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22 Comparison of Paper and Electronic Surveys for Measuring Patients’ Report- ed Outcomes After Anterior Cruciate Ligament Reconstruction. Jamie L Bign, MD; MPP; Valerie M Sue, PhD; Tom S. Huang; Gregory B Marks, MD; Maria CS Inacio, PhD

The Kaiser Permanente Anterior Cruciate Ligament Reconstruction Registry listed 1486 patients between 2005 and 2010, who were included in this study. The overall response rate was 42%. The 36% rate in the electronic-survey group was significantly higher than the 22% in the paper-survey group. The electronic response rate was also significantly higher than the paper response rate at all follow-up times of 1, 2, and 3 years. Although the electronic survey produced higher response rates, it is not sufficient alone to replace the traditional paper version among this Kaiser Permanente population.

23 An Audit of Clinic Compliance with Best Practice Recommendations to Repair Severe Obstetric Anal Sphincter Injuries. Shane D. Leach, MBBS, DTM, SWishtai Ramdial, MBBS, FRCCS; Michael Ramdial, MBBS, FRCS; Dile Hassenah, MBBS, FRCS; Ian Bambury, MBBS, DTM, Loxley K. Chmil, MBBS, DTM; Vicky Naranyan, MBBS, FRCS.

A retrospective review of the records of all consecutive obstetric patients with anal sphincter injuries between November 2007 and December 2012 found 26 women (mean age = 27), who had obstetric anal sphincter injuries. Nine cases earned clinic compliance scores above 8, and 17 had scores of 6 or below. Experienced clinicians repaired all the injuries in this study—65% fully for which compliance was 100%. There is a serious barrier to success because 65% of senior clinicians are noncompliant.

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33 Designed for Workarounds: A Qualita- tive Study of the Causes of Operацион- al Failures in Hospitals. Anita L. Tucker, DBA, MD; W Scott Stuart, MBA, RN; Laura D Joann, MFA

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**Review Articles**

### 61 Thoracic Endometriosis Syndrome: Case Report and Review of the Literature.

Parisa Azzizad-Pinto, MD; David Clarke, MD, FCCP

Thoracic endometriosis syndrome is the presence of endometrial tissue in or around the lung in 4 distinct clinical entities: catamenial pneumothorax, catamenial hemoptysis, and pulmonary nodules. The diagnosis is often delayed or missed by clinicians. The authors report the case of a 48-year-old woman with endometriosis causing bowel obstruction and concurrent catamenial pneumothorax.

### 66 Comparative Health Systems Research among Kaiser Permanente and Other Integrated Delivery Systems: A Systematic Literature Review.

Jared Lane K Maedo, PhD, MPH; Karen M Lee; Michael Horberg, MD, MAS

Because of rising health care costs, wide variations in quality, and increased patient complexity, the US health care system is undergoing rapid changes that include payment reform and movement toward integrated delivery systems. The authors conducted a literature search of 1605 articles from PubMed and the Kaiser Permanente (KP) Publications Library. Studies that compared KP as a system or organization with other health care systems or across KP facilities internally were included. Only a small proportion of articles (4%) was identified as being comparative health systems research.

### 88 Prediabetes and Lifestyle Modification: Time to Prevent a Preventable Disease.

Phillip Tuso, MD, FACP, FASN

More than 100 million Americans have prediabetes or diabetes; of the 34% of adults with prediabetes 37% may have diabetes in 4 years, if untreated. Lifestyle intervention may decrease the percentage of patients with prediabetes who develop diabetes by 20% and may decrease the risk of prediabetes progressing to diabetes for as long as 10 years. Indirect and direct costs to care for an individual with diabetes vs prediabetes may be as much as $7000 more per year.

### Commentary

82 Best Clinical Practices for Male Adult Survivors of Childhood Sexual Abuse: “Do No Harm.” Les Gallo-Silver, MSW, LCSW-R; Christopher M Anderson; Jaime Romo, EdD

Currently, there are no recommendations for best clinical practices for male survivors of childhood sexual abuse or other adverse clinical experiences. Physicians can address the needs of adult male survivors of childhood sexual abuse by changes in communication, locus of control, and consent/permission before and during physical examinations and procedures.

### Editorial

94 A Commentary on “Comparative Health Systems Research among Kaiser Permanente and Other Integrated Delivery Systems: A Systematic Literature Review.” Thomas E Kottke, MD, MSPH; Patrick T Coumeyra, MD

“Knowing is not enough, we must apply. Willing is not enough, we must do.” This quote attributed to von Goethe underscores the fact that biomedical research and health care are social investments that are expected to create value for the public. Friedson recognized that an effective care delivery system is the substrate that creates value from knowledge. It is now time for the health care research and practice communities to collaborate, increase comparative health systems research activity, and give Americans the value in health care that they deserve.

### Special Report

55 Treatment Progress Indicator: Application of a New Assessment Tool to Objectively Monitor the Therapeutic Progress of Patients With Depression, Anxiety, or Behavioral Health Impairment. Phillip Tuso, MD, FACP, FASN

A new tool called the Treatment Progress Indicator appears to offer clinicians an objective approach to assess patients with depression, anxiety, and chemical dependency, and to objectively measure a patient's response to therapy over time. This allows clinicians to compare their patients' responses to therapy with those of a cohort of patients with a similar diagnosis and severity, and allows for objective population-level management of disease. Implementation of the tool has the potential to improve behavioral health access and affordability.

### Case Studies

78 Special Medical Conditions Associated with Catatonia in the Internal Medicine Setting: Hyponatremia-Inducing Psychosis and Subsequent Catatonia. Andrei A Nowac, MD; Daniela Bota, MD, PhD; Joanne Witkowski, MD; Jorge Lizip, MD; Robert G Bota, MD, MSG

There are only 6 reports of hyponatremia-induced catatonia and psychosis in the literature. The authors present the case of a 30-year-old woman with catatonia and psychosis induced by hyponatremia, and use this report to exemplify the multitude of biologic causes of catatonia, and to propose a new way to look at the neuro-anatomical basis of processing, particularly the vertical processing systems the authors believe are involved in catatonia.
The use of a Foley catheter to protect the small and large bowel from radiation injury during stereotactic radiosurgery to the spine has not previously been described in the surgical literature. The proximity of visceral organs may preclude adequate target delivery of radiation. The authors describe the novel use of Foley catheters placed intraoperatively to displace the bowel during stereotactic radiosurgery, allowing for a full radiation dose to be safely delivered to the tumor.
ORIGINAL RESEARCH & CONTRIBUTIONS

An Adaptation of Family-Based Behavioral Pediatric Obesity Treatment for a Primary Care Setting: Group Health Family Wellness Program Pilot

Karin R Riggs, MSW; Paula Lozano, MD, MPH; Amy Mohelnitzky, MEd; Sarah Rudnick, MD; Julie Richards, MPH

Abstract

Objective: To assess the feasibility and acceptability of family-based group pediatric obesity treatment in a primary care setting, to obtain an estimate of its effectiveness, and to describe participating parents’ experiences of social support for healthy lifestyle changes.

Methods: We adapted an evidence-based intervention to a group format and completed six 12- to 16-week groups over 3 years. We assessed program attendance and completion, changes in child and parent body mass index (BMI; calculated as weight in kilograms divided by height in meters squared), and changes in child quality of life in a single-arm before-and-after trial. Qualitative interviews explored social support for implementing healthy lifestyle changes.

Results: Thirty-eight parent-child pairs enrolled (28% of the 134 pairs invited). Of those, 24 (63%) completed the program and another 6 (16%) attended at least 4 sessions but did not complete the program. Children who completed the program achieved a mean change in BMI Z-scores (Z-BMI) of -0.1 (0.1) (p < 0.001) and significant improvement in parent-reported child quality of life (mean change = 8.5; p = 0.002). Mean BMI of parents changed by -0.9 (p = 0.003). Parents reported receiving a wide range of social support for healthy lifestyle changes and placed importance on the absence or presence of support.

Conclusions: A pilot group program for family-based treatment of pediatric obesity is feasible and acceptable in a primary care setting. Change in child and parent BMI outcomes and child quality of life among completers were promising despite the pilot’s low intensity. Parent experiences with lack of social support suggest possible ways to improve retention and adherence.

Introduction

Years of clinical research have demonstrated the efficacy of family-based behavioral pediatric obesity treatment for school-aged children.1 The US Preventive Service Task Force (USPSTF) recently issued a recommendation to screen children aged 6 to 11 years for obesity and refer overweight children to intensive behavioral treatment.2 In contrast to information-focused weight management programs, effective behavioral interventions teach parents and children behavioral skills such as self-monitoring and goal setting to create and sustain lifestyle changes.3-5 Despite evidence for the efficacy of behavioral pediatric obesity treatment, few models exist for their implementation in health care settings.6,7 Few health care systems offer this type of treatment because delivery of behavioral obesity treatment requires a behavioral skill set not typically found among most physicians, nurses, nutritionists, or other primary care personnel, outside of mental health providers. Furthermore, behavioral obesity treatment requires frequent (usually weekly) contacts over time,8 a departure from the health care visit cadence for children this age. The considerable barriers to recruitment and retention encountered in clinical trials pose challenges in health care settings as well.9 Parents of obese children are often reluctant to commit to treatment because they minimize the short- and long-term consequences of obesity for their child, are reluctant to embark on family lifestyle changes, or simply lack readiness to change at any particular time.10 Families who do enroll in treatment universally experience some difficulties in adopting and adhering to lifestyle changes, which often disrupt family dynamics. Consequently, faced with the stress of making changes in the absence of social support for change, many families fail to complete treatment.11 Effective strategies for implementing family-based behavioral pediatric obesity treatment in real-world settings are needed.12,13

We developed the Family Wellness Program (FWP) in response to a growing demand for pediatric weight management among clinicians at Group Health (GH), where behavioral treatment for children was not available at the time of this pilot. We adapted the FWP intervention from a previous randomized controlled trial of individualized family-based behavioral pediatric obesity treatment (FOCUS, NIH grant R21-054871, Clinical Trial Identifier NCT00746629).14 The FWP differed from FOCUS in two important ways: The FWP relied on a group format rather than individual contacts, and it delivered fewer contact hours. These adaptations were designed to minimize resource demand and participant burden in order to improve the feasibility and acceptability of family-based behavioral pediatric obesity treatment in a primary care setting. Growing evidence suggests that behavioral obesity interventions can be effectively delivered in groups.1,15 As a proof-of-concept, the FWP relied on masters-level research interventionists to deliver treatment, bypassing the barriers
related to staffing behavioral interventions in primary care. We conducted a single-arm before-and-after feasibility pilot of the FWP with two principal aims:

1. to assess feasibility and acceptability of delivering group pediatric behavioral obesity treatment in a primary care setting, and
2. to estimate the effectiveness of the group program by exploring pre- and posttreatment differences in behavioral skills use, child and parent body mass index (BMI; calculated as weight in kilograms divided by height in meters squared), and child quality of life.

As a secondary aim, we used qualitative interviews of a subset of FWP participants to describe parents’ experiences of social support for making healthy lifestyle changes in their families, because these could inform future implementation efforts.

Methods

Design

We conducted a single-arm before-and-after trial of a group adaptation of family-based pediatric obesity treatment in a primary care setting.

Setting

The study was conducted in 2 GH clinics near Seattle, WA. GH is a consumer-governed, nonprofit health delivery system located in the Pacific Northwest. Member demographic characteristics are representative of the region’s population. As of May 2012, GH membership was 5.9% black or African American, 2.1% American Indian/Alaska Native, 10.6% Asian, 1.5% Native Hawaiian or other Pacific Islander, and 79.9% white; 5.5% were Hispanic. Similar to the US population, 15% of GH children are obese and 15% are overweight. GH maintains an evidence-based clinical guideline to aid clinicians in the diagnosis and management of overweight and obesity, but had no weight management program for obese and overweight children at the time of this study.

Recruitment

Eligible families were identified via electronic medical record as having a child age 6 to 12 years with a BMI at the 85th percentile or higher and at least one parent with a BMI of 25 or higher. Before the start of each of 6 groups, pediatricians and family medicine physicians reviewed a list of eligible patients and approved families for study contact. Study staff mailed invitation letters to families on behalf of their physician, and then followed-up with select families by phone. Families with children in the highest BMI percentile were prioritized for phone invitation until the upcoming group was filled. Eligible families who did not enroll and did not refuse study contact continued to receive invitations for upcoming groups. Family-based pediatric behavioral obesity treatment targets the parent as the primary change agent for the child’s eating and activity behaviors. For each participating child, we also enrolled 1 parent who was expected to attend sessions and was held accountable for implementing changes in the home.

Intervention

The FWP was delivered to six groups from May 2009 to December 2011. Group sessions were facilitated by Health Coaches with masters-level training (MSW, MEd) and eight to ten years’ experience delivering health behavior change interventions. The FWP was delivered weekly in a group format, incorporating only a small number of brief, ad hoc individual contacts as needed (e-mail or face-to-face). Each week, parents and children met together briefly (five to ten minutes) to review weekly goals jointly, after which participants met in separate, simultaneous hour-long parent and child groups.

To minimize participant burden and maximize potential acceptability of the FWP, the intervention was first delivered as 13 contact hours over 12 weeks (groups 1 to 4; years 2009-2010). On the basis of preliminary assessment of the feasibility and acceptability of this duration, in 2011, we increased the FWP to 20 contact hours over 16 weeks (groups 5 and 6). This decision was also informed by the USPSTF 2010 systematic review that concluded moderate- to high-intensity behavioral treatment (> 25 contact hours) is effective whereas lower-intensity treatment is not. Resource constraints precluded delivering a full 25 hours of treatment in the FWP.

The FWP intervention materials, protocol, and training manual were adapted from the FOCUS trial. Both interventions emphasized basic nutrition and physical activity education as well as behavioral monitoring, goal setting, contingency management, environmental control, and relapse prevention. The FWP Health Coach prescribed standardized weekly goals during the first 4 weeks of treatment to help families learn and apply the behavioral skills. For the remainder of the intervention, families were encouraged to set their own weekly goals and implement the skills that best fit the family’s needs and situations (as if choosing from tools in a toolbox). Content of the 12- and 16-week versions of the FWP did not differ. The additional contact hours reinforced previous content and largely focused on implementing behavior change strategies in families’ day-to-day lives. One author (PL) reviewed audio tapes of group sessions and qualitatively assessed them for treatment fidelity. The intervention team met weekly for supervision and discussion.

Measures

Parent and child BMI and child quality-of-life data were collected at baseline and at program completion. Children and parents were weighed weekly using standard anthropometric procedures in light clothing (no shoes) using a digital scale (Sacletronix; Wheaton, IL) with 0.1-kg accuracy. At baseline and after treatment, study staff weighed participants at least 3 times until agreement within 0.1 lb. Height was also measured at these same time points for children and once at baseline for adults using a Holtain stadiometer (Holtain; Crosswell, Wales) with 0.5 cm accuracy. Child BMI Z-scores (Z-BMI) were calculated using Centers for Disease Control and Prevention growth charts.

Parents were asked to complete a self-administered survey that included child quality of life and parent/child use of behavioral skills. Child quality of life was measured by parent proxy-report using the Pediatric Quality of Life Inventory, version 4.0. The instrument is responsive and distinguishes healthy children from ill children. The Pediatric Quality of Life Inventory meets reliability criteria for group and individual comparisons (self-report Cronbach $\alpha = 0.88$; proxy-report Cronbach $\alpha = 0.90$).
Parents were asked to rate the frequency of their use of behavioral skills in the past 3 weeks on a 5-point Likert scale (1 = never; 5 = very often) at baseline and at program completion. Skills included: 1) setting and reviewing goals for child’s eating and physical activity, 2) monitoring child’s eating and physical activity behaviors, 3) praising child for healthy eating and physical activity, and 4) improving parent’s own health behaviors (ie, modeling healthy diet and physical activity). These items were used in the FOCUS trial; validation studies are underway (Brian Saelens, PhD, personal communication, June 30, 2013).^a

Parent and child demographic characteristics were assessed at baseline by parent report (Table 1). Health Coaches recorded attendance at weekly sessions. Program completion was defined post hoc as attending either 1) at least 75% of sessions or 2) more than 50% including the last session.

