. (See Appendix II for greater detail.)

Multimedia Functions
Computer-based training, multimedia learning tools, and the ability to earn continuing medical education (CME) credits online will be developed. Such activities will use technology to seamlessly integrate intranet content and resources with multimedia skills-testing and directed learning. A network capable of supporting transfer of multimedia content (large files in a variety of formats) from servers to clinicians' computers will be developed.

Operational Plan
Funding
- The source of funding for the national clinical intranet will be through KP National budgets such as KP Information Technology (KP-IT), NCIS, or CMI. National funds will also be provided for building local sites provided there is agreement to adhere to the KP national standards. Each KP Local Market Area will be responsible for the funds used to expand existing local functionality.

Governance
- PKC, the KP National Clinical Intranet, will be governed by a National Clinical Web Integration Council with representative members from each Medical Group nationally. The Council will determine policy and serve as the decision-making body for the effort. This group will also have responsibility for approving content. Recommendations for National content will be submitted to the Council from groups of experts in the relevant areas. For example, all KP Health Education Directors might submit a set of patient tip sheets for inclusion.

Staffing
- A webmaster will have responsibility for daily monitoring and maintenance of the PKC, including technical support, user authentication, tracking use, errors, and updates, and troubleshooting. A librarian will oversee content acquisition and the approval process. Responsibilities include working closely with the council on policy to identify priority content areas and contacting appropriate experts for submissions. The librarian will also have responsibility for organizing and indexing approved content.

Risks and Potential Barriers
Political Barriers
- Several political barriers currently impede achieving consensus on national efforts by LMAs. Nationwide consistency has been problematic due to local reluctance historically to abdicate responsibility to a national initiative. Mitigating this tension is the emergence of several important KP national projects such as NCIS and CMI. The success of these initiatives should alleviate some of the historical concerns regarding projects that require national uniformity. The other mitigating factor is the recommendation of an approach which balances national and LMA needs.

Financial Barriers
- The reality of the current financial performance of KFHP/H has resulted in a budget cycle for 1998 in which many initiatives are competing for scarce resources. Despite the strength of the case for building the PKC, obtaining funding may be difficult. However, this barrier is offset by the commitment of senior leadership to move toward greater national consistency and their recognition of the importance of this effort.

Operational Risks
- The accuracy and currency of the information on the intranet is critical to its success.
In a rapidly changing organization and health care industry, information quickly becomes outdated. To avoid this potential barrier, a process to ensure that the information is credible, current, and relevant will be established.

**Technical Risks**
- Like the rapidly changing content, the technical aspects of the intranet also quickly become obsolete. To avoid building a tool with a limited life span, we will use flexible architecture and conduct constant surveillance regarding trends in the industry.

**User Barriers**
- Numerous barriers exist to clinician use of the PKC. For example, access to the intranet and some basic level of computer competence are minimum requirements. Once those requirements are met, clinicians must be educated in the capabilities of the tool. Demonstrations of the value of the content and its ready accessibility create an incentive for use. Communication and education are crucial, as is the ability to customize the tool to the needs of each user.

A final potential risk is of user malfeasance, for example, the submission of harmful applications or inappropriate content. To limit the extent of potential damage, we will limit the types of files that users can submit and install antivirus software. To limit the risk of inappropriate content, we will implement a content monitoring process and encourage accountability for content submissions. To mitigate risks from former, disgruntled employees, a process for maintaining the database of current users and revoking access privileges when necessary will be established.

**Outstanding Issues**
A process should be established to identify, investigate, and manage future outstanding issues. The issues identified to date include the following:

**Support**
- The support process for the PKC will differ from the local support mechanisms, but the source and structure of support remains an outstanding issue. On both the national and LMA level, the questions of how and by whom support will be provided need to be addressed. One consideration is how much of the national support will fall within the scope of NCIS.

**Clinical Data**
- If and how clinical data will be incorporated into the PKC remains to be resolved. An investigation of the feasibility and necessity of pulling data from the clinical data repository will need to be undertaken.

**Quantification of Benefit**
- For a comprehensive business case, more thorough analysis is necessary of the impact of a national solution to identifying factors that drive KP’s business. Although this position paper identifies some key benefits, we have not attempted to assess the magnitude of the impact of an intranet.

**Security**
- A web security policy is currently being created by the KP National Web Integration Team that will cover a range of security subjects, including authentication, authorization, revocation, nonrepudiation, acknowledgment, privacy, and encryption. The Web Integration Council Clinical Subcommittee recommends that the PKC include these web development recommendations when they are made available.

**Meta-data**
- Meta-data can be used in a number of ways, depending on how the intranet and its information is to be used. We have given some examples of meta-data (Appendix III) in this position paper, but a more detailed strategy will need to be determined.

**Summary**
A national website, such as Permanente Knowledge Connection, is a complex undertaking that strives to make it simple and easy for clinicians to find clinically useful information. That the content is carefully chosen and refined, that the information will be immediately up-to-date, that the links and associations to the site will be highly functional, that the visual design is pleasing and engaging, all demonstrate the dedication and superior capability of Permanente clinicians to meet each other’s needs to improve our members’ healthcare experience.
Appendix I: Hierarchy of Content Approval for the Permanente Knowledge Connection (PKC) Intranet Web Environment

We recommend that clinical web content be classified according to the highest level of Kaiser Permanente (KP) approval that has been designated for that content. Advantages include:

- **Maintaining and updating content that can be attributed to the appropriate sponsor of that content.** These designations will ease tracking and will facilitate maintenance and updating processes.
- **Filtering and focusing search and retrieval of desired content to allow the user to control the levels of content being searched.** For example, if the national web environment contained at least content approved at the national and regional levels, then the user should be able to configure a search engine to first find relevant documents that are approved both nationally and by the user's home Region. If that failed, the user could then ask the search engine to search for relevant content approved by any KP Region.
- **Encouraging consensus by promotion of content to the next highest level of approval.** As different versions of similar clinical material are presented to users at one level (eg, at the Facility level or at the Regional level), then there may be an opportunity to recognize these differences and arrive at a consensus position. This process will be dynamic: a consensus document could then be relegated to either a higher or a lower level of the content hierarchy.

The following definitions are offered as a starting point for delineating useful designations:

- **National**—This designation would apply to clinical content that has been approved at the highest level of the entire KP organization by a body charged with setting standards for the organization. An example would be the National Health Education core documents that have been approved for all Regions to use by representatives from health education departments throughout the Program. Some other examples of bodies that could designate national approval of clinical content would include the Care Management Institute, National Clinical Information Systems, and The Permanente Federation, among others.
- **Regional**—This designation would apply to clinical content that has been approved by regionally sanctioned groups within a particular geographic region (eg, Southern California, Southwest, Hawaii, etc). Examples of bodies that could determine this designation include Regional Clinical Chiefs Groups, Regional Staff Education, Regional Health Education, and Regional Administration, among others. Current clinical practice guidelines for a variety of clinical problems are examples of content that currently is usually approved at the Regional level. Content designated Regional must be further subclassified according to which Region has approved this material. So a cholesterol management guideline from the Southern California Region may be designated Regional—Southern California.
- **Local Market Area (LMA)**—In the larger Regions, where the organization has been divided up into geographic business units called Local Market Areas (LMA), this classification may be applied. Again, this would need to be subclassified according to the particular LMA. Policies and Procedures for the North East Bay Local Market Area of the Northern California Region may be designated as being approved at the level of Local Market Area—Northern California, North East Bay, for example.
- **Facility**—In areas where KP staff is affiliated with a particular facility (in California, often a hospital and its satellite clinics are considered one facility), content may be approved at the facility level by Facility administration or at the departmental level. These may be subclassified according to Facility name (probably central Facility, not satellites) and Region. An example might be a referral guideline for referring patients from internal medicine to urology for diagnostic evaluation of hematuria that had been agreed to by both local departments. In this example, the referral guideline may be designated as approved at the Facility—Northern California, Walnut Creek level.

Appendix II: PKC Web Discussion Groups and Consults

A Web area on the KP Clinical Intranet, or Permanente Knowledge Connection (PKC) for interaction and exchange among clinicians could have two component areas: discussion groups and “webside” consults. The discussion group capability would be more of a web-based function, and the consultation capability would be more of an electronic mail function.

- **Discussion Groups:** KP Exchange, the existing KP clinical research bulletin board group discussion already exhibits this capability. After registering with KP Exchange, a physician can identify and create a subgroup of physicians (ie, interregional asthma experts or guideline directors) who are given password access to a protected area where they can communicate electronically and post draft documents or works-in-progress for discussion.
- **Webside Consults:** In Regions with electronic mail capability, physicians can advise each other via an interactive consultation function. When e-mail is integrated with the electronic medical record (as in the Northwest Region with EpicCare), then you have a true electronic clinical consultation function.