### Table 1. Demographic characteristics of enrolled Family Wellness Program (FWP) participants by subgroup

<table>
<thead>
<tr>
<th>Participant characteristics</th>
<th>All enrolled families n = 38 ( % )</th>
<th>Families who completed n = 24 ( % )</th>
<th>Families sampled for interview n = 16 ( % )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>25 (66)</td>
<td>15 (63)</td>
<td>11 (69)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>19 (50)</td>
<td>13 (54)</td>
<td>6 (38)</td>
</tr>
<tr>
<td>More than one race</td>
<td>7 (18)</td>
<td>3 (13)</td>
<td>4 (25)</td>
</tr>
<tr>
<td>Hispanic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>3 (8)</td>
<td>2 (8)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>More than one race</td>
<td>3 (8)</td>
<td>2 (8)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-7</td>
<td>6 (16)</td>
<td>4 (17)</td>
<td>1 (6)</td>
</tr>
<tr>
<td>8-9</td>
<td>7 (18)</td>
<td>4 (17)</td>
<td>4 (25)</td>
</tr>
<tr>
<td>10-13</td>
<td>24 (63)</td>
<td>16 (67)</td>
<td>11 (69)</td>
</tr>
<tr>
<td><strong>Parents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>36 (95)</td>
<td>23 (96)</td>
<td>14 (88)</td>
</tr>
<tr>
<td>Married or partnered</td>
<td>25 (66)</td>
<td>16 (67)</td>
<td>10 (63)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; High school</td>
<td>4 (11)</td>
<td>4 (17)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>&lt; High school or GED</td>
<td>6 (16)</td>
<td>3 (13)</td>
<td>1 (6)</td>
</tr>
<tr>
<td>College or higher</td>
<td>19 (50)</td>
<td>14 (58)</td>
<td>9 (56)</td>
</tr>
<tr>
<td>Annual household income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; $25,000</td>
<td>5 (13)</td>
<td>3 (13)</td>
<td>1 (6)</td>
</tr>
<tr>
<td>$25,000 - $49,999</td>
<td>7 (18)</td>
<td>4 (17)</td>
<td>3 (19)</td>
</tr>
<tr>
<td>≥ $50,000</td>
<td>24 (63)</td>
<td>17 (71)</td>
<td>11 (69)</td>
</tr>
</tbody>
</table>

^a Data were missing for child age (1 family), parental education (1 family) and household income (2 families).
^b Families were considered to have completed the FWP if they attended at least 75% of the intervention, or more than 50% including the last session.
^c Sixteen families were chosen by purposeful sampling and invited to participate in qualitative interviews. This sample included families who did and did not complete the FWP. GED = general educational development.

**Quantitative Analyses**

Descriptive statistics were used to characterize the sample and summarize results. Engagement differences between the 12- and 16-week programs were examined using Welch’s independent samples t test. Pre- and posttreatment differences in BMI outcomes and quality of life among those who completed the program were explored using Wilcoxon matched-pairs signed-rank tests. We also estimated mean differences using paired t tests to facilitate comparison with the extant literature. We were not able to collect outcome data on individuals who did not complete the program, so an intent-to-treat analysis of before-and-after data was not possible. Demographic and engagement characteristics of the interview sample were compared with all enrolled FWP participants using descriptive statistics and the Fisher exact test. Quantitative analyses were conducted using Stata, version 12.1 (StataCorp, College Station, TX).

**Social Support Interviews and Qualitative Analyses**

We used purposive sampling to identify 16 parents for qualitative interviews, including some who did and some who did not complete the FWP. Two research assistants conducted 60- to 90-minute face-to-face qualitative interviews within 2 months after treatment. They followed a semistructured interview guide, using an open-ended interviewing style that allowed the interviewer to elicit the participant’s narrative.

Interviews focused on participants’ perceptions, experiences, and opinions related to presence or absence of social support for making family-based changes to diet and physical activity and implementing the program’s behavioral skills. Examples of questions are “What does it mean to you to say that a relationship is supportive?”; “If you decided to make changes to support your child’s healthy eating, how could a friend or family member help support you in that?”; and “Do you feel that participating in the Family Wellness Program affected any of your relationships in any way, positive or negative?”

Each interview was audio-recorded and transcribed for qualitative analysis. One author (KR) used an a priori manual to code each transcript for types of positive and negative support. Two authors (KR and PL) met weekly to review codes and discuss issues of discordance. After all support codes were assigned, these authors (KR and PL) met weekly to review codes and discuss issues of discordance. After all support codes were assigned, these two researchers examined quotations to explore the relationship between social support and making healthy lifestyle changes. They continued meeting weekly to discuss and refine the results.

**Human Subjects**

At baseline, parents provided informed consent; children provided informed assent before participation. In the first 4 FWP groups, families received a $20 incentive for completing the baseline and follow-up assessments. In the last 2 groups, parent feedback led to replacing the monetary incentives with a weekly prize drawing for children who were present and had met weekly goals (value at $10 to $40). All study activities were approved by the GH institutional review board.

**Results**

**Participants**

Thirty-eight families enrolled in the FWP (28% of the 134 pairs invited; see Figure 1). Demographic characteristics are reported in Table 1. The mean age (standard deviation [SD]) of enrolled
children was 10.1 (2.0) years; 34% were boys; and 50% were white, non-Hispanic. Parents were mostly female (95%), 66% were married, 50% had a college degree or higher, and about two-thirds (63%) had an annual household income of $50,000 or more. Characteristics of program completers were similar to those of all enrolled families (Table 1). The subset of participants sampled for qualitative interviews is shown in the rightmost column and discussed separately below.

Recruitment and Retention
Of 38 enrolled parent-child pairs, 24 (63%) completed the program and another 4 (11%) attended at least 4 sessions but did not complete the program. Ten (26%) dropped out of the program within the first 3 weeks of treatment. Completers attended an average (SD) of 79% (12%) of all sessions. There were no differences between the 12- and 16-week programs in the proportion of sessions attended (p = 0.86) or completed (p = 0.72).

Quantitative Findings

Parent Report of Behavioral Skills Use
Parents who completed the program reported an increase in recent use of each of the key behavioral skills at the end of treatment compared with baseline (Table 2). About 70% of parents reported setting and reviewing goals for their child’s eating or physical activity after treatment, whereas only about half (46%) reported actually monitoring these behaviors.

Slightly more than half (54%) reported praising their child for making healthy choices after treatment. Self-reported changes in parental behaviors (ie, modeling) were more common for eating than for physical or sedentary activity (79% and 33% after treatment, respectively).

Health Outcomes
Child and parent BMI outcomes and child quality of life results among the 24 families who completed the program are shown in Table 3. Among child completers, mean change (SD) in Z-BMI was -0.1 (0.1) (p < 0.001); nearly half (46%) had a Z-BMI reduction of 0.1 or greater after treatment. Mean change in BMI percentile among child completers was -0.8 (p = 0.006). Mean parent BMI change among completers was -0.9 (p = 0.003). Two-thirds (67%) of parent completers had a BMI reduction of 0.1 or greater. Child quality-of-life composite score rose by a mean of 8.5 points from a baseline of 71.2 (p = 0.002) (parent-report). In addition, child quality of life significantly improved from baseline to posttreatment in each separate domain: physical, emotional, social, and school functioning (Table 3). Notably, the proportion of children with meaningfully impaired quality-of-life scores (defined as ≥ 1 SD below the population mean)23 dropped by half from pre- to post-treatment (n = 8 [33%] to n = 4 [16%], respectively). Linear regression models showed that weight status at baseline was not associated with either changes in child or parent weight outcomes or child quality of life.

Table 2. Parent self-reported use of behavioral skills among those who completed the Family Wellness Program (n = 24)

<table>
<thead>
<tr>
<th>Skill used often or very often in the past 3 weeks*</th>
<th>Pretreatment n (%)</th>
<th>Posttreatment n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set and reviewed child's goals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Either eating or physical activity goals</td>
<td>7 (29.2)</td>
<td>17 (70.8)</td>
</tr>
<tr>
<td>Eating goals</td>
<td>2 (8.3)</td>
<td>13 (54.2)</td>
</tr>
<tr>
<td>Physical activity goals</td>
<td>6 (25.0)</td>
<td>14 (58.3)</td>
</tr>
<tr>
<td>Monitored child's habits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Either food and drink or physical activity</td>
<td>2 (8.3)</td>
<td>11 (45.8)</td>
</tr>
<tr>
<td>Food and drink</td>
<td>2 (8.3)</td>
<td>9 (37.5)</td>
</tr>
<tr>
<td>Physical activity</td>
<td>1 (4.4)</td>
<td>8 (33.3)</td>
</tr>
<tr>
<td>Praised child</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Either healthy eating or physical activity</td>
<td>10 (41.7)</td>
<td>13 (54.2)</td>
</tr>
<tr>
<td>Healthy eating</td>
<td>5 (21.7)</td>
<td>13 (54.2)</td>
</tr>
<tr>
<td>Physical activity</td>
<td>9 (37.5)</td>
<td>7 (29.2)</td>
</tr>
<tr>
<td>Improved own habits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any physical activity improvement</td>
<td>5 (21.7)</td>
<td>8 (33.3)</td>
</tr>
<tr>
<td>Increased own physical activity</td>
<td>3 (13.0)</td>
<td>7 (29.2)</td>
</tr>
<tr>
<td>Decreased own sedentary behavior</td>
<td>5 (21.7)</td>
<td>6 (25.0)</td>
</tr>
<tr>
<td>Any diet improvement</td>
<td>8 (34.8)</td>
<td>19 (79.2)</td>
</tr>
<tr>
<td>Decreased own calories</td>
<td>4 (17.4)</td>
<td>15 (62.5)</td>
</tr>
<tr>
<td>Decreased own unhealthy foods</td>
<td>5 (21.7)</td>
<td>15 (62.5)</td>
</tr>
<tr>
<td>Increased own fruits and vegetables</td>
<td>6 (26.1)</td>
<td>16 (66.7)</td>
</tr>
</tbody>
</table>

* 5-point Likert scale dichotomized as Often/Very often (4 or more) vs Sometimes/Rarely/Never (3 or less)
Qualitative Findings
Social Support Interviews
Demographic characteristics of the interview sample (n = 16) were similar to those of all enrolled families (Table 1); 69% of the interview sample completed the program compared with 63% of all enrolled (p = 0.74). Parents interviewed valued social support for making healthy changes to diet and physical activity. Parents who felt successful in the FWP attributed much of their success to positive support they received from others. At the same time, parents who were struggling to make changes to their family’s diet and physical activity described it to negative support or lack of positive support from others. Representative quotations from interviews among parents who did and did not complete the FWP are shown in Sidebar: Selected Quotations from Parent Interviews: Social Support for Making Family-Based Healthy Lifestyle Changes.

Discussion
Results from this mixed-method pilot suggest that it may be feasible and acceptable to deliver family-based behavioral pediatric obesity treatment in a clinic format in a primary care setting. Only about one quarter of eligible families agreed to participate despite outreach and endorsement by primary care clinicians. However, our retention rate (63%) was similar to other group-based clinical behavioral treatment programs. Moreover, program duration (13 hours in 12 weeks vs 20 hours in 16 weeks) did not appear to affect retention, which suggests a more intensive program may also be acceptable. Participating families represented the demographic characteristics of GH’s membership and of the geographic region, although college-educated parents were overrepresented.

Although we were able to assess outcomes only of families who completed the FWP, our as-treated estimates of effect on weight outcomes and quality of life suggest that delivering this group-based behavioral obesity treatment to families in a primary care setting has the potential to result in improved outcomes. Families who completed the program reported an increase in behavioral skills use and experienced significant improvements in all health outcomes. Mean improvement in child Z-BMI was comparable with group family-based treatment interventions in the extant literature and was above the threshold for clinically meaningful improvement. In addition, change in child quality of life reflected clinically meaningful improvement. The proportion of children with significantly impaired quality of life dropped by half from before to after treatment.

The parents’ experiences regarding social support for weight management suggest opportunities for enhancing this type of treatment. Overall, parents described the lifestyle change process as disruptive and stressful, and they received varying amounts and types of support from friends and family. Parents who had a supportive social network ascribed some measure of their support in the program to the support they received. The universality of this desire for and appreciation of support suggests that attending to the social context of pediatric weight management could help boost program retention, adherence, and outcomes.

The major strength of this study is that it was conducted in a real-world health care setting, in contrast to the many behavioral pediatric weight management trials conducted in research settings. Other strengths include the adaptation of a curriculum that has been evaluated in randomized controlled clinical trials, assessment of BMI outcomes, and the use of a validated quality-of-life measurement tool.

Certain limitations of this pilot study should also be noted. As a pre-post study without a control group and with incomplete follow-up (loss of families who did not complete the FWP), this pilot can provide only limited evidence about the effect of the intervention. The lower number of contact hours—below USPSTF recommendations—is also a limitation but was consistent with our aim of determining the program’s acceptability and feasibility in this setting. Participants are admittedly self-selected, but

Table 3. Pre- and posttreatment results among families who completed the Family Wellness Program (n = 24)

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Median</th>
<th>Wilcoxon signed-rank</th>
<th>Mean (SD)</th>
<th>Paired t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-</td>
<td>Post-</td>
<td>P*</td>
<td>Pre-</td>
</tr>
<tr>
<td>Weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child BMI percentile</td>
<td>98.8</td>
<td>98.3</td>
<td>&lt; 0.001</td>
<td>98.2 (1.4)</td>
</tr>
<tr>
<td>Child BMI Z-score</td>
<td>2.2</td>
<td>2.1</td>
<td>&lt; 0.001</td>
<td>2.2 (0.4)</td>
</tr>
<tr>
<td>Parent BMI</td>
<td>34.5</td>
<td>33.8</td>
<td>0.012</td>
<td>36.4 (8.1)</td>
</tr>
<tr>
<td>Child quality of life</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall score</td>
<td>71.7</td>
<td>75.0</td>
<td>0.002</td>
<td>71.2 (20.4)</td>
</tr>
<tr>
<td>Subscales</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychosocial</td>
<td>72.9</td>
<td>77.1</td>
<td>0.003</td>
<td>70.3 (20.8)</td>
</tr>
<tr>
<td>Emotional</td>
<td>65.0</td>
<td>77.5</td>
<td>0.004</td>
<td>69.1 (16.0)</td>
</tr>
<tr>
<td>Social</td>
<td>72.5</td>
<td>72.5</td>
<td>0.019</td>
<td>68.8 (28.3)</td>
</tr>
<tr>
<td>School</td>
<td>80.0</td>
<td>80.0</td>
<td>0.035</td>
<td>74.2 (23.7)</td>
</tr>
<tr>
<td>Physical</td>
<td>76.6</td>
<td>84.4</td>
<td>0.003</td>
<td>71.7 (23.5)</td>
</tr>
</tbody>
</table>

* P values < 0.05 are shown in bold.
* PedsQ parent-report. BMI = body mass index.
the motivation required for behavior change programs usually dictates a certain degree of self-selection. Finally, we used a self-report behavioral skills use instrument that is unvalidated, but it has been used in research settings and is currently being validated (Brian Saelens, PhD, personal communication, June 30, 2013).∗

To meet USPSTF recommendations for treating overweight and obese children and their families, evidence-based interventions must be adapted to address real-world challenges while maximizing their effective components. On the basis of this pilot study, group family-based treatment interventions based in primary care settings are a promising strategy for meeting this need. Nonetheless, important challenges remain. Recommended next steps are to conduct a randomized trial of this primary care-based group behavioral weight management program of moderate-to-high intensity (≥25 contact hours) and to evaluate key program processes and outcome measures, ideally with a 1-year follow-up to establish whether the approach is capable of producing significant, meaningful BMI changes. Future work should also address the feasibility of training primary care staff to deliver this intervention, for better generalizability. Acceptability and effectiveness may be enhanced by improving social support for making healthy lifestyle changes and by integrating the program more fully into the primary care setting through point-of-care enrollment, increased use of electronic health records, and ongoing relapse prevention support from primary care clinicians.