  This form of integration, however, does not require web-based utility. Even if this consult were accomplished on the web, it would require a secure and protected environment to function well, or at all, especially if patient information or clinical decision-making occurred. A desirable feature for consultation capability would be a prescribed response time. For example, a physician might expect 24-hour response, or even 1-hour response. This function would require on-call capability and continuous monitoring of an electronic mailbox. Another option would be to include chat functionality so that providers could have real-time, informal exchanges.
Appendix III: Optimal Document Retrieval over the PKC Intranet

The Permanente Knowledge Connection, or KP National Clinical Intranet can potentially become a mini-Internet, containing millions of online documents that must be waded through to find those most relevant to the user's information requirements. Providers need to find relevant documents among the millions that will be present on the Intranet, and they need to find them quickly. We want to direct providers to those documents that the KP organization feels are most important. Hard-wiring the links between the Electronic Health Record and all potentially relevant documents can be costly and will require ongoing maintenance. In many cases, this linkage can be dynamically determined by a sufficiently intelligent search engine that relies in part on the use of meta-data.

The amount of work necessary to associate meta-data with each document or document collection will vary. In some cases, we may apply meta-data to an entire document collection in a single automated step. In other cases, more extensive meta-data may be applied to individual documents. These meta-data elements (and sometimes the list of possible values) must be agreed upon for each document collection. An intranet search engine with the intelligence to use the meta-data elements agreed upon by KP will be required. User-friendly tools and templates will be created to make it as easy as possible for people to add meta-data elements to their documents. In many cases, document authors will create their content using their favorite word processor, and the computer will automatically extract meta-data. Such a process is illustrated by the Southern California Clinical Practice Guideline website (http://Kpweb.kpscal.org/CPG/)
Kaiser Works, Inc.: A New Way to Transfer Best Practices in Occupational Health

Introduction

Kaiser Works, Inc. is a management and consulting company created in April, 1996 to help Kaiser Permanente (KP) Divisions and noncompeting health care organizations improve occupational health (OH) and workers’ compensation (WC) services. Governed by a Board of Directors, this innovative organization—a for-profit corporation jointly owned by Kaiser Foundation Health Plan of the Northwest and Northwest Permanente, PC—is dedicated to collecting, interpreting, and sharing Best Practices in OH and WC. In the short period since its inception, Kaiser Works has aided six KP Divisions and two noncompeting health maintenance organizations (HMOs).

Basis for Kaiser Works, Inc.: Kaiser-on-the-Job

In the mid-1980s, KP Divisions were faced with the growing dissatisfaction of employers seeking effective OH/WC services. The Northwest Division’s (KPNW) experiences were typical: Employer costs were out of control (Oregon’s costs for medical benefits covering work-related injuries were the second highest in the United States), and surveys showed that employers were unhappy with the lack of timely communication, inconsistent case management, and haphazard emphasis on disability management and post-injury return-to-work efforts.

Although many of the factors necessary to provide high-quality OH services had been described, almost no research existed on how to develop OH/WC services within an HMO setting. Therefore, in 1986, without much external direction for assistance, KPNW began its own efforts to improve its OH program. After consulting with OH specialists and evaluating internal capacities, KPNW decided to reorganize OH services by creating OH specialty clinics. From 1987 through 1993, KPNW opened nine such OH clinics throughout Southwest Washington and Northwest Oregon. The clinics were staffed with a core group of board-certified OH physicians and a team of physicians specializing in family practice, emergency medicine, physical therapy, orthopedics, and psychiatry. Each clinic employed a lead nurse with formal occupational health training and several board-certified Occupational Health Nurses (COHN). Lead nurses were supported by a regional case coordinator (who was also a COHN).

In addition to efficiently matching patients with appropriate specialists, KPNW OH clinics provided the means to ensure good patient access, create standard operating procedures, and build a tracking system for referrals. OH staff and other departments in KPNW began to use the same unified medical records for all KP patients. This standardization, along with a computerized clinical encounter system, helped to preserve continuity of care regardless of whether patients were seen by the same physician or at the same facility.

After implementing these innovations, KPNW in 1991 sought and won approval as a State of Oregon-certified managed care organization (MCO)* under the name Kaiser-on-the-Job. Four KP Divisions (Northwest, California, Hawaii, Southwest) now operate Kaiser-on-the-Job Programs that share many of the same clinical guidelines, care philosophies and processes, and—most important—the same managed care culture.

The overall approach embraced by Kaiser-on-the-Job has provided clear evidence that high-quality OH services can be integrated within an HMO managed care system. The overall approach embraced by Kaiser-on-the-Job has provided clear evidence that high-quality OH services can be integrated within an HMO managed care system. Indeed, the Kaiser-on-the-Job Programs have made impressive gains. For example, based on 1994-1995 data from the Oregon State Accident Insurance Fund, KPNW’s Kaiser-on-the-Job Program has had 21% lower mean total claim costs than other MCOs. Ninety percent of patients have reported being “satisfied” or “very satisfied” with their OH care. The Washington Department of Labor and Industry Managed WC Pilot Project, in which KPNW’s Kaiser-on-the-Job Program participated, had 36% lower total medical care costs for members who stayed in the Program. A 1997

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“The overall approach embraced by Kaiser-on-the-Job has provided clear evidence that high-quality OH services can be integrated within an HMO managed care system.”

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*Employers who contract with an MCO are permitted to direct injured or ill employees to that MCO. As part of its certification requirements, the MCO must document its ability to provide high-quality, cost-effective care. The MCO is also required to contract for acupuncture, chiropractic, and naturopathic services. All outside contracts are expected to follow the rules of the MCO and to participate in utilization review, case management, and quality management.
study by the Ernst and Young consulting firm showed that California Kaiser-on-the-Job’s mean cost of caring for disabling injuries was 34% less than for cases treated elsewhere; duration of disability was 32% shorter. Savings resulted from cost-effective treatment and rapid return to work. Employer and patient satisfaction with all Kaiser-on-the-Job Programs has been high, and recognition of these Programs is growing.

**Kaiser Works, Inc.: A National Focus**

By working cooperatively, the Northwest, California, Hawaii, and Southwest Divisions slowly built a West Coast presence for Kaiser-on-the-Job. Unfortunately, the learnings of one Division were not always effectively or efficiently transferred to other Divisions. Many of the same mistakes were repeated, much unnecessary rework done, and Divisions still faced service gaps and lack of standardization. So, although Kaiser-on-the-Job led—Division by Division—to development of innovative OH and WC practices, dissemination and standardization throughout the rest of KP were not keeping pace.

Using Kaiser-on-the-Job as a laboratory, therefore, Kaiser Works was designed to help transfer and standardize OH/WC Best Practices. Collaborating closely with Kaiser-on-the-Job, Kaiser Works’ vision is to be the premier provider of management services and systems to promote workers’ health and productivity. To this end, it is our mission to share best practices and outcomes in Occupational Health, to cultivate and grow our relationships with our clients into a national alliance of providers, and to build an integrated data base that will lead to performance-based outcomes.

Start-up capitalization for Kaiser Works was provided equally by Northwest Permanente, PC and Kaiser Foundation Health Plan of the Northwest. Day-to-day operations are directed by a Medical Director/CEO. The company maintains minimal, fixed levels of staffing and uses a project-based, flexible staffing approach.

**Services Offered by Kaiser Works**

Kaiser Works provides Strategic Situation Assessment, Program Installation, and Shared Services/Consultation.

**Strategic Situation Assessment**

A multidisciplinary team of experts from Kaiser Works uses structured interviews and other survey tools to evaluate a health care organization’s ability to provide OH services. The assessment includes internal evaluation of current and future capabilities and external evaluation of the marketplace. This external evaluation is based on interviews with employers, insurers, brokers, and competitors. Kaiser Works then recommends a course of action and, if appropriate, a service delivery plan.

**Program Installation**

Kaiser Works contracts with clients to build or improve a service delivery model appropriate to their locale. To make the OH installation a success, areas of consideration can include administrative policies and procedures, job descriptions, clinical and case management guidelines, contract templates, staff training and strategies, and leadership consultation.

**Shared Services/Consultation**

Kaiser Works acts as a clearinghouse for several activities: updating medical protocols and guidelines, monitoring performance standards and Best Practices, assessing customer satisfaction, sharing sales promotion and advertising materials, monitoring national and regional OH/WC trends, and aiding or supporting new WC product development. In addition, Kaiser Works organizes leadership development conferences, provides consultation for problem resolution, and can provide system capability audits.

**Findings Made by Kaiser Works to Date**

Having completed eight strategic assessments, Kaiser Works has evaluated eight local health care entities, including six KP sites and two additional health plans. Locations were in the Northwest, Southwest, Southeast, Northeast, and Hawaii. Local entities varied from 100,000 to 500,000 members and 100 to 2000 physicians. Four entities were fully integrated group-model HMOs, and four were mixed models. Three plans wanted to improve existing Kaiser-on-the-Job Programs, and five plans wanted help in deciding whether to start new OH/WC programs.

**Marketplace Findings**

In general, WC claims are paid on a fee-for-service basis and represent a major cost for employers. Approximately 120 million workers in the US are at risk for work-related injury and illness. Estimates of total costs exceed $171 billion, making WC injury and illness expenditures as high as those for cancer and cardiovascular disease. In addition, WC costs tend to exceed group health costs for any given diagnostic category.

Given the high absolute cost and the high unit cost for WC care, employers are increasingly interested in managed care approaches. Expenditures for OH/WC medical care vary greatly by state, even after controlling for case mix and state characteristics. The presence of HMOs, general practitioners,
and rural settings is associated with lower claim costs. Although we found some geographic variation, employers and insurers are generally receptive to having KP offer OH/WC services. Employers in the West are more enthusiastic about managed care, although interest is emerging in the South and East. WC insurers are uniformly enthusiastic about managed care and partnering with HMOs. The situation is made even brighter by the current lack of any serious WC competition to KP from other HMOs. Instead, competition comes from preferred provider organization (PPO) networks, hospital-based medical offices, or freestanding urgent care facilities, which don’t appear to achieve the same quality of outcomes.

Although local markets share an interest in managed OH/WC care, these markets are not completely uniform. For example, four of the eight sites assessed by Kaiser Works have “facilitating” legislation for managed care: at two sites, workers’ care is directed by employers for 30 days; at one site, this direction is allowed for the first visit only; and at another site, workers’ care is directed for the life of the contract to a certified MCO.

Given this general trend toward managed WC care within a variable local context, what do employers want? Our evidence suggests that an increasing number of WC insurers and multistate employers wish to simplify their relationship with KP. One means of achieving this simplification would be for employers to have a single point of contact when forming agreements among multiple KP Divisions. Multistate employers also desire consistent products and services. Employers and insurers are also looking for OH/WC service providers who offer case management (and utilization review) services that can guarantee outcomes and can link clinicians located over a broad geographic area.

How well are KP and other assessment sites providing the services that employers want? According to our market assessments, room for improvement exists. Employers are particularly concerned about several areas:

- Lack of timely communication with health plans
- Employers’ inability to communicate directly with physicians
- Lack of mutual understanding between employer and health plan about “light duty” and disability management
- Lack of health care providers who understand the employers’ particular work environment
- Unwillingness of health plans to collect urine for employers’ drug-screening programs
- Absence of clear, concise patient reports to employers
- Employers’ uncertainty about how to gain access to OH/WC care
- Poor claims processing by health plans

**Internal Health Plan Assessment Findings**

In completing our health plan assessments, Kaiser Works also looked for potential internal barriers to successful implementation and improvement of OH/WC programs. Major impediments included the plans’ inability to fund capital investment (five of eight plans are losing money on their group health product; and seven of eight plans have severe budgetary constraints). Management teams are overworked and focused on other projects. Seven of eight plans are undergoing mergers and restructuring which results in distraction and low morale among personnel. The plans lack marketing staff trained in WC and have been faced with major constraints on service delivery. Assessment sites were unable to capture all WC revenue.

An important service delivery issue among all plans assessed was that primary care physicians lack adequate training in musculoskeletal medicine and are uncomfortable with this area, which is involved in 90% of all WC diagnoses. Clinical staff had little understanding of WC and no staff training in it. As a result, the clinical staff have no incentive—indeed, they have strong disincentive—to identify WC cases. No guidelines or procedures facilitate patients’ return to work. None of the plans we evaluated had WC- or OH-specific Quality Management Programs. In addition, seven of eight plans have difficulty recruiting qualified OH physicians. In six of eight plans, primary care is already fully utilized, preventing primary care clinics from absorbing more WC or OH cases. Four of eight plans do not routinely provide timely access to specialty care.

Plans failed to capture all WC revenues because, among other reasons, they did not correctly identify WC cases.

**“Plans failed to capture all WC revenues because, among other reasons, they did not correctly identify WC cases.”**

**“Our evidence suggests that an increasing number of WC insurers and multistate employers wish to simplify their relationship with KP.”**
culture of cost-effectiveness. They established and maintained facilities near industrial sites. In addition, the senior management team in seven of eight plans provided strong leadership and sponsorship for OH/WC care. Six of eight plans had established a strong physician-management partnership, and five of eight plans included internal services for physical/occupational therapy and orthopedics—key services for providing a positive return on investment.

**Current Kaiser Works Program Installations**

Kaiser Works is installing OH/WC programs in two HMOs. Implementation highlights include:

- Installation of a OH/WC program that can become fully functioning within 12 months;
- Implementation of clinical guidelines for OH/WC care within three months. Common OH/WC guidelines—useful for both work- and non-work-related conditions—address musculoskeletal and eye injury, effects of exposure to hazardous substances, as well as screening and treatment of psychiatric conditions. Using guideline templates and existing local guidelines, a multidisciplinary review committee has been organized to generate interdepartmental work agreements and implement guidelines;
- Implementation of a comprehensive Quality Management Program for OH/WC care can be effected in two months by using templates and an on-site Quality Management Committee. The implementation process emphasizes peer review, quality indicators, and high-priority, focused studies;
- Physician training that uses a self-study module, presentations, and ongoing case and process monitoring during program installation;
- Mentoring for project teams during the implementation phase.

**Discussion**

In the context of high employer and insurer interest in managed OH/WC care, integrated HMOs can effectively influence medical and administrative practices and deliver better WC outcomes. These abilities provide KP a unique market opportunity, especially given that other health care providers are currently struggling to provide WC care. This area of clinical competency can help differentiate Permanente Medical Groups from other providers.

The evidence is still preliminary, but Kaiser Works has been effective in quickly transferring Best Practices among OH/WC Programs. This work is essential because purchasers perceive a continuing gap in service delivery. Improved policies and procedures, clinical guidelines, Quality Management protocols, and claims billing systems have been shared among KP Divisions as a result of Kaiser Works’ efforts. Perhaps the keys to this successful transfer include 1) the close relationship between Kaiser Works and Kaiser-on-the-Job (and other OH/WC programs), and 2) the ability to create useful templates that are based on effective clinical practice.

Client satisfaction with Kaiser Works is very high (96% have reported being “very satisfied”). Among plans that have begun to implement recommendations, collection of WC revenue has been targeted to increase by 75% in the next three years. Early trends suggest that those goals will be reached.

Kaiser Works will continue to push forward in three areas: developing agreements on uniform quality measures across participating plans to allow for benchmarking; tracking rates of WC case identification, pre- and post-installation billing and collection, and contribution to margin; understanding the effect of OH care on stimulating new member and group enrollment.

The goal of having a national OH/WC product has not yet been achieved, but we believe it can be achieved with much continued hard work and with continued organizational support. The challenge to Kaiser Works will be to assist KP in overcoming the political, financial, and geographic barriers to maximize the opportunities available to our Program.
Skepticism and Research

We live in a world of fact and fiction: We are constantly discovering that old truths are fiction and that new truth comes from skepticism of the old truth. To skeptics who are really worth their salt, the new truth is not so apparent. Such skeptics are a rare breed; indeed, we recognize their type of intellect with the Nobel Prize. Their names reverberate in the scientific community. We have honored and esteemed these individuals from time immemorial.

More often than not, however, the new truth stares us in the face, and only blind bias keeps us from recognizing it. Such is the case I’d like to illustrate here.

Twenty-three years ago, Jack Gordon (now deceased) (Fig. 1) was our director of clinical pathology at Kaiser Permanente Medical Center in Los Angeles. A huge volume of surgical specimens gave Jack vast experience—and superb skills—in interpreting histology slides. As this story will tell, Dr. Gordon really deserves much of the credit for associating use of estrogen (Premarin®) with endometrial cancer.

Premarin® is actually a mixture of ten different estrogens (primarily sodium estrone sulfate) derived from the urine of pregnant mares. Eruption causes some women taking Premarin® to note a urinous odor and thus to think they have a bad case of halitosis!

At our weekly departmental meetings, Jack would project slides of interesting cases from the preceding week. A colleague, Emil G. Holmstrom (now also deceased) (Fig. 2) reviewed the slides and corresponding patient charts before the conference and would present the patients’ histories (drug exposure, age, parity, weight, etc). Because he had diligently abstracted information from the charts and correlated drug exposure with disease, Emil, too, deserves much credit for associating estrogen use with endometrial cancer. Emil had been chief of obstetrics and gynecology at the University of Utah Medical Center in Salt Lake City and had examined physicians for board certification after they had completed their residencies and had been in practice for several years. He had been a student of the famous German pathologist, Robert Mayer, and had himself become a thoroughly accomplished gynecologic pathologist.

At our weekly pathology conferences, the obstetric and gynecologic staff heard Premarin® (the principal brand of estrogen used in the 1970s) mentioned so often when a slide of endometrial cancer was projected on the screen that it didn’t take a genius to suspect a more-than-casual relation—in other words, a causal relation—between Premarin® use and malignancy. Jack became so convinced of an association between estrogen use and endometrial cancer that when he projected a slide of endometrial cancer, he no longer would say, “Endometrial cancer”; instead, he would say with a straight face, “Premarin effect!”

I agreed with Dr. Gordon, but how could the association be proved? Our medical director, T. Hart Baker, who formerly headed our department of obstetrics and gynecology, introduced me to an epidemiologist whom he had hired to help him study the quality of care. The epidemiologist was William D. Pinkle, PhD, whose father I had known as our radiation safety officer prior to his death. Bill and I just sort of clicked, and Bill knew immediately and decisively how to proceed with the estrogen question.

Moreover, doing a retrospective case-control study was child’s play for Bill, a brilliant MIT graduate, who became so excited about our study that he virtually stopped work on the study he had been hired to do.