Acknowledgments

We thank all the parents and children who participated in the Family Wellness Program; the research staff and clinic personnel who assisted with group sessions, particularly Pamela Mouser, MD; Jim Rogalla, PT; Allan Kam, PT; and Pam Rock, PT; Brian Saelens, MD, for sharing FOCUS trial protocols; and Group Health Research Institute for supporting this work.

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Disclosure Statement

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

References


Selected Quotations From Parent Interviews: Social Support for Making Family-Based Healthy Lifestyle Changes

Noncompleters

I do have to say my son’s father was very pessimistic … because I brought home all this paperwork to fill out and he was just being really pessimistic about [child] being in the program. I mean, he didn’t feel like taking him back, and I’m like, “You guys are the main ones causing this issue with food with him, and you don’t want him to be in the program?” He was not supportive at all.

— Parent of 8-year-old child, 0% of intervention attended.

My mom will actually cook two meals. One, which she’ll eat with my dad and two, whatever my daughter wants. And when I say no, she [child] gets angry, then she’ll go to my mom, and my mom will say yeah. My mom’s yes will override any decision I make.

— Parent of 13-year-old child, 50% of intervention attended.

When I would try to make healthy meals and stuff, my husband would basically say, “Well, I’m not the one that needs to lose weight.” And he would prepare a whole other meal. And of course, maybe his hamburgers looked more fun to eat than maybe a chicken breast. You can’t make kids eat what you cooked.

— Parent of 11-year-old child, 0% of intervention attended.

Completers

Now that my mom’s on board, I think it would be a lot easier to have a family gathering … because she’s gung-ho on this. Interviewer: That was a big transformation for her. Parent: Yeah, that was pretty huge. And honestly, if she hadn’t been on board, I’m not sure that we would have been successful [in the program]. Because we go there every day, you know? And she’s really changed her home environment, so that there’s not a lot of high-calorie foods [for my child] there.

— Parent of 8-year-old child, 92% of intervention attended.

[My husband] sets the pace. If I have something I want to go do, and [the kids] don’t want to come with me, and he’s willing to stay home, they stay home. So, instead of encouraging all of us to go do something, he tends to set a pattern. … [Grandma] likes to come over and hang out with the boys when I work, but she won’t come without cinnamon rolls or doughnuts or things that I’ve asked her numerous times not to. And, you know, [she says] “They’re kids. They’re going to outgrow it, they’ll work this off in a week, don’t worry about it …” So, yeah, she’s not so good on my support level as far as that goes. Emotionally, she’s very supportive of me, but not with what I’m trying to do with the kids.

— Parent of 11-year-old child, 75% of intervention attended.

Schedules are busy and we constantly sort of think, “Gosh, I don’t want to do this [healthy eating or physical activity].” But in our house, it’s just not an option. The one thing that I do feel about our family is that everyone has really come together. [Child] is kind of in the middle, and all the adults around, and even my kids and my niece and nephews, everyone’s been really supportive—that this is really serious for [child]. … I can remember [child’s dad] saying, “Well, you don’t need to go walking today, you can do it tomorrow.” But he’s kind of come around in that he has become very supportive. And he’s always checking in with [child], “How are you doing? Gosh, what should I do, should we go get this or should we go do that?” Or if they have an afternoon where the other two [kids] are off with their friends or doing something else, he’s really good about being like, “Let’s go outside and go for a walk.” Now he has taken on more of that supporter—kind of cheerleader—for [child].

— Parent of 13-year-old child, 83% of intervention attended.
An Adaptation of Family-Based Behavioral Pediatric Obesity Treatment for a Primary Care Setting: Group Health Family Wellness Program Pilot

Approaching the Ideal

To approach the ideal, precise scientific knowledge of the body machine must be supplemented with a more empirical attitude in the practice of medicine.

— René Jules Dubos, PhD, 1901-1982, French-born American microbiologist, experimental pathologist, environmentalist, humanist and Pulitzer Prize winner


11. Homer CJ. Responding to the childhood obesity epidemic: from the provider visit to health care policy—steps the health care sector can take. Pediatrics 2009 Jun;123 Suppl 5:S253-7. DOI: http://dx.doi.org/10.1542/peds.2008-2780B.


Temporal Trends in Mortality after Coronary Artery Revascularization in Patients with End-Stage Renal Disease

Ashok Krishnaswami, MD; Thomas K Leong, MPH; Mark A Hlatky, MD; Tara I Chang, MD, MS; Alan S Go, MD

Introduction

The use of cardiovascular operations and procedures has increased during the past one to two decades. This has been primarily caused by an upsurge in percutaneous coronary intervention (PCI) compared with coronary artery bypass grafting (CABG). This temporal trend has also been noted in individuals with end-stage renal disease (ESRD). Interestingly, accompanying the trend is an established knowledge that there has been a rise in the comorbidity burden in those referred for coronary revascularization procedures. Procedural success and symptom control have improved over time with PCI in patients with normal renal function. Similarly, perioperative outcomes have improved with CABG. However, early and late mortality after coronary revascularization have been consistently higher in patients with ESRD compared with those without kidney disease.

Recent studies of the comparative effectiveness of CABG and PCI in patients with ESRD that have included, as part of their main analyses, an assessment of the secular trends in mortality have shown mixed results. To specifically address this knowledge gap, we studied a large community-based sample of patients with ESRD who underwent coronary revascularization by PCI or CABG to characterize the temporal trends in mortality in the years 1996-2008. We hypothesized that there would not be any significant temporal changes in mortality in the extremely high-risk cohort of ESRD patients after undergoing coronary revascularization.

Methods

Study Population

Our source population included members of Kaiser Permanente Northern California (KPNC), a large integrated health care delivery system. This study was approved by the KPNC institutional review board. A waiver of informed consent was obtained owing to the nature of the study.

Our target population included adult members receiving chronic dialysis identified from a comprehensive Health Plan ESRD treatment registry who underwent coronary revascularization by either PCI or CABG from January 1, 1996, through December 31, 2008. We identified a coronary revascularization procedure on the basis of procedure codes for CABG or PCI (furnished upon request) without a concomitant valve or other cardiac surgical procedure. Patients were followed-up until death or they were censored when they met any of the following criteria: end of study as of December 31, 2008, organ transplantation, or disenrollment from the Health Plan.

Study Outcomes and Definitions

The primary outcome of the study was all-cause mortality at three years (see statistical analysis section), which was ascertained using Health Plan databases, state death certificates, and Social Security...
Temporal Trends in Mortality after Coronary Artery Revascularization in Patients with End-Stage Renal Disease

Administration files through December 2008, which was the latest available complete vital status data at the time of planned analysis. For analysis purposes, we categorized the primary predictor, index period of coronary revascularization, into three periods: 1996-1999 (reference), 2000-2003, and 2004-2008, because the type of stents being implanted became consistent around the year 2004.

We obtained information from Health Plan clinical and administrative databases on baseline and longitudinal patient demographic characteristics, clinical characteristics, medication exposure, and selected laboratory data using previously described approaches.13,14 The baseline clinical variables that were obtained included age at index revascularization, sex, duration of dialysis before index revascularization, and history of tobacco use, myocardial infarction, diabetes mellitus, hyperlipidemia, hypertension, heart failure, liver disease, lung disease, stroke/transient ischemic attack, and atrial fibrillation/flutter (codes available upon request). The baseline and time-varying medications that were obtained included angiotensin-converting enzyme inhibitor (ACE-I), angiotensin receptor blocker (ARB), beta-blockers, calcium-channel blockers, diabetes medications, and HMG-coenzyme A reductases (statins), on the basis of information from dispensed prescriptions and refill patterns as previously described.15

### Statistical Analysis

An initial bivariate analysis stratified by period was performed using the Fisher exact test or \( \chi^2 \) analysis for categorical variables and the Kruskal-Wallis rank test for continuous variables. Multivariable Cox regression models were created to estimate the hazard ratios (HRs) (95% confidence intervals [CIs]) for the primary predictor for the outcome 3-year mortality under the assumption of independent censoring.16 An assessment of the proportionality assumption was checked by hypothesis testing and by using scaled Schoenfeld residuals against time to determine nonproportionality by graphically assessing for a nonzero slope for each covariate one at a time.16 No gross departure from the proportionality assumption was noted. We then plotted the survivor function after a fully fitted Cox model. To assess whether baseline medications or time-varying medications affected the summary estimate of the primary outcome, a series of additional extended Cox regression models were conducted that adjusted for baseline and time-varying medications individually and together. All statistical analyses were performed using Stata, version 12 (College Station, TX).

#### Table 1. Baseline clinical variables stratified into three periods

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Age (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 65 years</td>
<td>52.8</td>
<td>52.4</td>
<td>51.9</td>
<td>0.86</td>
</tr>
<tr>
<td>65-75 years</td>
<td>34.7</td>
<td>33.3</td>
<td>32.3</td>
<td>0.86</td>
</tr>
<tr>
<td>&gt; 75 years</td>
<td>12.5</td>
<td>14.3</td>
<td>15.8</td>
<td>0.86</td>
</tr>
<tr>
<td>Sex (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>30.1</td>
<td>34.9</td>
<td>38.7</td>
<td>0.11</td>
</tr>
<tr>
<td>Men</td>
<td>69.9</td>
<td>65.1</td>
<td>61.3</td>
<td>0.11</td>
</tr>
<tr>
<td>Duration of dialysis (years ± SD)</td>
<td>2.3 ± 2.9</td>
<td>2.4 ± 2.5</td>
<td>2.4 ± 2.4</td>
<td>0.19</td>
</tr>
<tr>
<td>Baseline comorbidities (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tobacco use</td>
<td>30.7</td>
<td>46.0</td>
<td>47.9</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>31.8</td>
<td>40.4</td>
<td>46.6</td>
<td>0.002</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>64.8</td>
<td>68.9</td>
<td>79.1</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>54.6</td>
<td>82.2</td>
<td>93.8</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>75.6</td>
<td>93.5</td>
<td>97.4</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Liver disease</td>
<td>1.1</td>
<td>3.2</td>
<td>5.5</td>
<td>0.03</td>
</tr>
<tr>
<td>Lung disease</td>
<td>13.6</td>
<td>23.0</td>
<td>27.0</td>
<td>0.001</td>
</tr>
<tr>
<td>Heart failure</td>
<td>29.6</td>
<td>37.9</td>
<td>42.1</td>
<td>0.012</td>
</tr>
<tr>
<td>Stroke/transient ischemic attack</td>
<td>3.4</td>
<td>10.4</td>
<td>6.4</td>
<td>0.01</td>
</tr>
<tr>
<td>Atrial fibrillation/flutter</td>
<td>11.4</td>
<td>12.9</td>
<td>16.8</td>
<td>0.13</td>
</tr>
<tr>
<td>Number of comorbidities (mean ± SD)</td>
<td>1.9 ± 1.2</td>
<td>2.5 ± 1.3</td>
<td>2.9 ± 1.2</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Baseline medications (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE-I</td>
<td>31.3</td>
<td>34.0</td>
<td>31.1</td>
<td>0.67</td>
</tr>
<tr>
<td>ARB</td>
<td>5.1</td>
<td>11.6</td>
<td>18.9</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>44.9</td>
<td>61.8</td>
<td>71.5</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Diabetes medications</td>
<td>40.3</td>
<td>49.5</td>
<td>59.1</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>63.6</td>
<td>57.0</td>
<td>59.6</td>
<td>0.36</td>
</tr>
<tr>
<td>Statins</td>
<td>21.0</td>
<td>49.5</td>
<td>66.6</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Type of revascularization (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCI</td>
<td>36.9</td>
<td>53.1</td>
<td>64.2</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>CAGB</td>
<td>63.1</td>
<td>46.9</td>
<td>35.9</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

ACE-I = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; CAGB = coronary artery bypass grafting; PCI = percutaneous coronary intervention; SD = standard deviation.
Results
Baseline Characteristics
Figure 1 shows how patients entered into the current study. The characteristics at baseline of the 1015 patients in the cohort are shown in Table 1. The mean age, sex, duration of dialysis, and hemoglobin levels (not shown) were similar across the 3 periods (p = not significant). All comorbidities were significantly more prevalent during the later periods except for atrial fibrillation and stroke/transient ischemic attack. Also, the average number of comorbidities present at the time of coronary revascularization increased significantly by period (p < 0.001). The use of ARBs, beta-blockers, diabetes medications, and statins was higher in the later periods (p < 0.001) but use of ACE-I (p = 0.67) and calcium channel blockers (p = 0.36) was not. Table 1 and Figure 2 show that the proportion of patients treated with PCI within KPNC has increased over time compared with CABG (p < 0.001). The use of drug-eluting stents understandably has increased over time (p < 0.001). The number of vessels bypassed decreased significantly (p = 0.002), whereas the number of vessels that underwent PCI had a nonsignificant decrease (p = 0.48) during the study period.

Primary Outcome
Table 2 shows early and late survival estimates in the overall as well as in the revascularization-specific groups. The crude incident rate of death was 256.6 (95% CI = 216.1-304.7) per 1000 person-years for the period 1996-1999; 273.7 (95% CI = 238.2-314.5) per 1000 person-years for the period 2000-2003; and 234.5 (95% CI = 203.2-270.7) per 1000 person-years for the period 2004-2008.

The unadjusted HR for 3-year mortality in the 2000-2003 period was 1.01 (95% CI = 0.77-1.32), whereas in the 2004-2008 period it was 0.84 (95% CI = 0.64-1.09), compared with the reference 1996-1999 period. However, in the full model that was adjusted for age, sex, duration of dialysis, and baseline comorbidities, the HR for mortality in the 2000-2003 time period was 0.85 (95% CI = 0.63-1.14), whereas in the 2004-2008 time period it was significantly decreased at 0.66 (95% CI = 0.49-0.88), compared with the reference period, with a significant trend test of p = 0.01 across the periods. Furthermore, using index revascularization year as a continuous variable, we found that every 1-year increase in the index revascularization year was associated with a 6.0% decrease in the adjusted relative risk of death (p = 0.001). Further adjustment for baseline and/or time-varying medications did not qualitatively change the summary estimate (data not shown).

Timing of Mortality and Interaction with Type of Revascularization
Table 3 notes the adjusted HR for early and late mortality for each individual period compared with the reference period. Early (30-day) mortality after revascularization showed no significant adjusted differences for the periods 2000-2003 and 2004-2008, compared with the reference 1996-1999 period. However, late mortality at 1 year (HR 0.58, 95% CI = 0.39-0.85) and 3 years (HR 0.66, 95% CI = 0.49-0.88) in the 2004-2008 period had a significantly lower adjusted relative rate of death compared with the 1996-1999 period. This was not noted for the time period 2000-2003. Figure 3 is the fitted survival curve stratified by period of index coronary revascularization and demonstrates this improvement in mortality in the latest period. This overall decrease in mortality was seen in both the CABG and PCI subgroups as relatively equal (Figure 4). Furthermore, we specifically did not find

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**Figure 2.** Number of index coronary revascularization procedures (CABG and PCI) in the years 1996-2008.

CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention.