To speed our findings into print, Bill literally hand-carried a draft of our paper to various New England Journal of Medicine reviewers across North America and incorporated their criticisms and comments into the article before we submitted it. The editor, Franz Ingelfinger, accepted the paper without change in October and presented our paper just two months later—in the December 4, 1975 issue—along with a similar report by a group from The Mason Clinic in Seattle.2 We used community controls matched to the study patients; the Seattle researchers selected as controls women who had types of gynecologic cancer other than endometrial cancer. This selection of control patients was less desirable than our selection of community controls. The Seattle researchers reported a 4.5 times increased risk of endometrial cancer after exposure to estrogen, whereas our paper reported a 7.6 times increased risk of endometrial cancer after exposure to Premarin®. Our results meant that if the normal rate of endometrial cancer among women not exposed to estrogen were 1 case per 1000 women per year, the rate of endometrial cancer among women...
exposed to estrogen would be 7 to 8 cases per 1000 women per year. The lower 95% confidence limit—4.7—was far greater than 1.0, thus indicating a strong statistical probability that a causal relation existed. (A risk ratio >4.0 indicates certainly that a causal relation exists; it is nearly impossible for study bias—even deliberate bias—to mimic a true association when the risk ratio is >4.0.) With a risk ratio of 7.6, we knew that we had “hit pay dirt.” Kenneth Ryan, chief of obstetrics and gynecology at Harvard Medical School, wrote a very supportive editorial in the same issue of The New England Journal of Medicine.

We felt like the statisticians who had come up with a risk ratio of 13—the risk ratio which causally associated tobacco use with lung cancer. Bill had great fun testifying before the United States Senate about our study: Senator Edward (Ted) Kennedy was particularly interested, especially when Bill stated that the entire project was done for only $1800, the cost of the abstractors’ salaries! We were invited to present our findings at grand rounds at the University of Southern California. I even had occasion to appear on national television during the evening news hour! I also participated in panel discussions published in magazines such as Contemporary OB-GYN and Controversies in Therapeutics as well as several lively continuing medical education programs with the big names in our specialty. Some sessions were held as far away as Hilton Head, South Carolina. Much of what was said was less than complimentary.

After publication of the 1975 articles in the New England Journal of Medicine, the disbelievers had a heyday trying to discredit our findings. The critics even speculated that our pathologists couldn’t diagnose endometrial cancer properly. The manufacturers of Premarin®, Ayerst Pharmaceuticals, arranged with Jack Gordon to have three renowned, highly respected pathologists visit with us for one week to personally review the slides in question. The experts were Arthur T. Hertig from Boston, James W. Reagan from Cleveland, and Donald G. McKay from San Francisco. We were proved right.

I know of no other institution that has voluntarily opened itself to such a review. Nonetheless, although understandably nervous about it, Jack Gordon was equal to the challenge. Dr. Inglefinger was eager to publish the findings of the experts’ review, and I wanted Jack to be recognized for his efforts. When we finalized the last draft of the review, I made sure that Jack was credited with senior authorship of the paper. Only one expert (Reagan) allowed us to include his name on the paper. McKay, still disbelieving, required us to remove his name from the coauthorship credits. Ayerst Laboratories virtually forced Arthur Hertig to take his name from authorship.

By now, numerous other centers were using their own data bases to repeat our study. As each of their articles confirmed our findings, the critics were gradually silenced. The world biomedical literature now contains about 50 articles confirming the causal association between estrogen use and endometrial cancer. So ended an era of iatrogenically induced cancer. The U.S. Food and Drug Administration responded to these findings by saying estrogen given to control menopausal symptoms should be used only for the shortest time, at the lowest dose. Within two years, use of Premarin® dropped to one sixth the number of tablets dispensed in its peak sales year, 1975—the year our articles were published. The most commonly prescribed dose of Premarin® had been 1.25 mg; now, the most common dose represented a dose reduction by half, to 0.625 mg. The only women continuing to receive long-term estrogen therapy were those not at risk for endometrial cancer, ie, women who had already had a hysterectomy. Many mares were probably put out to pasture as a result of our findings.

Gambrell reported in 1980 that if a progestin were given in conjunction with estrogen, the progestin would protect the endometrium from neoplastic...
change. We recognize now that progestins reduce the number of estrogen receptors in endometrial tissue so that the tissue is unable to incorporate estrogen into its DNA. At first, too little progestin (only 5 to 8 days per month) was prescribed, and some endometrial cancer still occurred. Ultimately, we learned that taking progestin for at least 10 (better yet, up to 14) days per month was needed to prevent estrogen-induced endometrial cancer. At first, the progestin was added to estrogen on the last days of a treatment cycle. We later learned that this type of sequential hormone therapy given for more than five years was still associated with a 2.7 times increased risk of endometrial cancer. Consequently, most physicians now prescribe estrogen and progestin combined. Combination hormone replacement therapy (HRT) is not associated with endometrial neoplasia (Fig. 3) unless HRT was started after a period of unopposed estrogen use (ie, no progestin added). We have found that the neoplastic effect of unopposed estrogen use will last (ie, has a latency period) as long as four years after estrogen therapy is stopped. 

References
It’s 7:30 am on a Saturday at the Kaiser Permanente (KP) Medical Center in Hayward, and today a group of physicians and nurses are volunteering their time and expertise to help young people aged 13-25 years remove vestiges of their troubled past. Through an innovative community partnership, these volunteers provide laser treatments to remove tattoos—professionally made and homemade, in all shapes and colors—from the visible areas of the face, neck, arms, and legs of young men and women. As the tattoos fade, so do reminders of gang life or drug problems. In exchange, the young people commit to making positive lifestyle changes. A similar clinic at the KP Medical Center in Fremont serves young people in that area.

**Partnerships Help Youth and Community**

Both the Hayward and Fremont medical centers of KP’s Northern California Division have joined with community agencies and local government to advance KP’s social mission. They are contributing medical expertise and resources such as space, supplies, medications, and small subsidies to the Hayward New Start Tattoo-Removal Program (launched in 1996) and Fremont’s Project New Start (initiated in April 1997) respectively.

Hayward New Start’s Tattoo-Removal Program is a collaborative effort between KP, the City of Hayward, and Eden Youth Center, which recruits and counsels the young people participating in the program. Hayward’s mayor, Roberta Cooper, raises funds for the program with the help of local businesses. These funds support the rental of a mobile laser machine at a cost of $550 per half day. KP administers and provides staff for the tattoo-removal clinic.

Project New Start is structured similarly but is part of a countywide effort led by Alameda County Supervisor Gail Steele and encompasses two tattoo-removal projects: one in Fremont (KP participates in this project) and another in Oakland. In Fremont, a community-based youth agency—the Community Counseling and Education Center—recruits, screens, and counsels the youth, and tattoo removal is done at the KP Medical Center there.

Both programs are modeled after San Jose’s Project Clean Slate,
the San Francisco Bay Area’s first tattoo-removal program. Numerous communities in the Bay Area have copied this model to start their own programs, sometimes in direct consultation with KP. Napa County, for example, reviewed KP’s protocols, medical consent forms, and other documents to facilitate development of a tattoo-removal program in that county.

Outside Northern California, KP has taken other approaches to support tattoo removal. In December 1997, KP awarded a $25,000 Good Neighbor Grant to help jump-start development of a tattoo-removal program in Kern County, California. In Los Angeles County, dermatologist Nancy Jasso, of KP’s Panorama City facility, volunteers her time at a tattoo-removal program jointly sponsored by Holy Cross Hospital and the Los Angeles County Probation Department.

“We know that community health and public health programs have a far greater impact on overall societal well-being and morbidity than the work we do in our individual medical practices,” says Dr. Jed Weissberg, former Physician-in-Chief of KP’s Fremont Medical Center and now The Permanente Federation’s Associate Executive Director for Quality and Performance Improvement. A long-time advocate of tattoo-removal programs, Dr. Weissberg believes that supporting these efforts is simply “the right thing to do” to help address gang violence in the community and to contribute to the overall good of Health Plan members and the general public.

Nancy Buell, LCSW, former KP community health manager and administrative coordinator of both KP tattoo-removal clinics in Northern California agrees. She adds that the clinics address all three KP community health priorities for the East Bay: increasing access to health care, implementing programs for children and youth, and preventing violence. These priorities are determined by a community needs assessment, conducted every three years in collaboration with neighboring hospitals.

Exchanging Commitment for a Clean Slate

To be eligible for KP’s tattoo-removal programs, participants must be enrolled either in school or in a job training program or must have a stable job; and they must be willing to contribute at least 50 hours of community volunteer work. Moreover, before being eligible for their first tattoo-removal session, these young people must complete certain goals and then stay on track to receive each subsequent treatment. A sponsor at one of the associated youth agencies helps program participants to develop their own goals and supports them throughout the process of reaching them. Indeed, by receiving incremental awards, participants keep moving toward their goals. Advertised primarily by word-of-mouth, the tattoo-removal programs usually have a waiting list of young people hoping to participate.

Rocky Villasana is the project coordinator at Eden Youth Center. He serves as coach, mentor, and confidant to the 18 to 20 young people who are scheduled for tattoo removal as well as up to 40 others who are working toward qualification.

Villasana believes tattoo-removal services are urgently needed. A faded tattoo can help remove the threat of violence, especially for former gang members. And highly visible tattoos (eg, a teardrop near the eye) can be detrimental for individuals seeking jobs that necessitate frequent customer contact.

“A tattoo can take up to a year to be completely removed,” says Rocky, explaining that treatments are given every eight weeks and that at least four to eight sessions are needed to finish the process. Although the procedure hurts a bit, Rocky says that most of the kids are not fearful. For many of them, the program affords the only real opportunity they’ll have in the near future to get tattoos removed. On the open market, a single tattoo-removal session costs anywhere from $300 to $500, which amounts to thousands of dollars for a full course of treatment.
Augusta Ortiz, a 23-year-old single parent, is grateful for the help in changing her life. “I used to be a follower and not a leader,” she said in explaining why she got tattoos in the first place. “I thought they were cool. My friend had a [tattoo] machine at home, and I was involved in the gangster life in Los Angeles. The tattoos mean nothing to me now.”

Ortiz is a recent graduate of a two-year program in computer office administration. She says she used to wear lots of jewelry to cover the dots and initials tattooed on her hands and wrists but that she could never easily conceal the “smile now, cry later” tattoo on her ankle—especially when wearing business attire. Now into her fourth treatment, Augusta sees that the tattoos are fading away. “It’s great,” she says, because “a lot of people judge you from the outside.”

Working Together for a Common Cause

Establishing a tattoo-removal program or any community partnership project requires the commitment of a team as well as a lot of hard work. Nancy Buell recalls the launch of Hayward New Start. “Over a dozen community groups came together to create this program. We borrowed protocols and procedures from other programs and modified them as we went along. The program structure is really quite simple, and it transfers easily to new communities,” she said. KP’s direct involvement has set an example for other community hospitals, which are now joining these collaborative efforts and expanding program capacity.

Dr. Lorraine Weinstein, a general surgeon at the Fremont KP Medical Center and a regular volunteer in the tattoo-removal program, attributes its success to excellent organization and a collaborative spirit. Dr. Weinstein says that volunteers find the effort worthwhile, results are visible, and patients are appropriately screened and motivated. “No one feels overly burdened, she says, ‘and there is a team feeling among us.’”

Physician training and certification for tattoo removal are relatively simple to obtain and usually involve a seminar in which participants learn how to use the equipment and how to comply with safety procedures. Experienced physicians proctor all new volunteers. At the Hayward and Fremont KP Medical Centers, any and all physicians are encouraged to participate in the project. So far, several general surgeons, including a plastic surgeon, a dermatologist, and a gastroenterologist, have received certification.

Dr. Daniel Tuerk, a former plastic surgeon at the KP Medical Center in Hayward, has volunteered for the Hayward clinic since its inception and was the first KP physician at his site to be certified to perform laser tattoo removal. “I’m not idealistic enough to think that we’re changing all of these kids,” he says, “but it’s gratifying to me to be able to help them undo at least one mistake that used to be irreversible.” Dr. Tuerk, now retired, continues to volunteer for Hayward New Start.

With Dr. Vic Narurkar, a dermatologic laser surgeon and researcher from the University of California at Davis, Dr. Tuerk set up the medical aspects of the Hayward tattoo-removal program. Dr. Narurkar has worked with many programs throughout Northern California to develop their own tattoo-removal services.

Through his contacts with laser manufacturers in Silicon Valley, Dr. Narurkar helps programs to gain access to the latest equipment. According to Dr. Narurkar, today’s lasers are less expensive to rent or purchase and are less cumbersome to operate than in the past. Using the latest technology, a single portable unit is able to use multiple wavelengths of light to shatter different colors of ink into particles. The body’s defense cells (macrophages) then sweep the particles away. Both the Hayward and Fremont programs rent equipment to avoid maintenance costs and the need to transport machines between facilities. In addition, renting allows old technology to be easily exchanged for new, and all rentals come with a certified laser technician. Currently, the programs use a Versapulse/C laser.
"In truth, the technological part is easy," says Narurkar. "The tough part is putting together the community alliance that sets up a framework to reach these kids."

He may be right, but advocates are committed to keeping the programs alive, especially after seeing the positive reaction of participants who complete the treatment and make concrete steps toward achieving their goals. Earlier this year, the Hayward tattoo-removal program held its first graduation ceremony: graduates received certificates of accomplishment, accolades from their sponsors, and congratulatory hugs from families and friends. They also posed for the cameras and waving tattoo-free hands smiled delightedly without any visible labels of their past.

For more information regarding the tattoo removal program, please contact the KP Northern California Division’s Public Affairs Department at (510) 784-4207.

“Princess Pine” by Terry Laskiewicz, MD

To see her biography and another piece of her work, please turn to page 68.
Purchaser Demands for Care (Disease) Management

Employer group purchasers are requesting increasingly specific information from health plans about “disease management” because they understand that better management of chronic diseases—which account for a disproportionately large use of health care resources—reduces health care costs and increases employee productivity. Responding adequately to some employer group purchasers was difficult initially, but Kaiser Permanente (KP) is preparing to show its commitment and effectiveness in Population Health Care Management by responding to employer groups from our strength and experience as an integrated delivery system and as a health maintenance organization (HMO) designed on the group-practice model.

California employer groups (purchasers) are holding health plans accountable for their clinical and administrative performance by issuing performance standards and (financial) guarantees. In 1997, the Kaiser Permanente California Division (KP-California) returned several hundred thousand dollars to California employers for not meeting negotiated 1996 clinical performance improvement targets based on the Health Plan Employer Data Information Set (HEDIS) measures and returned several more hundred thousand dollars for not meeting administrative and membership services guarantees. At first, in 1997, Atlantic Richfield Company (ARCO) chose Foundation Health Systems (HealthNet) and did not pick KP as its 1998 benchmark health plan for their employees and dependents, in part because KP scored low in demonstrating use of population-based “disease management” for our members. However, that choice occurred at the same time that KP-California was selected as the Blue Ribbon HMO by the Pacific Business Group on Health (PBGH) and was shown to have among the lowest risk-adjusted perinatal mortality and acute myocardial infarction mortality in California.

Heavily influenced by their health benefits consultants (William M. Mercer, Towers Perrin, Deloitte & Touche, Watson Wyatt), the larger, sophisticated purchasers (Southern California Edison, Hughes Electronics, Disney, Digital) have understood the 80-20 rule, ie, that 20% of their employees—mostly those with chronic conditions—account for most of the companies’ insurance costs as purchasers of health care. The population of current and future insured employees, dependents, and retirees is aging, and the prevalence and incidence of chronic disease in that population is increasing. These demographic and epidemiologic changes predict an even greater economic burden for purchasers of health care. Employer groups are requiring evidence that health plans are effectively managing these populations, which they hope will help lower health care costs and increase employee productivity (function) as well as time on the job.

Employer Group Purchasers’ Expectations

As part of their “value purchasing” strategy to assess and compare competing health plans, employer groups are requesting more clinical data, performance results, and information from health plans in their Requests for Proposals (RFPs)—much more information than is provided by HEDIS measures. Over the last couple of years, these requests have become increasingly specific in asking for information and outcomes of “disease management.”

A representative sampling of RFP questions from purchasers is shown (Fig. 1). Purchasers have specific expectations about how health plans should engage in disease management. For example, the RFP from the University of California (UC) framed questions as if disease management were a study with its own report cards. Hughes and UC (advised by Deloitte & Touche), for example, use their Value Equation® to grade a health plan’s performance. Based on these evaluations, employer groups are now requesting employer-specific outcomes and results. Responding to these kinds of detailed questions presents a formidable task.

Employer groups are evaluating, grading, and comparing health plans based on RFP responses, sometimes supplementing these processes with on-site interviews and audits. Some employers have created their own report cards. Hughes and UC (advised by Deloitte & Touche), for example, use their Value Equation® to grade a health plan’s performance. Based on these evaluations, employer groups are selecting health plans to offer their employees and are promoting specific health plans as preferred or benchmark plans, sometimes providing attractive underwriting or subsidizing the cost to encourage enrollment.

Reaction to KP Responses

Overall KP clinical quality in the California marketplace has been judged to be good based on HEDIS results; however, overall clinical performance was good.
Figure 1. Representative examples of Request for Proposal (RFP) questions from employer group purchasers about KP’s “disease management” practices.

From University of California (UC), 1997
UC (and Hughes)-specific disease management programs will be conducted during 1998 for asthma, diabetes, and heart disease. In addition, the following information will be provided to UC for each program:
- hypothesis of the study
- proposed measurement criteria
- workplan and timeline for each study
- baseline data
- objective measures that will determine the success of the program

From University of California (UC), 1998
- Describe any care management programs you have in effect and provide outcome reporting.
- Summarize the results of your programs; include health improvement and financial impact.
- At a minimum, UC would like an annual analysis of prescription drug data identifying UC employees and retirees by chronic disease. Please confirm you will provide this information for diabetes, asthma, hypercholesterolemia, hypertension, depression, AIDS, cardiovascular disease, coronary heart disease, and other.