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**Table 2.** Comparison of early (30-day) and late (1-, 3-year) unadjusted survival probability in the overall, CABG, and PCI cohort stratified by period of revascularization

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Overall</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 day</td>
<td>92.6</td>
<td>90.9</td>
<td>93.6</td>
</tr>
<tr>
<td>1 year</td>
<td>72.2</td>
<td>73.1</td>
<td>77.9</td>
</tr>
<tr>
<td>3 year</td>
<td>47.4</td>
<td>47.1</td>
<td>52.1</td>
</tr>
<tr>
<td>PCI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 day</td>
<td>95.4</td>
<td>92.1</td>
<td>94.4</td>
</tr>
<tr>
<td>1 year</td>
<td>63.3</td>
<td>72.3</td>
<td>77.6</td>
</tr>
<tr>
<td>3 year</td>
<td>42.5</td>
<td>44.3</td>
<td>48.8</td>
</tr>
<tr>
<td>CABG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 day</td>
<td>91.0</td>
<td>89.6</td>
<td>92.1</td>
</tr>
<tr>
<td>1 year</td>
<td>77.5</td>
<td>74.0</td>
<td>78.4</td>
</tr>
<tr>
<td>3 year</td>
<td>50.3</td>
<td>50.6</td>
<td>57.6</td>
</tr>
</tbody>
</table>

CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention.
Temporal Trends in Mortality after Coronary Artery Revascularization in Patients with End-Stage Renal Disease

Table 3. Adjusted hazard ratio with a 95% CI p value for early (30-day) and late (1-year, 3-year) mortality in the 2000-2003 and 2004-2008 periods compared with the reference period of 1996-1999.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hazard ratio (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-year mortality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2000-2003</td>
<td>0.84 (0.57-1.25)</td>
<td>0.39</td>
</tr>
<tr>
<td>2004-2008</td>
<td>0.58 (0.39-0.85)</td>
<td>0.01</td>
</tr>
<tr>
<td>3-year mortality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2000-2003</td>
<td>0.85 (0.63-1.13)</td>
<td>0.27</td>
</tr>
<tr>
<td>2004-2008</td>
<td>0.66 (0.49-0.88)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

*Model includes the primary predictor categorized year of revascularization adjusted for age, sex, duration of dialysis before revascularization, and baseline comorbidities (tobacco use, myocardial infarction, dyslipidemia, hypertension, heart failure, liver disease, lung disease, atrial fibrillation/flutter, stroke/transient ischemic attack). CI = confidence interval.

Discussion

The findings from this study provide further insight and clarification into the temporal trends of mortality in the years 1996-2008 in a known high-risk cohort of patients with ESRD. Although recent studies have noted some mixed results,11,12 we believe that the findings from our study are consistent with an optimistic perspective. We found that among a diverse, community-based cohort of adults with ESRD receiving chronic dialysis who underwent coronary revascularization at KPNC, there was a 34% decrease in the adjusted relative risk of 3-year all-cause mortality in patients revascularized in the 2004-2008 period compared with the 1996-1999 period. Therefore, the presence or absence of medications at baseline or in follow-up during the study period did not explain our findings. Of note, this study did not address the comparative effectiveness between CABG and PCI. Future work from our group will address this further.

There have been 2 recent observational studies that included, as part of their main analyses, data on temporal trends in mortality after coronary revascularization in the ESRD cohort. Chang et al.,11 using the US Renal Data System, primarily assessed the differences in death and myocardial infarction between CABG and PCI in ESRD patients receiving chronic dialysis. Their analysis, which included secular trends in survival at 1, 2, and 5 years after multivessel coronary revascularization, is relevant to the current discussion. They noted crude 1-year survival in 1997 at 71% (95% CI = 69%-74%) similar to that in 2008 of 72% (95% CI = 70%-74%). Two- and 5-year risks similarly showed no significant variation over time, and they noted that “survival rates remained relatively constant over the study period.” Shroff et al.8 showed that 2-year survival after CABG in the 2004-2009 period was 60%, which had increased from 56% in the 1995-1998 period. They noted that “survival has improved somewhat in the contemporary era.” Our current study noted that crude 30-day survival was not materially different between the periods. However, 1-year survival was 72.2% in the reference period and improved to 77.9% in the 2004-2008 period. Moreover, 3-year survival was 47.4% in the reference period but increased to 52.1% in the 2004-2008 period. Although these values were crude survival probabilities, this corroborated the decreased incidence rate from 273.7 per 1000 person-years in the period 2000-2003 to 234.5 in the 2004-2008 period. As incidence rate incorporates person and time, it is thought to be a better unit for comparison, and this also showed a nonsignificant decrease in mortality.

In comparison with the previous studies mentioned, we expanded our analysis further and addressed the important issue...
of confounding by secular changes in baseline comorbidity to obtain a risk ratio. Specifically, there was an increase in all of the examined baseline comorbidities, except for prior stroke or transient ischemic attack and atrial fibrillation, as well as in the average number of comorbidities. This has been well documented in the general population, and our findings of this similar trend existing in patients with ESRD should not be of any surprise even in this high-risk population. In fact, we noted that for each 1-unit increase in baseline comorbidities there was an independent 11.4% increased risk of death. Therefore, to appropriately account for the confounding of baseline comorbidities over time and to obtain the direct effect of the index period of coronary revascularization, we appropriately adjusted for this case-mix in baseline comorbidities to obtain what we feel is an accurate estimate of the effect size of the association of the index period of coronary revascularization to mortality.

The use of cardioprotective medications in our cohort differed from previous studies. In comparison with a study of hospitalized ESRD patients presenting with an acute myocardial infarction, the use of cardioprotective medications in our study was much higher; beta-blocker use in the later years was 71.5% (vs 37.7%), and the use of ACE-I and ARB in our study was close to 50% (vs 27.6%). However, when comparing medication usage with patients who have preserved renal function, use of ACE-I, beta-blockers, and statins was higher. In our study, which focused only on patients with ESRD, the variation in use of these agents could be reflective of physician knowledge of the varying benefit: risk ratio (variations in dialysis clearance, nonpressor effects, and anaphylactoid dialyzer reactions) in medications such ACE-I or ARB or of no presumed benefit with the use of statins. Although we noted an improvement in mortality, the mechanism of this improvement is not fully understood and was beyond the scope of the present study. Whether this improvement was because of changes in dialysis techniques, increased use of implantable cardiac defibrillator, improvements in PCI or CABG technology, or other mechanisms is presently unknown. There was an increase in the use of cardioprotective medications at baseline over time, possibly correlating with the associated increased comorbidities as well as the more aggressive population-based prevention efforts at KPNC during the period, but adjusting for baseline and time-varying medication use did not change the summary estimate. Of note, we were not able to appropriately capture aspirin use in all patients because many patients obtain it over the counter.

Finally, our finding of lower mortality in the most recent period for patients with ESRD undergoing revascularization appears to be congruous with the overall 28.4% decrease amongst all dialysis patients noted in the 2012 US Renal Data System. Although our cohort would probably be considered a “sicker” cohort, we believe the finding from this study allows room for optimism in the setting of a disease with an arduous future. The Healthy People program was an initiative set forth by the US Department of Health and Human Services initially in 1979 and updated most recently for “Healthy People 2020.” The goal is to reduce the total death rate for patients on dialysis to 190.8 deaths per 1000 patient-years by the year 2020 from a rate of 192.5 in 2010 (an understandably small decrease in this high-risk cohort). Achieving a similar difference for the subset of ESRD patients receiving coronary revascularization will be an even bigger challenge because they represent an even higher risk category among those on ESRD. Their incidence of death in our study for the 2004-2008 period was 234.5 per 1000 patient-years, and the more aggressive use of pharmacologic therapies for secondary prevention in later years did not appear to explain the improved outcomes. Our findings strongly support the need to develop and to test novel interventions for ESRD patients who continue to be underrepresented in clinical trials.

**Strengths and Limitations**

Our study had several strengths. A primary strength is the inclusion of a community-based cohort of ESRD patients whose clinical characteristics and longitudinal care were comprehensively captured through electronic medical records and other complementary databases. Ascertainment of the primary outcome relied on multiple sources and previously validated methods. Unlike typical claims data, our data set included important clinical and treatment information to provide a more detailed characterization of this study sample. We were also uniquely positioned to assess how differential use of medications over time may have affected the observed outcomes. The limitations of this study are those that are inherent in all observational studies. Specifically, to truly assess secular trends one would need to obtain a large set of covariates that includes angiographic, physician, and hospital characteristics as well as incorporating all the changes in technology of PCI and CABG and also details on the specific indications for referral for revascularization. These were beyond the scope of the current study. Although not a true weakness, our findings may not be fully generalizable to other ESRD populations or practice settings, although it is known that the KPNC population is highly representative of the local surrounding and statewide population except for slightly lower representation at the extremes of age and income.

In summary, in patients with ESRD receiving coronary revascularization by either PCI or CABG, there was a decrease in all-cause mortality with the advantage
Temporal Trends in Mortality After Coronary Artery Revascularization in Patients with End-Stage Renal Disease


This photograph was taken with a Nikon J1 during a springtime hike in a portion of the Carrizo Gorge, east of San Diego, CA. A cold front had just blown through, leaving behind a crystalline blue sky, total solitude, and excellent light and contrast for capturing the magnificent landscape.

Dr Nelson is a Pediatrician at the Otay Mesa Office and Medical Director of the Cleft Lip and Palate Clinic in the Department of Pediatrics in San Diego, CA.
ORIGINAL RESEARCH & CONTRIBUTIONS

Improving Care for Older Adults: A Model to Segment the Senior Population

Yi Yvonne Zhou, PhD; Warren Wong, MD; Hui Li, PhD

Abstract

Context: Risk stratification and tailored interventions are key population-level care management strategies among older adults, whose needs range from screening and prevention to end-of-life care.

Objective: To validate the Senior Segmentation Algorithm, a tool using administrative and clinical data from the electronic health record to identify each member aged 65 years and older as belonging to 1 of 4 Care Groups with similar needs: those without chronic conditions, with one or more chronic conditions, with advanced illness or end-organ failure, or with extreme frailty or nearing the end of life.

Design: Multiple validation methods.

Main Outcome Measures: Concordance with physician judgment, stability of segmentation over time, convergence with mortality, hospitalization, and readmission rates, and costs of care.

Results: Concordance of the algorithm with physician-assessed segmentation of 1615 Medicare recipients was 85%. After 1 year, approximately 85% of 86,140 surviving seniors remained in the same care group: 3.9% moved to a lower need group; and 11% moved to a higher need group. Six-month and 12-month mortality rates varied substantially across care groups. The algorithm performed similarly to the likelihood of hospitalization score in predicting hospitalization and readmissions.

Conclusions: The Senior Segmentation Algorithm accurately identifies older adults in care groups with similar needs, trajectories, and utilization patterns. It is being implemented in all Kaiser Permanente Regions, with the goal of determining key elements of care for members in each group. In addition, future efforts will aim to slow progression to higher need care groups and to identify necessary improvements in delivery system design.

Introduction

Tailored interventions are disease management strategies widely applied to patients who share chronic conditions, such as diabetes or congestive heart failure. Stratification of older adults into distinct risk categories is also relatively common. Clinical guidelines recommend incorporating life expectancy into decision making, leading to the development of general prognostic mortality indexes. Other indexes assess the risk of readmission or death after hospital discharge in community-dwelling seniors, risk of functional decline among those with an Emergency Department visit, risk of functional dependence, and likelihood of hospitalization within six months. Hierarchical condition categories risk-adjust Medicare and Medicaid payments on the basis of diagnostic categories.

However, beyond disease management and risk stratification, broad segmentation of a population can better identify and address the distinct health care profiles and priorities of different groups comprising it. The care needs of seniors vary from screening and prevention to management of complex conditions such as frailty, advanced illness, and the end of life. Consequently, a senior segmentation model was developed at Kaiser Permanente (KP) in which seniors fit best into one of four population care groups (Table 1). Care Group 1 consists of robust seniors without chronic conditions. Care Group 2 consists of seniors with one or more chronic conditions, such as diabetes, heart disease, and depression. Care Group 3 consists of seniors with advanced illness and end-organ failure, such as heart failure or chronic obstructive pulmonary disease. Care Group 4 includes seniors with advanced frailty or at the end of life. Although individuals may and do move between care groups over time, interventions and programs should be tailored and designed to meet the distinct needs of patients within care groups.

Operationalizing the senior segmentation model requires accurately identifying the care group within which each older adult best fits. This report describes the development of an algorithm for doing so and its validation by multiple methods.

Methods

Algorithm Development

The Senior Segmentation Algorithm (SSA) was developed using readily available data. We began with relatively simple rules based on risk scores and clinical criteria. Risk scores included the prospective risk score (DxCG Intelligence, Verisk Health Inc, Waltham, MA) and likelihood of hospitalization scores (Verisk Health Inc, Waltham, MA). Clinical indicators were based on hierarchical condition categories and chronic disease registries. Table 1 presents the risk score and clinical indicator profile for each care group.

Multiple data sources for the indicators in Table 1 are required. The DxCG scores require a DxCG data mart (Verisk Health Inc, Waltham, MA). Sources vary for chronic conditions’ diagnoses and utilization data; for example, they may include point-of-care panel management tools and enterprise data warehouses.

Other clinical data can be found in the electronic health record (EHR)—KP HealthConnect—and include encounter diagnoses, the use of home oxygen and home hospital beds, surgeries and procedures, severe organ failure, and hospice or palliative care...
orders. In addition, risk scores and indicators have been tailored to specifications in individual KP Regions, and regional implementation can add data specifically available and valuable to that Region.

The prototype SSA was improved on the basis of feedback from primary care physicians (PCPs). Patients in PCP panels were categorized into care groups for PCPs to review and provide feedback. Rules were then added, deleted, and tailored to reproduce as closely as possible PCP clinical judgments about appropriate care groups. For instance, long-term wheelchair use was deleted as a decision rule when PCPs identified that it did not correlate well with functional and/or ambulatory status. We retained rules that improved sensitivity and specificity.

Analysis

We assessed performance and the validity of the SSA in several ways. We examined the distribution of members across care groups and its stability over time. To assess the stability of population segmentation over time, we assessed the proportion of seniors who remained in their algorithm-assigned care group at one year and the proportion who moved to either a higher- or lower-need care group. Although the algorithm is intended to tailor care and not function as a predictive modeling tool, we hypothesized that utilization, mortality, and costs of care would all increase from care group to care group. Consequently, we assessed care group-specific mortality and hospital discharge rates and, among seniors with a hospital discharge, readmission rates. To assess care group-specific costs of care, we used monthly claims data to calculate an average cost per member per month in each care group. Finally, to examine concordance of the algorithm-assigned care group for individual seniors with physician clinical judgment, we asked physicians to review results from the algorithm and to make a clinical assessment as to whether classifications for individual patients in their panels were correct. We assessed concordance between physician judgment and the SSA using the \( \kappa \) coefficient. For comparison, we also assessed concordance of SSA-assigned care groups and segmentation on the sole basis of likelihood of hospitalization.

Results

Distribution of Seniors by Care Group and Stability of Care Groups over Time

Among 91,113 KP Northwest (KPNW) and KP Hawaii members aged 65 years and older, 13.5% were in Care Group 1; 62.3% in Care Group 2; 15.7% in Care Group 3; and 8.5% in Care Group 4. At 1 year, the majority remained in their initial care group. Most seniors whose care group changed at 1 year had moved to a higher need care group (Table 2). Migration to a lower need care group happened infrequently and typically resulted from lower utilization (which is incorporated into risk scores used in the SSA).

Utilization, Mortality, and Costs

Among 61,189 KPNW members older than age 65 years as of January 1, 2010, we examined hospital discharges during the quarter following segmentation. The percentage of seniors with a hospital discharge doubled between each care group (Table 3). Among segmented KPNW seniors with hospital discharges, we examined 30-day, all-cause readmissions during the quarter following segmentation. The percentage of seniors with a readmission also increased across care groups.

Using the same data set, we examined mortality. At 6 and 12 months, 0.4% and 0.6% of members in Care Group 1 had died, compared with 15.2% and 28% of those in Care Groups 3 and 4 (Table 3). At 24 months, 50% of members in Care Group 4 had died.

Annualized costs of care increased approximately twofold between each care group and the next higher need one (Table 3).
**Concordance with Physician Judgment**

Six PCPs in 2 Regions assigned the members of their panels older than age 65 years to a care group; 1615 members were 65 or older and assigned by a physician to a care group. Physicians were aware of the SSA-assigned care group, and the physician-assigned group was identical to that of the SSA in 85% (1369) of senior panel members (Table 4). With few exceptions, the physician-assigned and SSA-assigned care group differed by only 1 level. Kappa coefficients calculated for each Region were 0.74 and 0.75, indicating substantial agreement between physician- and SSA-assigned care groups. In contrast, regional κ coefficients for SSA-assigned care group and likelihood of hospitalization were only 0.36 and 0.19, indicating slight to fair agreement.

**Discussion**

Senior segmentation is a health care system approach to population-based care for older adults. Care group stability over time, hospitalization, readmission, mortality, and cost data and concordance with physician clinical judgment support its further development. In contrast, the likelihood of hospitalization concordance with physician clinical judgment about assigned care group was less robust. The utility of SSA in practice will be ascertained when it is used to assess detailed patient needs and identify appropriate interventions.

Much individual variability remains in care groups. Nevertheless, the goal of senior segmentation is to ensure that the distinct needs of older adults in each care group are met. For example, in the absence of illness, the health care needs of individuals in Care Group 1 revolve around disease prevention, screening, and health promotion services. Individuals in Care Group 2 need more emphasis on disease management services and self-management. Among those in Care Group 3, care needs are more complex and require approaches above and beyond disease management. In Care Groups 3 and 4, aggressive efforts to reach target goals for chronic diseases are potentially counterproductive. In addition, more focus is needed on determining optimal nontraditional care design approaches for these care groups.

A strength of our work is that it is, to the best of our knowledge, the first report of a population-level approach to tailoring care to the varying health needs of older adults. Our ability to apply the SSA to more than 90,000 members reflects the efficiency of using administrative and clinical data to segment the large population of adults aged 65 years and older.

Several limitations deserve mention. PCPs were aware of the SSA results when assigning their patients to a care group; this may have affected the concordance we observed. Further study should include blinded validation of concordance. In this preliminary report, we are unable to comment on the impact of segmentation on indicators of care processes and outcomes, such as Healthcare Effectiveness Data and Information Set (HEDIS) measures, utilization patterns, and health status over time. Given that our goal is to optimize care for each group in the senior population, efficiency and member satisfaction are also pivotal outcomes that will need to be measured.

Another limitation pertains to functional status, which is a well-established predictor of health care utilization, outcomes, and quality of life in older adults. We were unable to incorporate direct measures of functional status into care group categorizations because of the lack of consistently accurate and available data in the EHR and logistically simple data collection methods. Instead, proxy measures for functional status, such as the presence of a hospital bed in the home, proved useful.

Last, the SSA was developed and validated in an integrated health care delivery system with a comprehensive EHR. The availability of the data elements in the algorithm determines its generalizability to other settings.

The senior segmentation algorithm is likely to evolve over time. Enhancements under consideration include incorporating member-reported health data related to general health status, frailty, health behaviors, and history of age-related risks (eg, falls, urinary incontinence, poor nutrition, and pain). Similarly, measures of the progression of primary disease would provide useful information, as would clinical trends related to specific diagnoses. Another type of clinical information useful for population segmentation relates to cancer diagnoses and includes staging, intent of treatment, and progression. Revisions of the algorithm will require additional validation.

---

**Table 2. Surviving seniors in each initial care group who remained in that group or moved to another group at one year**

<table>
<thead>
<tr>
<th>Care group at one year</th>
<th>Seniors in each initial care group, number (%)</th>
<th>1 (n = 11,751)</th>
<th>2 (n = 55,241)</th>
<th>3 (n = 13,375)</th>
<th>4 (n = 5773)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8350 (71.1)</td>
<td>1438 (2.6)</td>
<td>39 (0.3)</td>
<td>6 (0.1)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>3140 (26.7)</td>
<td>49,229 (89.1)</td>
<td>1162 (8.7)</td>
<td>276 (4.8)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>186 (1.6)</td>
<td>3499 (6.3)</td>
<td>10,803 (80.8)</td>
<td>686 (11.9)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>75 (0.6)</td>
<td>1075 (1.9)</td>
<td>1371 (10.3)</td>
<td>4803 (83.2)</td>
<td></td>
</tr>
</tbody>
</table>

*Values in bold indicate surviving seniors who remained in their initial care group.

**Table 3. Utilization and mortality by care group**

<table>
<thead>
<tr>
<th>Care group</th>
<th>Hospital discharges among seniors, %</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>7</td>
<td>8</td>
<td>10</td>
<td>17</td>
</tr>
<tr>
<td>三十年, all-cause readmissions among seniors with hospitalizations, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annualized total costs of care, % of costs in Care Group 1</td>
<td>NA</td>
<td>220</td>
<td>440</td>
<td>840</td>
<td></td>
</tr>
<tr>
<td>Mortality, %</td>
<td>6 months</td>
<td>0.4</td>
<td>0.5</td>
<td>2.8</td>
<td>15.2</td>
</tr>
<tr>
<td></td>
<td>12 months</td>
<td>0.6</td>
<td>1.2</td>
<td>5.5</td>
<td>28.0</td>
</tr>
</tbody>
</table>

*Values in bold indicate concordance.

---

**Table 4. Concordance between physician judgment and segmentation by algorithm for 1615 seniors**

<table>
<thead>
<tr>
<th>Algorithm-assigned segment</th>
<th>Physician-assigned segment</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>237</td>
<td>23</td>
<td>0</td>
<td>1</td>
<td>261</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>9</td>
<td>831</td>
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<td>3</td>
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<td>84</td>
<td>209</td>
<td>14</td>
<td>313</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>7</td>
<td>38</td>
<td>92</td>
<td>137</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>252</td>
<td>945</td>
<td>307</td>
<td>111</td>
<td>1615</td>
<td></td>
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</tbody>
</table>

*Values in bold indicate concordance.
Improving Care for Older Adults: A Model to Segment the Senior Population

Other methods might provide a more complete picture of older adults. Patients’ self-reports yield important dimensions of information that are not usually available in the EHR. However, self-report is not currently uniformly available; it is also logistically intensive, requires interval reporting, and may be inaccurate at critical points in the patient journey. Clinician-based reports are also logistically intensive and prone to inconsistency.

Segmentation of the senior population provides a foundation for individualized assessment and patient-centered care. It is a tool intended to ensure that the individualized needs of all patients in each care group are met by informing clinical decision making. For instance, patients in Care Groups 3 and 4 may benefit from assessment of complex social and caregiver needs. Conversely, members of these care groups may be less likely to benefit from traditional disease prevention and management strategies, such as rigorous diabetes control. In the Hawaii Region, care group status is now documented in the EHR, which is used across all settings. Patients in Care Group 4 who are hospitalized are evaluated for complex care needs. Clinicians use segmentation to manage population health, identify patients who are eligible for complex case management, prioritize patients with higher levels of need, and start conversations about needed services, such as mental health and caregiver support. In addition, care groups can be used to predict and plan for more resource-intensive care needs.

Senior segmentation is being implemented across KP. Risk scores and indicators can be tailored to specifications in individual KP Regions, and regional implementation can add data from clinical encounters, such as the problem list and encounter diagnostic codes. The experiences and comparative data of multiple Regions will contribute invaluable knowledge about care processes and outcomes across care groups, furthering our goal of optimizing health care for KP’s one million older adult members.

Conclusion
Senior segmentation is a promising new method for identifying four Care Groups defined by member needs. The care for members within each group can be focused to address their varying health and utilization needs. Our assessment indicates that senior segmentation can form the foundation for population-level health delivery design. 

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

Acknowledgments
We thank the following individuals for their contributions to this work: Jim Bellows, PhD, Jann Dorman, MA, MBA, and Moira M Belikoff, MSc, from Kaiser Permanente’s Care Management Institute, Oakland, CA; Walter S Schroeder, Pharm D, and Anthea Wang, MD, from Kaiser Permanente Hawaii; and Adrienne Feldstein, MD, and Robert Untan, MD, from Kaiser Permanente Northwest. Jenni Green, MS, provided editorial assistance with the manuscript.

Kathleen Louden, ELS, of Louden Health Communications provided editorial assistance.

References

The Right of Dignity
A proud and resourceful nation can no longer ask its older people to live in constant fear of a serious illness for which adequate funds are not available.

We owe them the right of dignity in sickness as well as in health.

— John F Kennedy, 1917-1963, 35th President of the United States
Comparison of Paper and Electronic Surveys for Measuring Patient-Reported Outcomes After Anterior Cruciate Ligament Reconstruction

Jamie L Bojcic, MPH; Valerie M Sue, PhD; Tomy S Huon; Gregory B Maletis, MD; Maria CS Inacio, PhD

Perm J 2014 Summer;18(3):22-26

http://dx.doi.org/10.7812/TPP/13-142

Abstract

Objective: This study compared response rates of paper and electronic versions of the Knee injury Osteoarthritis and Outcome Score questionnaire and examined the characteristics of patients who responded to each survey method.

Methods: A total of 1486 patients registered by the Kaiser Permanente Anterior Cruciate Ligament Reconstruction Registry between 2005 and 2010 were included in this study. Response rates by survey modality for the overall cohort, by the specific time periods, and by age and sex at time of anterior cruciate ligament reconstruction were compared using \( \chi^2 \) tests or the Fisher exact test when appropriate. Independent Student t tests were used to compare the Knee injury Osteoarthritis and Outcome Scores of survey respondents.

Results: The overall survey response rate was 42%. The 36% response rate in the electronic-survey group was significantly higher than the 22% response rate in the paper-survey group (\( p < 0.001 \)). The electronic response rate was also significantly higher than the paper response rate at all follow-up times (35% vs 25% at 1 year, \( p = 0.004 \), 38% vs 20% at 2 years, \( p < 0.001 \), and 35% vs 21% at 3 years; \( p < 0.001 \)) and among all age groups 19 years and older.

Conclusion: Although the electronic survey produced higher response rates, it is not sufficient alone to replace the traditional paper version among this Kaiser Permanente population.

Introduction

Patient-reported outcome measures are tools often used before and after medical interventions to assess patients’ perspectives of symptoms, function, treatment preferences, and general well-being. These tools are important for evaluating the effectiveness of treatments and changes in disease trajectory. The Knee injury and Osteoarthritis Outcome Score (KOOS), a patient-reported outcome measure developed in 1995 by Ewa Roos and colleagues, evaluates both short- and long-term symptoms and function after knee injury and osteoarthritis progression. The questionnaire consists of 42 items in 5 separately scored subscales: “Pain,” “Other Symptoms,” “Function” (activities in daily living), “Function in Sport and Recreation” (Sport/Rec), and knee-related Quality of Life (QOL). The KOOS has been validated for a number of orthopaedic interventions, including anterior cruciate ligament (ACL) reconstruction, meniscectomy, and total knee replacement. The KOOS has also been validated within a number of populations consisting of varying ages, activity levels, and diseases. Traditionally, patient-reported outcome measures, like the KOOS, have been administered using paper questionnaires, with data collected, recorded, and computerized manually. This time-consuming and costly process can also compromise data quality.

Today, patients are increasingly using the Internet to obtain and to exchange health-related information, allowing new modalities for the collection of patient-reported outcomes. Electronic questionnaires are desirable in both the health care and clinical research fields because they often allow for the collection of good-quality data, without missing or problematic responses. In addition, results from electronic questionnaires are often compiled automatically and are immediately available for use. Numerous studies have shown comparable results between patient-reported outcome measures administered via paper and those administered electronically. Among certain populations, several studies have reported electronic questionnaires to be preferred over traditional pen and paper methods.

The objective of this study was to develop an Internet-based electronic KOOS questionnaire, to investigate its feasibility in replacing the traditional paper version, and to examine the characteristics of the patients who respond to the electronic and paper surveys.

Methods

A cross-sectional evaluation of two methods of data collection processes for the KOOS questionnaire was conducted. The KOOS questionnaire was implemented by the Kaiser Permanente (KP) Anterior Cruciate Ligament Reconstruction Registry (ACLRR) to track the current health status of its registered cohort of patients who underwent ACL reconstruction. This KP registry, developed in 2005, tracks surgical procedures, techniques, graft types, fixation types, surgical outcomes, complications, and patient-reported outcome measures. The registry’s data collection process and population has been previously described. In brief summary, the registry collects information from multiple Medical Centers located in six geographical Regions, all part of a large integrated...
Comparison of Paper and Electronic Surveys for Measuring Patient-Reported Outcomes After Anterior Cruciate Ligament Reconstruction

Data Collection Tools and Procedures

Paper Survey

The routine ACLRR KOOS data collection process involved both preoperative and postoperative administration of paper forms. Postoperative data collection occurred at 1, 2, and 5 years after surgery. At each participating Medical Center, the KOOS form was completed during regular office visits both before and after ACL reconstruction. The surgeons’ staff members were responsible for data collection and mailed all completed KOOS forms to the KP ACLRR data repository center. Because most patients did not return for office visits at 1, 2, and 5 years after surgery, a paper postoperative KOOS questionnaire was mailed to all patients. Approximately 6 months after their ACL reconstruction, all 1486 patients included in this study were mailed a letter informing them that at 1, 2, and 5 years after their ACL reconstruction, they would receive a questionnaire regarding their knee. Paper questionnaires along with self-addressed stamped envelopes were then mailed to all 1486 patients at the designated follow-up times. All patients were instructed to complete the survey even if they were no longer KP members. Patients were also informed that their answers were strictly confidential and would not be shared.

A week after the invitation e-mail was sent, a follow-up reminder e-mail containing the link to the questionnaire was sent to all nonrespondents. Two weeks later, a second reminder e-mail was sent to nonrespondents. Finally, three weeks after the invitation e-mail was sent, a voice message was sent to patients who had not yet responded. All questions of the electronic survey were presented in the same order and with the same instructions as the paper KOOS questionnaire. Patients were unable to progress through the questionnaire without answering each question, but they could go back to modify previous responses. Identifiable information (ie, patients’ name, medical record numbers, and dates of surgery) was autopopulated into the first page of the questionnaire, but patients could make changes if for any reason the information was incorrect. The electronic KOOS survey was not connected to the patients’ electronic medical records.

Electronic Survey

An electronic version of the KOOS was created internally at KP. After thorough pretesting for usability and comparability with the paper survey, the electronic survey was also adopted for follow-up at 1, 2, and 5 years after ACL reconstructive surgery. Of the 1486 patients included in this study, 830 (56%) had an e-mail address on file. Those patients were sent an electronic survey in addition to the mailed paper survey. A week before receiving the electronic survey, patients were sent a prenotification e-mail informing them that in a week they would receive an e-mail containing a link to a questionnaire regarding their knee. A week later, patients were sent an e-mail invitation containing the link to the questionnaire. All patients were informed that the survey would take 5 minutes to complete and were also given the option to opt out. Similar to the paper questionnaire, patients were instructed to complete the survey even if they were no longer KP members. They were also informed that their answers were strictly confidential and would not be shared.