From Los Angeles Unified School District, 1997
Has your plan sponsored, become a partner in, or outsourced any specific disease management programs (for example, asthma and diabetes management)? If so, provide a detailed explanation of the program(s) including: type of program and parties involved, start date, organization, funding/risk sharing, operational details, data collection, and provider and member satisfaction.

From General Motors, 1998
Identify the key elements below for the following disease management programs the HMO currently has in place: asthma care, chronic obstructive pulmonary disease, depression, low back pain, diabetes, gastroesophageal reflux disease/PUD/H. pylori, HIV/AIDS, pregnancy/childbirth, low-birthweight infants, heart disease, hypertension, coronary artery disease/hyperlipidemia, post-heart attack/ASA therapy, other coronary artery disease programs, congestive heart failure, atrial fibrillation/stroke prevention/anticoagulation, elder care, prevention of falls, management of hip fractures, cancer care, breast cancer, prostate cancer, or other disease states.

- Indicate the number of members who have this disease or condition and the number who are enrolled in your disease management program.
- Do you have Clinical Practice Guidelines that guide each disease management program?
- Are Clinical Practice Guidelines updated at least annually?
- Do you have physician performance measures tied to the Clinical Practice Guidelines?
- Are physicians routinely provided with lists of their eligible/at-risk patients?
- Do you have targeted member outreach designed to draw at-risk members into the disease management program?
- Do you track the results of process and outcome measures associated with this disease management program?
- Do you routinely re-evaluate and modify the disease management program-based results of the tracking of process/outcome measures?

From Southern California Edison, 1998
For your HMO’s top five disease management efforts, please attach a copy of the Clinical Practice Guidelines currently used (with the most recent date reviewed) and complete the following questions:
- How are members targeted? Please define criteria used to identify the at-risk population (age, gender, familial history, health risk assessment questions, pharmaceutical use, etc.).
- What is the number of current enrollees eligible for and currently in the program?
- How does the HMO identify potential enrollees to physicians? How often does this occur?
- How does the HMO factor physician participation in its disease management programs into physician performance measures and incentives?
- Please list the objectives or performance measures the HMO has used or will use to evaluate the success of this program?
- Please provide the date of the most recent program evaluation and the recommendations that evolved from this process? If feedback was collected from participating physicians and patients, please attach a copy of the tool(s) used to gather this information.

From Pacific Business Group on Health (PBGH), 1999
How does your plan oversee the management of chronic conditions for the over-65 population? On which chronic conditions, if any, are current programs focused? Do you conduct outreach/early intervention programs? If yes, how do you measure the progress of these programs? Is it available to all locations and members?

From Interim Services, 1997; TWA and Toys R Us, 1998
- There is (is, health plan shall have) a disease management program with member enrollment for the following clinical conditions: allergy, asthma, cancer, diabetes, drug and alcohol abuse, hypertension, mental health, migraine headaches, osteoporosis, smoking cessation.
- Is disease management subcontracted to an outside entity?
goals: 1) learn more from purchasers and their consultants, 2) develop better ways to effectively show KP's strengths in managing the care of members who have chronic conditions, and 3) encourage KP in Southern California (KPSC) to focus on improved approaches to managing the care of members who have chronic diseases.

After receiving this feedback, we committed ourselves to three goals: 1) learn more from purchasers and their consultants, 2) develop better ways to effectively show KP’s strengths in managing the care of members who have chronic conditions, and 3) encourage KP in Southern California (KPSC) to focus on improved approaches to managing the care of members who have chronic diseases.

First, our purchasers mentioned that several other health plans have established relationships with many of the more than 40 leading disease management vendors, eg, HealthNet with Schering-Plough Corporation, Lovelace Health Systems (CIGNA) with Greenstone Solutions (Upjohn). Other health plans, such as PruCare, have implemented their own centralized, claims-based tracking systems; targeted mailings to providers and members; telephone outreach; and health risk assessments. Using health plan claims, membership files, and data from pharmacy benefit management services, disease management vendors have analyzed health plan populations to develop data bases from which the vendors create member mailings, initiate telephone interventions with care managers, and give limited notification to the providers. Although the effectiveness of these methods has not yet been shown, employer groups have seemed satisfied that these health plans were actively conducting disease management.

Second, interviews were conducted with consultants from Deloitte & Touche, Watson Wyatt, and other firms who were willing to advise us on how to better respond. In large part, employers and KP seemed to be speaking in different dialects. But once we began to speak in terms of clinical populations and of managing health or care for defined populations of members or patients, our approach to care management could be understood as comparable to the “disease management” models. Employers could find persuasive the description of KP as always having been focused on improving the health of our members—a focus which is part of our core values as stated in the KP Aspiration Statement (Fig. 2). The specific, population-based KPSC Clinical Strategic Goals for improving outcomes in cardiovascular disease, cancer, communicable diseases, pregnancy and newborn care, and asthma—all along with evidence of objective clinical measures and results—would further illustrate the KP approach to “disease management,” which we now call Population Health Care Management.

Third, KPSC committed to increasing its focus on population-based care management. Care management is not new to KP. For example, KPSC has a long history of specific regionwide care management programs like that for Elder Care (1986) as well as others for perinatal services/high-risk pregnancy (1983), HIV/AIDS (1988), and end-stage renal disease (1992). In addition, local programs for treating diabetes, asthma, coagulation dysfunction, and congestive heart failure are flourishing. We had an opportunity to build on this base of experience by greater coordination, facilitation, and transfer of successful practices.

Beginning in 1998, KPSC is targeting clinical populations for greater alignment with our Clinical Strategic Goals and purchasers’ expectations (eg, for treating congestive heart failure, diabetes, and asthma).
and with patient registry capabilities, our physicians already have a growing appreciation of the power of coordinated, integrated systems for effectively managing the care of our large clinical populations.

**Demonstrating the Value of KP Population Health Care Management to Purchasers in 1998**

KP-Southern California has begun to respond to purchasers requests for information about “disease management” by noting that KP is an integrated, group-model HMO with extensive experience in Population Health Care Management and with the following strengths:

1. Outcome- and performance-driven model (eg, our Clinical Strategic Goals for populations) with objective and measurable targets for improvement;
2. Provider-driven medical delivery system with central support instead of central or vendor add-on programs;
3. Clinical information systems and registries that support clinical practice in the care delivery setting, support production of measurable clinical results, and give feedback and assistance to providers;
4. Organizational structure, priorities, and accountabilities for clinical performance that foster learning in the organization; innovation and local initiatives to identify, actively transfer, and replicate successful practices;
5. Objectively measured process and outcome results (beyond HEDIS), eg, raw and risk-adjusted perinatal mortality, risk-adjusted mortality after acute myocardial infarction, and improvement in diabetes testing and blood sugar control.

Our recent experiences with employer groups in 1998 have been positive. Since late 1997, we have totally rewritten our responses to RFPs so that we describe our Population Health Care Management. We have presented our descriptions and results of Population Health Care Management to many employer groups and consultants. Subsequently, ARCO was very impressed with our Population Care Management Initiatives, and PepsiCo announced that KPSC will be their benchmark health plan for 1999. We were told that our ability to show the population focus of our integrated delivery system along with objective clinical results and outcomes was very persuasive. Hughes has given KP “A” grades this year on the Value Equation® for disease management. This rating will be taken into consideration in these employers’ open-enrollment communications with employees about health plans.

We continue to develop and improve our approaches to Population Health Care Management and show the value of Permanente Practice for measurably improving health outcomes. With purchasers and accreditors (ie, the National Committee for Quality Assurance, NCQA) setting expectations for care management and with the changing demographics and diseases seen in our health plan member population, KP’s future success will depend greatly on its effectiveness in managing the care and services provided to specific populations of members. Indeed, the most successful HMOs will be those that produce the best population outcomes most efficiently and with the highest patient satisfaction.

References

Where will the Health Reform Debate Lead?

The “Patient Bill of Rights”—the “Patients’ Bill of Rights”—the “Promoting Responsible Managed Care Act”—the “Patient Access to Responsible Care Act”—the “Patient Protection Act”—who can keep them straight? This summer, we are caught in a deluge of lengthy proposals to reform—and perhaps to weaken or destroy—managed care. In the few legislative days left this year, the 105th Congress is determined to milk the anti-HMO sentiment in the country for all its potential political worth. Proposals for health care reform are proliferating, and harsh rhetoric from the President, both parties, and both houses of Congress suggests to some that irreconcilable differences will block passage of any legislative bill again this year. Other informed opinion knows that this issue has major political traction going into the fall campaigns and that to do nothing may risk many incumbents' jobs. Will any of these proposals pass?

Some Proposals: D éj á Vu?

The various bills have common elements that mimic the protections applied to Medicare last year in the Balanced Budget Act. For example, the bills generally agree that all insured persons should have access to emergency care and that provision of this care should apply the prudent layperson standard. Other requirements that everyone seems comfortable with would provide more information to beneficiaries and ban gag rules—contractual limitations to what physicians may tell their patients. (This implicit indictment of the managed care industry belies a recent General Accounting Office study indicating that no health plan contractual clauses limit patient/clinician communication.) Women’s access to obstetricians/gynecologists and children’s access to pediatricians for routine services and primary care are common features of most proposals. All sponsors want internal and external mechanisms for appealing disputed coverage determinations when health plans deny services. Other provisions within these complex bills, however, are very controversial.