A week after the invitation e-mail was sent, a follow-up reminder e-mail containing the link to the questionnaire was sent to all nonrespondents. Two weeks later, a second reminder e-mail was sent to nonrespondents. Finally, three weeks after the invitation e-mail was sent, a voice message was sent to patients who had not yet responded. All questions of the electronic survey were presented in the same order and with the same instructions as the paper KOOS questionnaire. Patients were unable to progress through the questionnaire without answering each question, but they could go back to modify previous responses. Identifiable information (ie, patients’ name, medical record numbers, and dates of surgery) was autopopulated into the first page of the questionnaire, but patients could make changes if for any reason the information was incorrect. The electronic KOOS survey was not connected to the patients’ electronic medical records.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Paper, no. (%): 1486</th>
<th>Electronic, no. (%): 830</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number</td>
<td>1486</td>
<td>830</td>
</tr>
<tr>
<td>Men</td>
<td>996 (67.0)</td>
<td>537 (64.7)</td>
</tr>
<tr>
<td>Women</td>
<td>490 (33.0)</td>
<td>293 (35.3)</td>
</tr>
<tr>
<td>Mean age, years (SD)</td>
<td>27.7 (11)</td>
<td>28.3 (11)</td>
</tr>
<tr>
<td>Age group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 19 years</td>
<td>395 (26.6)</td>
<td>86 (10.4)</td>
</tr>
<tr>
<td>19-29 years</td>
<td>497 (33.4)</td>
<td>320 (38.6)</td>
</tr>
<tr>
<td>30-39 years</td>
<td>310 (20.9)</td>
<td>212 (25.5)</td>
</tr>
<tr>
<td>40-49 years</td>
<td>216 (14.5)</td>
<td>157 (18.9)</td>
</tr>
<tr>
<td>≥ 50 years</td>
<td>68 (4.6)</td>
<td>55 (6.6)</td>
</tr>
<tr>
<td>Follow-up time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 year</td>
<td>507 (34.1)</td>
<td>291 (30.1)</td>
</tr>
<tr>
<td>2 years</td>
<td>597 (40.2)</td>
<td>361 (43.5)</td>
</tr>
<tr>
<td>5 years</td>
<td>382 (25.7)</td>
<td>178 (21.4)</td>
</tr>
</tbody>
</table>

Table 2. Survey response rate by follow-up time and sample characteristics

<table>
<thead>
<tr>
<th>Response rate</th>
<th>Total participants, mail</th>
<th>Paper response rate, no. (%)</th>
<th>Electronic response rate, no. (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>1486</td>
<td>328 (22.1)</td>
<td>830</td>
<td>301 (36.3)</td>
</tr>
<tr>
<td>1 year</td>
<td>507</td>
<td>127 (25.0)</td>
<td>291</td>
<td>101 (34.7)</td>
</tr>
<tr>
<td>2 years</td>
<td>597</td>
<td>121 (20.3)</td>
<td>361</td>
<td>137 (38.0)</td>
</tr>
<tr>
<td>5 years</td>
<td>382</td>
<td>80 (20.9)</td>
<td>178</td>
<td>63 (35.4)</td>
</tr>
<tr>
<td>Patient characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>996</td>
<td>206 (20.7)</td>
<td>537</td>
<td>182 (33.9)</td>
</tr>
<tr>
<td>Women</td>
<td>490</td>
<td>122 (24.9)</td>
<td>293</td>
<td>119 (40.6)</td>
</tr>
<tr>
<td>Age group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 19 years</td>
<td>395</td>
<td>118 (29.9)</td>
<td>86</td>
<td>21 (24.4)</td>
</tr>
<tr>
<td>19-29 years</td>
<td>497</td>
<td>92 (18.5)</td>
<td>320</td>
<td>102 (31.9)</td>
</tr>
<tr>
<td>30-39 years</td>
<td>310</td>
<td>49 (15.8)</td>
<td>212</td>
<td>84 (29.6)</td>
</tr>
<tr>
<td>40-49 years</td>
<td>216</td>
<td>57 (26.4)</td>
<td>157</td>
<td>64 (40.8)</td>
</tr>
<tr>
<td>≥ 50 years</td>
<td>68</td>
<td>12 (17.6)</td>
<td>55</td>
<td>30 (54.5)</td>
</tr>
</tbody>
</table>

*Statistically significant.
Comparison of Paper and Electronic Surveys for Measuring Patient-Reported Outcomes After Anterior Cruciate Ligament Reconstruction

Statistical Analysis

Frequencies, proportions, means, and standard deviations (SDs) were employed to describe the study sample and response rate of the surveys. Response rates by survey modality for the overall cohort, by the specific time periods, by age, and by sex at the time of ACL reconstruction were compared using chi-square tests or the Fisher exact test when appropriate. Independent Student t tests were used to compare the KOOS scores of survey respondents. SAS (Version 9.2; SAS Institute, Cary, NC) was used to analyze the data, with p < 0.05 as the statistical threshold.

Results

A total of 1486 patients were included in the study. The average age of study participants was 28 years (SD = 11) and 67% of participants were male (Table 1). Overall, the 36% response rate in the electronic group was significantly higher than the 22% in the paper group (p < 0.001). The electronic response rate was significantly higher than the paper response rate at 1 year (35% vs 25%, p = 0.004), 2 years (38% vs 20%, p = 0.004), and 5 years (35% vs 21%) after surgery (Table 2).

Thirty-four percent of men in the electronic questionnaire group responded, and 21% of men in the paper survey group responded (p < 0.001). The corresponding response rate among women was 41% and 25%, respectively (p < 0.001) (Table 2). There was a significant difference in the response rates to electronic and paper surveys in participants between the ages of 19 and 29 years old (32% vs 19%, p < 0.001), those 30 to 39 years old (40% vs 16%, p < 0.001), those 40 to 49 years old (41% vs 20%, p = 0.003), and those 50 years and older (55% vs 18% p < 0.001). There was no significant difference in response rates to paper and electronic KOOS surveys in participants under 19 years of age.

With the exception of the Symptoms scale, there were no significant differences between any of the KOOS subscales in patients who responded to the electronic or paper survey (Table 3).

Discussion

This study found that an Internet-based electronic KOOS questionnaire is at present not sufficient to replace the paper version among the KP ACL reconstruction population. Although the Internet-based electronic KOOS questionnaire yielded a significantly higher response rate than the paper version, it cannot yet completely replace the paper questionnaire. In this study, e-mail addresses were available for only 56% of study participants. Until this proportion increases to include nearly all eligible respondents, the paper version of the KOOS questionnaire will remain a necessary supplemental to the data collection process.

The low overall response rate of 42% including both the electronic and paper methods could be partially because of the age of this study population. Numerous studies have found that younger people are less likely to participate in surveys. Dunn et al. examined data from 7 general-population pen and paper surveys conducted in the United Kingdom between 1996 and 2002, to which a total of 27,797 people responded. They found that the overall survey response rate was lowest in the youngest age group of 18 to 29 years and increased with age until age 70 years in women and 80 years in men. The response rate among women age 18 to 29 years was 52%, whereas the response rate among the same age range in males was 32%. These are comparable response rates obtained in our sample.

In addition to the average age of our study cohort, the length of the questionnaire (42 questions, 1198 words, and 5 pages on paper) may have contributed to the low overall response rate. Although it is unknown how many patients started the paper survey but did not finish because of its length, we found that 3% (24/830) of participants who received the electronic survey failed to finish and were considered incomplete. Jeppson et al. examined associations between questionnaire length and response rate of mailed surveys among 1700 physicians and found that questionnaires above a threshold of 1000 words had lower response rates than those below it (38% vs 59%). The KOOS-Physical Function Shortform (KOOS-PS), a shortened KOOS questionnaire containing only 7 questions, may produce a higher response rate among the ACLRR population.

In this study, financial incentives were not used to motivate patients to complete the KOOS questionnaire. In a systematic review of 481 randomized controlled trials, Edwards et al. found that the use of monetary incentives for completing mailed paper questionnaires can double the odds of response. In a meta-analysis of

Table 3. Average Knee injury and Osteoarthritis Outcome Score subscale score by survey method and follow-up time

<table>
<thead>
<tr>
<th>Survey method</th>
<th>Follow-up time</th>
<th>Total response, no.</th>
<th>Function in daily living score (SD)</th>
<th>Pain score (SD)</th>
<th>Quality of Life score (SD)</th>
<th>Symptoms score (SD)</th>
<th>Function in sport and recreation score (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper</td>
<td>1 year</td>
<td>127</td>
<td>93.6 (8.6)</td>
<td>87.5 (12.7)</td>
<td>61.3 (23.9)</td>
<td>65.8 (14.7)</td>
<td>72.7 (20.7)</td>
</tr>
<tr>
<td></td>
<td>2 years</td>
<td>121</td>
<td>90.9 (15.0)</td>
<td>85.6 (16.6)</td>
<td>65.3 (25.6)</td>
<td>65.3 (15.0)</td>
<td>72.9 (24.6)</td>
</tr>
<tr>
<td></td>
<td>5 years</td>
<td>80</td>
<td>94.0 (11.1)</td>
<td>89.6 (14.7)</td>
<td>77.6 (23.4)</td>
<td>67.6 (14.8)</td>
<td>79.1 (22.6)</td>
</tr>
<tr>
<td>Paper total</td>
<td></td>
<td>328</td>
<td>92.7 (11.9)</td>
<td>87.3 (14.8)</td>
<td>66.7 (25.2)</td>
<td>66.0 (14.9)</td>
<td>74.3 (22.8)</td>
</tr>
<tr>
<td>Electronic</td>
<td>1 year</td>
<td>101</td>
<td>92.7 (11.0)</td>
<td>86.9 (12.3)</td>
<td>62.9 (22.3)</td>
<td>80.7 (14.0)</td>
<td>70.9 (22.4)</td>
</tr>
<tr>
<td></td>
<td>2 years</td>
<td>137</td>
<td>91.2 (13.1)</td>
<td>85.3 (15.3)</td>
<td>63.8 (24.8)</td>
<td>79.6 (15.2)</td>
<td>73.2 (23.3)</td>
</tr>
<tr>
<td></td>
<td>5 years</td>
<td>63</td>
<td>93.7 (11.1)</td>
<td>87.3 (16.0)</td>
<td>71.7 (22.3)</td>
<td>82.3 (15.6)</td>
<td>75.6 (22.3)</td>
</tr>
<tr>
<td>Electronic total</td>
<td></td>
<td>301</td>
<td>92.2 (12.0)</td>
<td>86.3 (14.5)</td>
<td>65.1 (23.6)</td>
<td>80.6 (14.9)</td>
<td>72.9 (22.8)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>629</td>
<td>92.5 (12.0)</td>
<td>86.8 (14.7)</td>
<td>66.0 (24.5)</td>
<td>73.0 (16.5)</td>
<td>73.7 (22.8)</td>
</tr>
</tbody>
</table>

SD = standard deviation.
Web-based questionnaires, Görtz\textsuperscript{26} found that material incentives increase both response and retention rates. They found that material incentives increase the odds of a person responding to an electronic survey by 19\% over the odds without incentives. They also found that an incentive increased retention by 4.2\% on average. Beebe et al\textsuperscript{20} found that even a $2 cash incentive helped increase participation rates (54\% response rate in an incentive group and 45\% in a nonincentive group). The use of a small incentive may have helped increase the overall response rate in our specific population.

Our study found that regardless of a patient’s sex, time from surgery, and age older than 19 years, the electronic KOOS questionnaire produced significantly higher response rates than the paper survey. There are many advantages to using the computerized KOOS questionnaire, including improved data quality, faster data output, and reduced workloads. The electronic KOOS survey was designed to allow only complete responses, so no data elements were missing and more than one answer was never selected. Data entry was eliminated and results were ready for analysis the day after the survey was closed for participation. Manual preparation of the paper questionnaire is expensive and requires exhaustive work, which is greatly reduced with the use of the electronic questionnaire. Another benefit of the electronic KOOS is that all entries are date and time stamped. Velikova et al\textsuperscript{7} found significant problems with inaccurate entry of names, dates of birth, and postal codes when entered manually. To avoid such errors in the present study, we autopopulated the patient name, medical record number, and date of surgery into the first page of the electronic KOOS questionnaire.

In our study, 4 of the 5 average KOOS subscale scores were not different by survey modality or time from surgery. However, there was a difference in the Symptoms subscale between patients who completed the electronic survey and those who completed the mailed survey (80.6 vs 66.0, respectively). This difference in scores could be because of a selective response that may have occurred. It is possible that patients who were more likely to respond to the electronic survey did so because they were experiencing worse symptoms after surgery.

A major limitation to this study is the high percentage of patients whose e-mail addresses were not available. Of the total study population, 44\% received only the paper questionnaire because their e-mail addresses were not on file. Because the electronic response rate was significantly higher than the paper response rate, the overall study response rate may have been higher if all participants had the option of answering either the paper or the electronic questionnaire. Several studies have demonstrated the use of hybrid data collection for increasing participation rates. Fowler et al\textsuperscript{25} achieved a 46\% response rate to a mailed survey among 800 health care members, but they increased the response rate to 66\% after following up with nonrespondents by phone. Similarly, Beebe et al\textsuperscript{20} achieved a 45\% response rate to a mailed survey, which increased to 64\% after completion of telephone follow-ups. McMahon et al\textsuperscript{21} used postal mail, fax, and e-mail to distribute a vaccine-related questionnaire to pediatric physicians. Their overall response rate increased from 39\% before mixed mode of contact to a final of 53\% after mixed modes. Although multimodal data collection has been found to increase participation rates, it also has the potential to cause measurement error and create challenges when combining the data obtained.\textsuperscript{22} Therefore, in this study, questions to the electronic survey were presented in the same order and with the same instructions as in the paper questionnaire. The paper and the electronic surveys were both scored in the same manner following instructions from the KOOS User’s Guide 2003 and scoring software (www.koos.nu). As the use of patient-reported outcome measures increases, organizations should focus their efforts on obtaining and maintaining all current modes of contact for their members.

Results from this study show that use of an Internet-based KOOS questionnaire among the younger ACL reconstruction population is promising, but not sufficient to replace the paper version at this time. As the proportion of e-mail addresses on file increases, replacing paper questionnaires with electronic versions may become more feasible. In addition, other electronic survey delivery modes, such as via mobile devices, may be more attractive to this population, thereby increasing the reach of the electronic survey. Future research should investigate the use of various devices for the delivery of the electronic KOOS questionnaire combined with a shortened version of the survey. Additional focus on the underlying characteristics of patients who opt to complete the electronic version would aid in designing an attractive questionnaire.

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

Acknowledgment
Kathleen Louden, ELS, of Louden Health Communications provided editorial assistance.

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Comparison of Paper and Electronic Surveys for Measuring Patient-Reported Outcomes After Anterior Cruciate Ligament Reconstruction


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An Art or Craft

Scientific research is not itself a science; it is still an art or craft.

— The Scientist in Action, William H George, London, UK: Williams and Norgate Ltd; 1938
An Audit of Clinician Compliance with Best Practice Recommendations to Repair Severe Obstetric Anal Sphincter Injuries

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Abstract

Context: Obstetric anal sphincter injuries occur uncommonly in Caribbean practice but are accompanied by substantial morbidity.

Objective: To evaluate clinicians’ compliance with management guidelines at a national referral hospital in Jamaica.

Design: Retrospective review of the records of all consecutive obstetric patients with anal sphincter injuries between November 1, 2007, and December 30, 2012.

Main Outcome Measures: The primary end point was the completion of each of 8 tasks from existing management guidelines: 1) interdisciplinary consultation, 2) perineal examination with the patient under anesthesia, 3) injury repair in the operating room, 4) prophylactic antibiotics at induction, 5) repair by an experienced clinician, 6) repair method appropriate for injury grade, 7) slowly absorbable suture chosen for sphincter repair, and 8) rapidly absorbable suture for mucosal repair. We quantified clinician compliance with the guidelines by assigning a score of 1 for each task completed and 0 for an incomplete task. Individual task scores were summed. Clinicians were considered compliant when their overall score was above 6.

Results: Twenty-six women (mean age = 27 years; standard deviation = 5.78 years) had obstetric anal sphincter injuries. Nine cases (34.6%) earned clinician compliance scores above 6, and 17 (65.4%) had scores of 6 or below. Experienced clinicians repaired all the injuries in this study—the only task for which compliance was 100%.

Conclusion: Despite attempts at improving therapeutic outcomes by creating tailored guidelines for repair of obstetric anal sphincter injuries, there is a serious barrier to success because 65% of senior clinicians were noncompliant.