Objections to Provisions

We often hear the phrase “poison pill” used to describe provisions that are highly objectionable to various special interest groups. For example, in H.R. 4250, officially titled the “Patient Protection Act of 1998” and passed by a slim majority in the House, Republican members of Congress have included provisions that would allow aggregate purchasing by small businesses through association health plans and through Healthmarts, a mechanism that would afford small businesses their choice of health plan options. However, because these new programs would all come under ERISA protections, they would not be required to meet the state-regulated standards that Kaiser Permanente (KP) and other health plans are required to obey. Moreover, large businesses, insurance interests, and state regulatory agencies object to these provisions as anticompetitive. We also are opposed to these provisions because they could allow manipulation of insurance pools, resulting in much higher premiums for sicker people, who might drop their traditional and managed care coverage. Similarly, the bill's provision for the widespread expansion of Medical Savings Accounts—touted by conservative Republicans as critical to fulfilling the promise of expanding choice in the marketplace—could divert the healthiest and wealthiest people into low-cost, high-deductible insurance programs, leaving the sick and the poor in very expensive comprehensive care programs. In addition, medical malpractice reform provisions included in H.R. 4250 are anathema to President Clinton and Congressional Democrats who are supported heavily by contributions from trial attorneys.

The Democratic health reform proposal, S. 1890, also contains a “poison pill” provision: health plan liability, or the right to sue any health plan for perceived bad outcome. Self-insured large and small businesses alike have warned that if this legislation passes, many businesses will simply drop their voluntarily offered insurance programs because no business wants to risk its treasury on the outcome of a malpractice suit over which it had little control. This is not an idle threat. The President has promised to veto any legislation that lacks this provision. KP and other health plans and insurers regard this provision as the single most objectionable proposed piece of legislation. Potential health plan financial losses for delay or denial of care could undermine utilization programs and vitiate care management.

Other Movements for Reform

In addition to the partisan bills offered by the two political parties, Senators John Chafee (R-RI), Robert Graham (D-FL), and Joseph Lieberman (D-CT) have established the nucleus of a mainstream bipartisan coalition in the Senate by introducing S. 2416, the “Promoting Responsible Managed Care Act of 1998.” Their hope is that when the Senate Republicans fail to garner the required 60 votes to stop a Democratic filibuster and when Senators Kennedy and Daschle and the President concede that the Democrats’ “Patient Bill of Rights” cannot prevail over opposition from the Republican majority, enough right-minded Senators will support a middle-of-the-road proposal.
This strategy has failed twice in recent years, beginning with the Clinton health care reform initiative. We wonder: Is there time for accomplishing anything other than acrimonious accusations that have dominated the Congressional debate so far? Only four weeks remain on the legislative calendar, and distractions have surfaced.

**KP Involvement**

Where is KP in the debate? One channel for our influence is the process of drafting original bills. Because this influence is indirect, however, it can be difficult to track. For example, three years ago, we spent almost a year collaborating with the American College of Emergency Physicians to draft the Cardin/Graham "Prudent Layperson Access to Emergency Medical Services Act" (S. 356/H.R. 815). Although this bill per se has not been passed, its fundamental concepts and much of its language have surfaced in subsequent proposals. Many 1998 proposals on emergency access can trace their lineage back to the Cardin bill. More directly, KP has participated in drafting parts of the Dingell/Kennedy bill as well as the Chafee proposal. We will also add our voice to future debates. If a bill passes this year, we hope it will be compatible with our Principles of Consumer Protection, a statement that has influenced the President's Commission on Consumer Protection and Quality in the Health Care Industry in writing its report on the Patients' Bill of Rights (and succeeding iterations and proposals). We won't get everything we want, but any legislation that passes will be likely to hold our competitors to standards that we have defined in Permanente Practice and that are fundamental to the workings of the Kaiser Foundation Health Plan.

**Current Forecast: Turbulence Ahead**

Will we or won't we have health reform this year? The debate is turning into a political free-for-all. Harsh campaign rhetoric has resulted in hardening of partisan positions in Congress and veto threats from the President. Special-interest advocates are weighing in with specific objections to key elements of all proposals. And distractions on both domestic and international fronts are sapping energy and attention. We hear threats of stalling the 12 remaining appropriations bills, which could lead to another government shutdown at year-end. This strategy worked to discredit the majority party three years ago—why not try it again? We expect the last month of the 105th Congress to be consumed with bitter exchange over several political issues, leaving the health care bills for a new Congress convening in January.

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Doctors’ “Eidetic Imagery”

Researchers at Harvard University released a study in 1993 that estimated 1 million potentially preventable medical errors lead to 120,000 deaths each year. "What is not as often discussed is how all mistakes, including minor ones that harm nobody, are potentially devastating to the doctors involved," according to Dr. Steven Small of Massachusetts General Hospital. Doctors are scarred by "eidetic imagery" from such events, that is, moments that are vividly recalled and readily reproducible in one's memory long after they have occurred. Doctors carry these events with them for their entire careers, feeling a mixture of embarrassment, humiliation, guilt and shock that extends long past the incident.

Michael Luo, Associated Press, 10/11/98
As indicated in the preface, this volume is "a guide to decision making in the care of approximately 300 common musculoskeletal conditions." As such, the book achieves this goal very well by providing a useful, structured review of many problems seen in the office.

Included are sections on general orthopedics as well as separate discussions of the shoulder; elbow; hand and wrist; hip and thigh; knee and leg; foot and ankle; spine; and pediatric conditions. For each disease or entity, separate paragraphs present the definition; clinical symptoms; examination and laboratory tests; differential diagnosis; adverse outcomes; treatment; and discuss referral decisions as well as "red flags" to be aware of. Each section starts with a "pain diagram" that suggests possible entities associated with pain at a given anatomic location. Each anatomic area is afforded a brief overview discussing type of pain, instability, stiffness, and age-related considerations. This overview is followed by heavily illustrated pages (using x-ray films and excellent drawings) on examination, diagnosis, and injection techniques.

Emphasis is placed on common musculoskeletal problems such as animal bites; hand arthritis; crystalline deposit diseases; osteoarthritis of the spine, hip, and knee; and various shoulder conditions. Extensive coverage is given to hand conditions, including Dupuytren's contracture; carpal tunnel syndrome; sports injuries to the fingers; ganglions; and "trigger finger."

**Highlights of the book:**

- The section on osteoarthritis of the hip provides for each age group an overview of examination techniques; differential diagnosis; prognosis, with symptoms; and treatment options other than hip replacement.
- The section on foot and ankle disorders offers excellent illustrations of various conditions, suggests possible treatments; lists referral indications, describes management of foot pain, and presents points to discuss with patients who have been referred for surgical evaluation.
- The spine section includes a concise review of the vertebral levels associated with specific neurologic symptoms or findings and illustrations that may help clinicians to distinguish psychogenic from mechanical symptoms.
- The section on pediatric orthopedics is valuable because many conditions seen in adults do not translate directly into corresponding pediatric conditions. For example, many pediatric conditions can be attributed to fragility of the growth plates, and many injuries and infections are manifested differently in children.

In summary, this volume is a valuable desk reference for primary care physicians, for pediatricians, and for orthopedists who seek to quickly review a differential diagnosis that may be outside their subspecialty area.


William H. Browning, MD, is Chief of the Department of Orthopedics at Kaiser Permanente Medical Center, San Diego.

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This volume is one hundred tenth in an extraordinary series of publications on lung biology sponsored by the National Heart, Lung, and Blood Institute. The book addresses problems that are usually covered only briefly in standard texts of allergy, immunology, and pediatrics: namely, effects of asthma and allergies on pregnant women and, conversely, effects of pregnancy on allergic, immunologic, and autoimmune diseases. Also addressed are the developmental aspects of allergic disease in infants.

The editors of this large, state-of-the-art book are recognized authorities in the areas covered. Dr. Schatz has devoted many years to studying the impact of allergic disease and asthma on pregnancy and has authored numerous articles on this subject. Dr. Zeiger, too, has been recognized for his developmental studies of allergies, natural history of allergic disease, and
management of childhood allergies. Both editors are physician-researchers in the Southern California Permanente Medical Group (SCPMG), San Diego. Dr. Claman is a distinguished professor of immunology at the University of Colorado Health Sciences Center, Denver, CO. In addition to Dr. Claman, seven physicians from SCPMG—including the editors—have contributed chapters to the book.

The chapters are organized into seven sections: Basic Science; General Therapeutics; Allergic Diseases; Asthma During Pregnancy; Immunological Diseases in Pregnancy; Development and Prevention of Allergic Diseases in Infancy; and Allergic and Immunological Diseases During Infancy.

All 51 contributing authors are experts in their specific areas and have written an assortment of easily readable, clinically instructive chapters—even a chapter on the medical-legal aspects of prescribing drugs during pregnancy. Although the references are extensive, researchers specializing in allergy-immunology will find that several chapters written in review format do not cover the world literature in full depth; nonetheless, the author index alone—100 pages in length—gives some sense of this book’s attention to detail. Overall, this volume will be valuable to family physicians, allergists, obstetricians, pediatricians, and internists who are interested in discovering the nuances of asthma and allergy-immunology during pregnancy and early infancy.