Introduction

In Caribbean practice, obstetric anal sphincter injuries occur after 0.2% to 0.3% of vaginal deliveries. This is lower than the 0.5% to 6% incidence in non-Caribbean populations, but the therapeutic outcomes in this setting are poor. An audit at the national referral hospital in Jamaica revealed that women experienced high overall morbidity (43%) and fecal incontinence (23%) after operative repair of obstetric anal sphincter injuries. The study uncovered several deviations from best practice and prompted corrective measures in an attempt to improve therapeutic outcomes. These measures included educational campaigns, development of local practice guidelines, and the implementation of clinical care pathways at the facility.

It is reasonable to expect improved outcomes with these corrective measures, but the caveat is that clinicians must adhere to the practice guidelines. If clinicians were noncompliant, it would be unreasonable to expect a reduction in morbidity. Therefore, we carried out an audit to document clinicians’ compliance with these institutional guidelines five years after they were introduced in 2007. We did not set out to evaluate the evidence supporting the practice guidelines. Instead, our aim was to evaluate clinicians’ compliance with the existing guidelines, which has been shown to be an independent predictor of guideline success.

Methods

This study was performed at the Obstetric Department of the University Hospital of the West Indies. This is 1 of 2 tertiary referral hospitals that serve an estimated catchment population of 826,880 persons in and around Kingston, the capital of Jamaica. This hospital facilitates 1696 vaginal deliveries each year.

The new practice guidelines were introduced at this institution in 2007 and rolled out in four stages. First, local outcomes data were presented at institutional grand rounds, and the guidelines were presented to the target clinician population. Clinicians were also targeted by posted signage in and around the labor and delivery rooms. In the third stage, guidelines were presented and discussed at national clinical conferences. Finally, the guidelines were published in the regional medical literature, whose readership included clinicians at the host institution.

The primary aim of this study was to evaluate clinician compliance to practice guidelines 5 years after they were introduced.

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An Audit of Clinician Compliance with Best Practice Recommendations to Repair Severe Obstetric Anal Sphincter Injuries

Therefore, the local institutional review board granted permission to access the records of all patients who had vaginal deliveries between November 1, 2007, and December 30, 2012. All women who sustained anal sphincter injuries in an obstetric setting were identified by manually reviewing the delivery logs maintained by the labor ward. In an attempt to reduce selection bias and ensure inclusion of all study subjects, a search of medical discharge codes for obstetric anal sphincter injury was also performed in a database maintained by the Medical Records Department. This was a convenience sample including all women with obstetric anal sphincter injuries.

The hospital records of women who sustained obstetric anal sphincter injuries were retrieved, and data were extracted retrospectively. The clinical outcomes in this study could not be blinded, but in an attempt to reduce data extraction bias, we recruited multiple, independent data collectors to review patient files. The data collectors also attempted to reduce interrater variability of the grade of obstetric anal sphincter injury by cross-referencing surgeon-assigned grades with documented findings in the operative notes. Any missing data from patient records were excluded from the analysis.

The practice guidelines documented eight concrete tasks for clinicians to complete when managing obstetric anal sphincter injuries. Therefore, the primary study end points were to document the completion of these tasks: 1) interdisciplinary consultation requested, 2) perineal examination performed with the patient under anesthesia, 3) injury repaired in the operating room, 4) a single dose of prophylactic second- or third-generation cephalosporin administered intravenously at induction of anesthesia, 5) repair performed by an experienced clinician, 6) recommended repair method appropriate for the injury grade, 7) recommended suture chosen for sphincter repair, and 8) recommended suture chosen for mucosal repair. The completion of each task was considered compliance with the practice guideline.

We sought to quantify compliance by assigning a score of 1 for each completed task and 0 for an incomplete task. The individual task scores were summed to arrive at an overall compliance score that could range from 0 to 8.

Although a score of 8 (100% compliance with all tasks) would be ideal, we thought this would be an unrealistic finding. Therefore, we attempted to define a threshold score below which compliance would be unacceptable. As there were no existing standards, 7 senior authors participated in a consensus meeting to define a clinically relevant value for an unacceptable score. It was agreed that this would be determined by administering a blinded questionnaire to 5 attending surgeons and obstetricians outside the study population. Their responses were similarly graded. The mean overall compliance score for the 5 experts (6.8; SD = 1.30) was used to define a value for an unacceptable compliance score. On the basis of this mean score, we defined 2 groups of clinicians: compliant clinicians had an overall compliance score above 6, and noncompliant clinicians had scores of 6 or below.

Figure 1. Clinical care pathways for management of obstetric perineal lacerations at the University Hospital of the West Indies in Jamaica.

EAS = external anal sphincter; IAS = internal anal sphincter; OR = operating room; PDS = polydioxanone suture.
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The Statistical Package for Social Sciences (SPSS) version 12.0 (IBM SPSS, Chicago, IL) was used for data analysis. Descriptive statistics were generated as appropriate.

Results

There were 8108 vaginal deliveries over the 62-month study period. Twenty-six women (0.32%) with a mean age of 27 years (SD = 5.78 years; range = 17-38 years) sustained obstetric anal sphincter injuries. Of these 26 injuries, 23 (88.5%) were third-degree (8 Grade 3a injuries, 10 Grade 3b injuries, and 5 Grade 3c injuries), and 3 (11.5%) were fourth-degree obstetric anal sphincter injuries. All hospital records were recovered for patients with obstetric anal sphincter injury.

The guidelines called for interdisciplinary consultation and perineal examination of the patient under anesthesia to be performed. This would be followed by appropriate repair by attending staff in the operating room. In this study, a request for interdisciplinary consult was made in 8 cases (30.8%). Only 10 patients (38.5%) underwent an examination under anesthesia (7 under general and 3 under regional anesthesia), and they went on to have repair in the operating room. The remaining repairs were performed in patients on delivery beds in the labor wards.

Although antibiotics were always administered, the recommended regimen was used in only 2 cases. In the remaining 24 cases, different agents were chosen and/or administered for longer than 72 hours' duration. Therefore, the recommendations for antibiotic therapy were observed in only 2 (7.7%) of the cases.

In all cases, the injuries were repaired by experienced clinicians: attending clinicians (n = 11) and resident physicians in their final year of postgraduate training (n = 15). Regardless of the method of repair, the guidelines required the use of nonabsorbable or slowly absorbable sutures. In this series, the sphincter was reconstructed with nonabsorbable polypropylene (Prolene) sutures in only 8 cases (30.8%) and with rapidly absorbing polyglactin sutures (Vicryl Rapide) in the remainder.

The guidelines stratified the repair method according to the injury grade. In 5 cases, the method of repair was not recorded. There were 18 patients with Grade 3a or 3b obstetric anal sphincter injuries who should have been treated preferentially with end-to-end (approximation) repair according to the existing guidelines. In this group, there were 13 end-to-end repairs, 3 overlapping repairs, and 2 unspecified repairs performed. Eight patients had Grade 3c or 4 injuries and should have been treated preferentially by sphincter mobilization and overlapping repair. In this group, overlapping repair was performed in 5 patients and unspecified repairs in 3 patients. Therefore, there was adherence to the guidelines for repair method in 18 cases (69.2%). To complete the repair, absorbable sutures (2-0 or 3-0 Vicryl) were selected for closure of the mucosa in 24 cases (92.3%).

According to overall compliance scores, 9 cases (34.6%) earned compliance scores above 6 (compliant). There were 17 cases (65.4%) with scores of 6 or less (noncompliant).

Discussion

In the Caribbean, obstetric anal sphincter injuries are uncommon injuries, which occur in 0.2% to 0.3% of vaginal deliveries. Therefore, the average clinician would be relatively inexperienced in the management of these complex injuries. Furthermore, these injuries occur unpredictably and are often diagnosed and managed by junior obstetric staff on an emergent basis. This is exactly the reason that practice guidelines were developed: to guide clinicians who are faced with an uncommon clinical problem through its management, encouraging them to adhere to the principles of best practice. Therefore, learning that 65% of clinicians are noncompliant with existing guidelines is disappointing, especially in light of the poor therapeutic outcomes documented in this setting.14-16

There was a single guideline for which compliance was 100%; experienced clinicians performed all the repairs in this study. Although it was encouraging to see that experienced clinicians performed repair in keeping with the guidelines, it was also concerning because it meant that the senior clinicians were the ones who were noncompliant with the other guidelines. We cannot expect junior staff members to be compliant when their mentors are not.

The task with the worst compliance record related to antibiotic use, despite the local guidelines mirroring existing recommendations in medical literature for prophylaxis against wound infections in obstetric anal sphincter injuries.11,12 The poor compliance was not limited to this setting, however. Schimpf et al13 reported the antibiotic prescribing practice of clinicians surveyed at the 2011 Annual Scientific Meeting of the Society of Gynecologic Surgeons. They uncovered substantial variability in practices, with 30% of respondents having practices inconsistent with recommendations from the American College of Obstetricians and Gynecologists.12 The respondents reported that hospital policy affected their choice of antibiotic prophylaxis 15% of the time.12 Admittedly, there is little evidence supporting this guideline. A Cochrane review attempted to evaluate the role of antibiotic prophylaxis in severe perineal tears after vaginal birth but returned no randomized controlled trials evaluating the outcomes with or without antibiotics.13 Despite the paucity of evidence, most authorities do recommend antibiotic prophylaxis in patients with severe obstetric anal sphincter injuries.11,12 However, these recommendations are supported only by expert committee opinions and the experience of respected authorities (Level IV evidence). The absence of strong evidence for this recommendation may have produced a lack of confidence in the local guidelines, hence contributing to the clinicians' noncompliance.

This study has uncovered a failure in clinician compliance with all tasks except repair by experienced clinicians. There are several potential reasons for this. First, for clinicians to be compliant, they must be aware of the guidelines. Although there were four phases of guideline introduction, all focusing on different ways to target the clinicians, there could have
Health Care Funding

The health care sector in Jamaica is underfunded, with only 4% of the national budget being allocated to health. This translates to a chronic shortage of drugs, sutures, and surgical disposable supplies. Often, clinicians must improvise to deliver care and may not be able to comply with the guidelines when the required supplies (recommended sutures, for example) are unavailable. Additionally, without a consistent supply of anesthetic drugs, ventilators, monitors, and/or staff, access to the operating room is not always available. Therefore, clinicians may opt to forgo examination using anesthesia and/or perform repairs while the patient is on the delivery bed, without proper lighting and instrumentation.

Although much good work is performed in Jamaican health care facilities, it is no secret that the health care workers are expected to provide patient care in extreme circumstances. However, simple maneuvers may improve compliance. For example, the procurement process should be prioritized to ensure that the requisite supplies are readily available for clinicians to use. Another maneuver is to seek partnerships with health care facilities in developed countries that may donate supplies or provide them at nominal cost.

Surveillance and Enforcement

An integral part of quality service delivery is surveillance of clinical practices. In Jamaica, this has traditionally been achieved through strong leadership from senior clinicians because the use of technologic aides would not be financially feasible. This is not ideal in this instance because the senior clinicians are noncompliant with clinical guidelines. Disciplinary action may not be required for accountability. The simple knowledge that there is active monitoring might be sufficient to bring about behavioral modification without the threat of sanctions. This could be achieved by training a small team to carry out clinical audits and by providing them with the necessary hardware, software, and support staff for surveillance and reporting.

Training in Operating Room Best Practice

We recognize that knowledge improvement alone does not necessarily translate to sustained improvement in compliance. However, without knowledge of best practice principles for repair of obstetric anal sphincter injuries, clinicians may not appreciate the need to comply with guidelines. The fact that there was poor compliance suggests that our facility’s attempts at imparting knowledge during guideline introduction were not successful. It is interesting that these findings mirror those from compliance studies conducted in developed nations, where there is wide variation in compliance to existing practice guidelines. Despite the abundance of supplies and better monitoring that exists in developed countries, there are still only incremental improvements in performance, suggesting that this is a complex, multifactorial problem. Perhaps alternate methods of training are needed, such as dedicated workshops and in-service training sessions.

Study Limitations

There are several limitations to our study. Although it is ideal to have 100% compliance with existing guidelines, this is not a realistic expectation because there are no reports of 100% compliance in the medical literature. Nevertheless, we acknowledge that the method of defining compliance may introduce a degree of bias. It is difficult to determine the degree of noncompliance that is tolerable in clinical practice. This study was carried out using a convenience sample. The resultant study population is small, and this makes statistical relationships difficult to appreciate. However, the incidence of obstetric anal sphincter injury is generally low in most series, so it would be difficult to accrue large numbers of patients with this clinical problem.

The issue of selection bias in identifying study participants has already been discussed. In an attempt to overcome this, we employed cross-referencing between the codified discharge records and labor ward registries. However, we acknowledge that there may still be potential selection bias because we may not have been able to identify all patients using this method.

Data source cross-referencing was also used to minimize bias from interrater variability in the assessment of severity of obstetric anal sphincter injury that may have been introduced through data extraction by chart review. However, we do acknowledge that there may still be potential bias with this method.

Potential bias may have arisen from the data collection personnel not being blinded to therapeutic outcomes. We attempted to overcome this by having several persons collecting data from medical charts, but acknowledge that this would not completely eliminate bias from the study design.

Finally, a presumption was made that the lack of documentation meant that a task was incomplete. Again, data cross-referencing was used to strengthen this, but we acknowledge that this remains a potential limitation of the study design.

Conclusion

Despite attempts at improving therapeutic outcomes by creating tailored guidelines for repair of obstetric anal sphincter injury, there is a serious barrier to success because 65% of senior clinicians are noncompliant with existing clinical guidelines for the management of this type of injury. Policymakers must address this problem if there is a genuine desire to improve therapeutic outcomes after repair of these anal sphincter injuries.
An Audit of Clinician Compliance with Best Practice Recommendations to Repair Severe Obstetric Anal Sphincter Injuries

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

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References
Named for his homeland by a Scottish émigré, the idyllic community of Inverness, California sits on the southwest shore of Tomales Bay about 15 miles from the Pacific Ocean. It began as a summer resort for San Francisco Bay area residents in the 1890s and remains both a destination and a stopping-off point for those wishing to explore the Point Reyes National Seashore and Tomales Bay State Park.

Dr Glassner is an Emergency Physician practicing at the Walnut Creek Medical Center in CA.
Designed for Workarounds: A Qualitative Study of the Causes of Operational Failures in Hospitals

Anita L Tucker, DBA, MS; W Scott Heisler, MBA, RN; Laura D Janisse, MFA

Abstract

Frontline care clinicians and staff in hospitals spend at least 10% of their time working around operational failures: situations in which information, supplies, or equipment needed for patient care are insufficient. However, little is known about underlying causes of operational failures and what hospitals can do to reduce their occurrence. To address this gap, we examined the internal supply chains at 2 hospitals with the aim of discovering organizational factors that contribute to operational failures. We conducted in-depth qualitative research, including observations and interviews of more than 80 individuals from 4 nursing units and the ancillary support departments that provide equipment and supplies needed for patient care. We found that a lack of interconnectedness among interdependent departments’ routines was a major source of operational failures. The low levels of interconnectedness occurred because of how the internal supply chains were designed and managed rather than because of employee error or a shortfall in training. Thus, we propose that the time that hospital staff members spend on workarounds can be reduced through deliberate efforts to increase interconnectedness among hospitals’ internal supply departments. Four dimensions of interconnectedness include: 1) hospital-level—rather than department-level—performance measures; 2) internal supply department routines that respond to specific patients’ needs rather than to predetermined stocking routines; 3) knowledge that is necessary for efficient handoffs of materials that is translated across departmental boundaries; and 4) cross-departmental collaboration mechanisms that enable improvement in the flow of materials across departmental boundaries.