From 1969 to 1984, M. Michael Glovsky, MD, was an SCPMG partner who was also Chief of the Department of Allergy-Immunology at the KP Los Angeles Medical Center. He later became Professor of Medicine at the University of Southern California as well as Chief of Allergy-Asthma at Huntington Memorial Hospital in Pasadena.

The World’s Most Admired Companies

In last year’s FORTUNE survey of most admired companies, the single best predictor of overall excellence was a company’s ability to attract, motivate, and retain talented people. CEO’s said that corporate culture was their most important lever in enhancing this key capability. In a Hay Group study, the corporate cultures of high-performing companies are dramatically different from those of average companies. In the most admired companies, the key priorities were teamwork, customer focus, fair treatment of employees, initiative, and innovation. In average companies the top priorities were minimizing risk, respecting the chain of command, supporting the boss, and making budget.

Cost-Effectiveness of a Hospital-Based Smoking Cessation Intervention
Meenan RT; Stevens VJ; Hornbrook MC; La Chance PA; Glasgow RE; Hollis JE; Lichtenstein E; Vogt TM. Med Care 1998 May;36(5):670-8.

Objectives: This study evaluated the cost-effectiveness of a smoking cessation and relapse-prevention program for hospitalized adult smokers from the perspective of an implementing hospital. It is an economic analysis of a two-group-model health maintenance organization. The intervention included a 20-minute bedside counseling session with an experienced health counselor, a 12-minute video, self-help materials, and one or two follow-up calls.

Methods: Outcome measures were incremental cost (above usual care) per quit attributable to the intervention.

Results: Cost of the research intervention was $159 per smoker, and incremental cost per incremental quit was $3,697. Incremental cost per incremental discounted life-year saved ranged between $1,691 and $7,444, much less than most other routine medical procedures. Replication scenarios suggest that with realistic implementation assumptions, total intervention costs would decline significantly and incremental cost per incremental discounted life-year saved would be reduced by more than 90%, to approximately $380.

Conclusions: Providing brief smoking cessation advice to hospitalized smokers is relatively inexpensive, cost-effective, and should become a part of the standard of inpatient care.

Body Size and the Risk of Colon Cancer in a Large Case-Control Study
Caan BJ; Coates AO; Slattery ML; Potter JD; Quesenberry CP Jr; Edwards SM. Int J Obes Relat Metab Disord 1998 Feb;22(2):178-84.

Objective: To investigate the risks of height, weight, and body fat distribution associated with colon cancer in subcategories of gender, age, and site in the colon. Interaction with family history of colorectal cancer is also examined.

Design: Nineteen hundred eighty-three colon cancer cases (age 30-79 years) and 2400 age- and gender- matched population controls.

Measurements: Height, weight, and waist and hip circumferences were obtained by trained interviewers. Body Mass Index (BMI) and Waist-Hip Ratio (WHR) were calculated.

Results: Of all anthropometric measurements examined, only BMI was consistently associated with an increased risk of colon cancer. The test for trend for BMI was significant for men and women overall and for the majority of subgroups examined. In younger persons, those with a family history of colorectal cancer had a greater risk of colon cancer associated with BMI (men: odds ratio (OR) = 7.76, 95% confidence interval (CI) 2.60 - 23.1; women: OR = 4.85, 95% CI 2.33 - 10.12) comparing the third tertile to the first, than those with no family history (men: OR = 1.70, 95% CI 1.25 - 2.32; women: OR = 1.53, 95% CI 1.22 - 1.92). WHR, after controlling for BMI, was not associated with colon cancer in men and was associated with a slight increase in women (primarily in those with distal tumors).

Conclusion: This study contributes to mounting evidence that excess weight is associated with an increased risk of colon cancer.
Prevalence and Causes of Undernutrition in Medical Outpatients

Purpose: To assess the prevalence, common causes, and frequency of recognition and treatment of undernutrition in older and younger medical outpatients using a cross-sectional survey design with 2-year follow-up of undernourished subjects.

Patients and Methods: Charts of 1017 adult patients attending a hospital outpatient department were reviewed for the presence of undernutrition, and 85 patients meeting inclusion criteria for undernutrition were evaluated and followed for 2 years. An initial evaluation focused on nutritional, cognitive, and affective status and on nutritional attitudes using two subscales of the EAT-26 eating disorder inventory. After 2 years, initial data plus outpatient records were evaluated by 2 independent reviewers to determine a primary cause of undernutrition and to assess the recognition and treatment of undernutrition by the primary physician.

Results: Undernutrition was identified in 46 (11%) and 44 (7%) of older and younger subjects respectively; odds ratio (OR) (95% confidence interval (CI)) for older versus younger = 1.65 (1.06 to 2.51). The primary cause of undernutrition differed between age groups but was deemed treatable in nearly 90% of all subjects. Undernutrition was recognized in 19 (43%) older subjects and 5 (12%) younger subjects (OR = 5.47 1.87 to 16.0), and appropriate intervention(s) were instituted in 6 (14%) and 2 (5%) of older and younger subjects, respectively (OR = 3.08 (0.668 to 14.2)). Older subjects scored higher on the EAT-26 oral control subscale than did younger subjects (4.7 versus 2.5, P = 0.004) but similarly on the EAT-26 dieting subscale (5.2 versus 6.3, P = 0.332); these relationships did not change with control for potentially confounding variables.

Conclusions: In this study, undernutrition was relatively common, usually amenable to treatment, but frequently undetected and undertreated in both older and younger medical outpatients. Older undernourished subjects exhibited higher oral control needs than younger persons, which may have implications for the pathophysiology and treatment of their malnutrition. Further improvement in detection and intervention is warranted in both younger and older age groups.

Effectiveness and Cost-Effectiveness of Letters, Automated Telephone Messages, or Both for Underimmunized Children in a Health Maintenance Organization
Lieu TA; Capra AM; Makol J; Black SB; Shinefield HR. Pediatrics 1998 Apr;101(4):E3.

Background: Immunization rates have improved in the United States but are still far from the national 90% goal for the year 2000. There is scant evidence about the effectiveness and costs of automated telephone messages to improve immunization rates among privately insured children.

Objective: To evaluate the effectiveness and cost-effectiveness of sending letters, automated telephone messages, or both to families of underimmunized 20-month-olds in a health maintenance organization (HMO).

Methods: In this randomized trial, underimmunized 20-month-olds identified by the HMO’s computerized immunization tracking system were assigned to one of four interventions: 1) an automated telephone message alone; 2) a letter alone; 3) an automated telephone message alone but left 1 week later; and 4) a letter followed by an automated telephone message 1 week later. The primary outcome was receipt of any needed immunization by 24 months of age. Decision analysis was used to evaluate the projected cost-effectiveness of the alternative strategies.

Results: A total of 648 children were randomized. A letter followed by a telephone message (58% immunized) was significantly better than either a letter alone (44% immunized) or a telephone message alone (44% immunized). A telephone message followed by a letter (53% immunized) also was more effective than either alone, although the differences were not statistically significant. Among a similar comparison group that received no systematic intervention, 36% were immunized. The estimated cost per child immunized was $7.00 using letters followed by automated telephone messages, $9.80 using automated telephone messages alone, and $10.50 using letters alone. Under alternative cost assumptions for automated telephone messages and mailed messages, the cost per child immunized ranged from $2.20 to $6.50.

Conclusions: For underimmunized 20-month-olds in this HMO setting, letters followed by automated telephone messages were more effective and cost-effective than either message alone. The cost-effectiveness of automated telephone messages and letters may vary widely depending on the setting, and choices among strategies should be tailored to the populations being served.
Obesity, Health Services Use, and Health Care Costs Among Members of a Health Maintenance Organization


**Background:** Obesity is an independent risk factor for a variety of chronic diseases and is therefore a potential source of avoidable excess health care expenditures. Previous studies of obesity and health care costs have used group level data, applying estimates of population-attributable risks to estimates of US total costs of care for each obesity-related disease.

**Objective:** To quantify the association between body mass index (BMI) and health services use and costs stratified by age and use source at the patient level, a level of detail not previously reported.

**Methods:** In 17,118 respondents to a 1993 health survey of members of a large health maintenance organization, we ascertained through computerized databases all hospitalizations, laboratory services, outpatient visits, outpatient pharmacy and radiology services, and the direct costs of providing these services during 1993.

**Results:** There was an association between BMI and annual rates of inpatient days, number and costs of outpatient visits, costs of outpatient pharmacy and laboratory services, and total costs (P ≤ 0.003). Relative to BMI of 20 to 24.9, mean annual total costs were 25% greater among those with BMI of 30 to 34.9 (rate ratio, 1.25; 95% confidence interval, 1.10-1.41) and 44% greater among those with BMI of ≥ 35 (rate ratio, 1.44; 95% confidence interval, 1.22-1.71). The association between BMI and coronary heart disease, hypertension, and diabetes largely explained these elevated costs.

**Conclusion:** Given the high prevalence of obesity and the associated elevated rates of health services use and costs, there is a significant potential for a reduction in health care expenditures through obesity prevention efforts.

He Turned It Down Once

“He turned it down once;
he turned it down once too often.”

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