Introduction

In hospitals, operational failures—missing information, supplies, or equipment necessary to complete one’s work tasks—can erode staff efficiency1–5 and contribute to staff burnout6 and medical errors.6,7 Despite the seriousness of their impact, the most common response to operational failures is to work around them without expending additional effort to prevent recurrence.8,9 In fact, studies have found that workarounds to operational failures consume around 10% of nurses’ time9—a significant amount given that nurses account for one-fourth of hospitals’ budgets.10 However, less is known about the causes of operational failures in hospitals. This article reports on a study that examined 2 hospitals’ internal supply chains to discover organizational factors that contribute to operational failures. This is an important contribution because understanding the causes of operational failures can aid development of effective solutions to reduce occurrence.

We define an internal supply chain as a set of interdependent departments that provide patient-facing employees with the stream of resources (supplies, information, and equipment—which we will refer to as “materials”) that they need to provide service.2,7,11–15 Materials flow through multiple departments as they make their way from the start of the process to the patient. For example, equipment needed for patient care flows through multiple departments as it is unloaded from delivery trucks, moved to storage, delivered to the nursing unit, used on the unit, and then cleaned after use and returned to service.14

To provide a specific example of an internal supply chain in hospitals, let us consider the internal supply chain for medication administration.6 A physician uses the computerized physician order entry system to order a medication for a patient. This system relays the order to the pharmacy, where a pharmacist verifies the order and dispenses the medication. The medication can be delivered to the nursing unit by a pharmacy technician or a pneumatic tube system. The technician places the medication in one of several locations: a refrigerator, a drawer designated for the patient, or an automated dispensing device. Engineering is responsible for maintaining the refrigerator and the pneumatic tube system. Information technology (IT) is responsible for the computers and the IT systems used to order and to dispense medications. A nurse administers the medication to the patient, often using supplies, such as a syringe, that are stocked on the unit by the central supply department. They also may need food (eg, applesauce), which is stocked by dietary services. Finally, the medication could be administered with a piece of equipment, such as a pump, that is maintained by the biomedical equipment department and cleaned by the sterile processing department. Thus, the internal supply chain for medications consists of nine departments: medical staff, pharmacy, nursing, engineering, central supplies, dietary, IT, biomedical equipment, and sterile processing.

Prior studies15,16 have found that explicit efforts to map the flow of materials in hospitals can identify opportunities for improvement. Work design principles, such as lean manufacturing’s emphasis on standardizing processes, can be used to improve reliability of internal supply chains to improve patient care.
We build on these studies by explicitly examining underlying causes of operational failures in hospitals' internal supply chains. We spent approximately 79 hours with 89 different people, of which 22 hours were spent observing support departments. Observations consisted of shadowing participants while they did their jobs, along with having open-ended conversations to understand why they were thinking, feeling, and behaving in certain ways. Each observation lasted about 2 hours, and we conducted 2 sets of observations per day for 4 days at each hospital.

We conducted the observations in conjunction with 22 other people, including support department managers and frontline employees from the 2 hospitals, nurse managers from the nursing units on which we observed, and staff nurses. People observed at a hospital different from the one in which they worked. A large team enabled us to simultaneously be in multiple departments in the same internal supply chain and observe the interdependence between people and departments following standardized instructions. For example, we traced a medication administration problem and the repair process for nonfunctioning vital signs. We used data sheets to collect information about the background of the person being observed, the most common reasons for being taken away from their normal duties, and, for nurses, what support they received. We also took photographs to help capture key aspects of each experience.

In addition to the observations, we interviewed managers and staff from all departments in the internal supply chain. We conducted interviews either individually or in dyads, which allowed for more in-depth conversations. We asked about the process of getting a room ready for a new patient, what they considered necessary for a room to be “ready” for patient care, challenges they faced, how departments coordinated their work, how work requests were transmitted across boundaries, and how they felt throughout the process. Table 1 provides details on the number of people who participated in observations and interviews and their departments.

<table>
<thead>
<tr>
<th>Role</th>
<th>Number observed and interviewed</th>
<th>Total hours of observations and interviews</th>
<th>Person or activity observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>2</td>
<td>2</td>
<td>Physician</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>3</td>
<td>3</td>
<td>Technician, pharmacist</td>
</tr>
<tr>
<td>Nursing</td>
<td>47</td>
<td>61.4</td>
<td>Nurse, patient care technician, nurse manager, charge nurse</td>
</tr>
<tr>
<td>Engineering</td>
<td>1</td>
<td>2</td>
<td>Responding to calls</td>
</tr>
<tr>
<td>Central supplies</td>
<td>1</td>
<td>2</td>
<td>Delivery</td>
</tr>
<tr>
<td>Dietary</td>
<td>1</td>
<td>2</td>
<td>Preparation and delivery</td>
</tr>
<tr>
<td>Sterile processing</td>
<td>2</td>
<td>2.5</td>
<td>Technician</td>
</tr>
<tr>
<td>Biomedical equipment</td>
<td>2</td>
<td>2</td>
<td>Technician (repair)</td>
</tr>
<tr>
<td>Environmental services</td>
<td>8</td>
<td>6.25</td>
<td>Cleaners</td>
</tr>
<tr>
<td>Information technology</td>
<td>1</td>
<td>0.5</td>
<td>Information technology specialist</td>
</tr>
</tbody>
</table>
After each observation block, the team members gathered to share stories from their observations. “Storytelling” is a way to transfer information about what a person saw and heard during his/her observations so that it becomes shared knowledge that the entire team can use to envision solutions.24-26 Following the IDEO Human-Centered Design Toolkit (IDEO: HCD Connect, Palo Alto, CA, 2011),27 storytelling began with gathering relevant photographs, artifacts, and/or notes collected during the observation to share with the group. The observer then stated who was observed and what her/his role was. The observer then told specific stories that s/he had directly observed. The group succinctly wrote key quotes, thoughts, and observations on sticky notes to document the findings. These debrief discussions were recorded and transcribed using pseudonyms.

The second phase of the process was synthesis. We first coded the transcripts by highlighting sentences that described a problem with the internal supply chains. To establish interrater reliability, we each coded the same transcript and compared which sentences in the transcript we individually highlighted as being important. Our interrater reliability was 0.72, which indicated substantial agreement. Our interrater reliability provided confidence that we could divide the transcripts among us to pull out key information for synthesis. We transcribed the main idea from each selected sentence onto a single sticky note, resulting in over 680 notes. This process created a data set of internal supply chain breakdowns, key quotes, and stories that highlighted functioning and problematic chains.

The second step of synthesis was to organize the sticky notes into buckets or themes, using an iterative, grounded theory approach.27 28 We initially grouped the sticky notes into 13 categories that emerged from coding the transcripts. We then dropped categories that were not useful, recombined the notes to collapse buckets into higher-level themes, and allowed new categories to emerge. We organized the categories to depict relationships between them. The goal of this stage was to create a set of insights and a framework, presented in this article, that summarized key findings and opportunity areas for innovation.

**Results**

We spent a total of 54.2 hours observing nursing units, during which we directly witnessed 120 operational failures that interfered with nursing work. Thus, on average, a nurse experienced one operational failure every 37 minutes. For 72.5% of the operational failures (n = 87) we had data on the amount of time spent working around the failure. Table 2 categorizes these 87 operational failures by the department in which they originated. Nursing unit-related failures consumed the most time (24%), followed by pharmacy-related failures (22%) and those related to IT (20%).

To better understand why the nursing unit was the largest source of operational failures, we interviewed 10 nurses about what items they needed when a new patient arrived on the unit and which department was responsible for these items. All of the nurses mentioned 12 items. All but 3 were purchased by the nursing unit and thus were under their budgetary responsibility. However, the responsibility for supplying, cleaning, and maintaining the items fell to other departments. Furthermore, there were no designated storage locations for 5 of the items, nor were there standard stocking levels (periodic automatic replenishment levels) for any of them, making it challenging to know whether the quantities kept on the units and the frequency of cleaning were sufficient. We audited the equipment on one of the units and found that all items had smaller quantities than what nurses felt was required for a unit that was full

<table>
<thead>
<tr>
<th>Department</th>
<th>No. of operational failures with time estimates</th>
<th>Total minutes</th>
<th>Minutes per operational failure, mean</th>
<th>Minutes per operational failure, standard deviation</th>
<th>Total minutes on operational failure, %</th>
<th>Cumulative percentage of total minutes</th>
<th>Cumulative percentage of departments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing unita</td>
<td>14.0</td>
<td>106.0</td>
<td>7.6</td>
<td>8.8</td>
<td>24.0</td>
<td>24</td>
<td>10</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>15.0</td>
<td>97.5</td>
<td>6.5</td>
<td>6.4</td>
<td>22.0</td>
<td>46</td>
<td>20</td>
</tr>
<tr>
<td>Information technology</td>
<td>12.0</td>
<td>88.7</td>
<td>7.4</td>
<td>11.0</td>
<td>20.0</td>
<td>66</td>
<td>30</td>
</tr>
<tr>
<td>Othera</td>
<td>12.0</td>
<td>48.0</td>
<td>4.0</td>
<td>2.4</td>
<td>11.0</td>
<td>77</td>
<td>40</td>
</tr>
<tr>
<td>Environmental services</td>
<td>4.0</td>
<td>8.0</td>
<td>2.0</td>
<td>0.8</td>
<td>1.8</td>
<td>79</td>
<td>50</td>
</tr>
<tr>
<td>Biomedical equipment</td>
<td>8.0</td>
<td>24.5</td>
<td>3.1</td>
<td>1.3</td>
<td>5.6</td>
<td>85</td>
<td>60</td>
</tr>
<tr>
<td>Engineering</td>
<td>9.0</td>
<td>20.9</td>
<td>2.3</td>
<td>2.7</td>
<td>4.7</td>
<td>90</td>
<td>70</td>
</tr>
<tr>
<td>Central supply</td>
<td>4.0</td>
<td>29.0</td>
<td>7.3</td>
<td>8.7</td>
<td>6.6</td>
<td>96</td>
<td>80</td>
</tr>
<tr>
<td>Dietary</td>
<td>3.0</td>
<td>12.0</td>
<td>4.0</td>
<td>3.6</td>
<td>2.7</td>
<td>99</td>
<td>90</td>
</tr>
<tr>
<td>Space on unit</td>
<td>6.0</td>
<td>5.1</td>
<td>0.9</td>
<td>0.7</td>
<td>1.2</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Average</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4.5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Total                       | 87.0                                           | 439.6         |                                      |                                                     |                                        |                                        |                                        |

a Nursing unit = equipment that is responsibility of nursing unit (chairs, room furniture, intravenous poles).
b Other = documentation, discharge/admission process, interruption from people.
with patients. We suspect that the high frequency of failures stemming from the nursing unit resulted from the ambiguity about whether supplies of necessary equipment were sufficient, and if not, which department was responsible for addressing the shortfall. Table 3 lists the patient care items, the responsible units, and the quantities required versus available.

Nurses compensated for the lack of available equipment with workarounds. Seven of the nurses whom we interviewed stated that equipment needed to do their jobs was often unavailable and that it was accepted practice to “go shopping” in the dirty utility room, in other patients’ rooms, or on other units. For example, one nurse said, “If you can’t find it, you go get it, no matter where it is.” Similarly, in response to the shortage of functional items, we observed nurses violating policy by personally claiming shared equipment for their entire shift by putting notes (e.g., “Mary’s computer”) or personal items on computers and vital sign monitoring devices so that other people would feel social pressure to not use these items. We also observed nurses intentionally making functional equipment appear broken. For example, one nurse changed the way text was displayed on a computer screen (rotated by 90 degrees) so that others would find it cumbersome to use and would leave it alone. These compensatory behaviors exacerbated the shortage of functional equipment. Other studies of caregivers in hospitals also document similar behaviors in response to unreliable internal supply chains. 7,20,30

When reflecting on operational failures, people attributed poor performance to shortcomings of other departments rather than to a suboptimal system design. They also failed to recognize that their own department’s routines could be contributing to poor internal supply chain performance. For example, a pharmacy technician blamed the nurse “Jones” who called for a missing medication because Jones didn’t know the pharmacy’s algorithm for where medications were placed on the unit. The pharmacy technician stated, “The medication could be on a shelf, in a bin, or in the refrigerator. Nurses don’t know where things go.” Similarly, a sterile processing worker attributed poor performance to a general lack of training in the organization.

No one in the support departments expressed the belief that their department’s routines could be changed in a way that would improve overall internal supply chain performance. We spoke with employees from many departments, such as pharmacy, biomedical, sterile processing, environmental services, engineering, and dietary, and everyone expressed satisfaction with their own department’s work. Our observations confirmed their assessment. Employees mastered a complex array of technical procedures, worked hard, and completed their assignments according to standard procedure.

### Four Actions to Increase Interconnectedness

We propose that the high frequency of operational failures stemmed from a lack of interconnectedness between the supply departments and the nursing units. We define interconnectedness in hospitals as the degree to which departments’ routines and performance metrics have been designed to efficiently meet the needs of patients by enabling entities (e.g., patients), resources (e.g., supplies and equipment), and knowledge (e.g., relevant critical patient information) to flow smoothly and swiftly across interdependent departments. Our definition emphasizes the importance of designing department routines to meet patients’ needs, rather than to achieve outcomes that are beneficial to the department but may not align with patients’ needs. Second, our conceptualization of interconnectedness highlights the importance of smooth, efficient flow of materials through the organization.51

We assert that the goal of interconnectedness is to minimize the time required for patients to receive treatment, while balancing metrics of cost, performance, 

<table>
<thead>
<tr>
<th>Table 3. Nurses’ responses to questions about equipment and supplies needed to ensure the readiness of patient rooms, n = 10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Response number</strong></td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
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<tr>
<td>10</td>
</tr>
<tr>
<td>10</td>
</tr>
</tbody>
</table>
clinical quality, and patient experience. This goal is appropriate for the hospital system that we studied because it seeks to minimize the time that its patients spend in its hospitals without reducing quality of care. Our study highlighted the importance of four dimensions of interconnectedness: hospital-level metrics, designing processes for the efficient flow of materials and equipment from the beginning of the supply chain to the patient’s bedside, knowledge translation across departments to facilitate smooth flow of resources, and mechanisms for cross-departmental efforts to monitor and improve internal supply chain performance. We describe each dimension and develop a proposition to be tested in future research.

**Hospital-Level Metrics**

Metrics to assess the collective performance of an internal supply chain would facilitate interconnectedness among the departments in the chain. However, we found few such measures in the 2 hospitals we studied. Instead, departments measured their own productivity, such as the number of medications delivered by the pharmacy, the time taken to clean a vacated room, or conformance to a department’s labor budget. The delivery time along the entire chain, such as the elapsed time from when a physician ordered the medication until it was administered to the patient, was not tracked. A notable exception was the measurement for the percentage of Emergency Department patients admitted to the hospital who were in their inpatient bed in less than 60 minutes from when the inpatient bed request was made. In general, however, there was limited visibility into internal supply chains’ performance. As a result, upstream departments were unaware of ineffective handoffs of materials to downstream departments.

Furthermore, there were few shared rewards for good internal supply chain performance. Research suggests that shared rewards are an important facilitator of improvement in external supply chains. Similarly, we believe that the lack of shared rewards was an impediment to improving internal supply chain performance at the two hospitals. The interdependent, sequential nature of internal supply chains means upstream departments can change their processes to benefit downstream departments’ performance but may not receive any benefit from the change themselves. Thus, without shared rewards, departments may be unwilling to make changes that benefit other parts of the organization. For example, a nurse manager responsible for two units commented that the central supply department stocked the same materials in different locations on the two units. This made it difficult for her nurses, who worked on both units, to locate materials. However, the nurse manager was unable to convince the central supply manager to invest staff time in standardizing stocking locations. She commented, “Budget is the big divide.”

**Design Supply Process to Meet Current Patients’ Needs**

Processes were designed to optimize departmental performance rather than internal supply chain performance. The underlying assumptions seemed to be that a series of well-functioning departments would make a well-functioning hospital and that the departments’ routines were sufficiently connected to meet patients’ needs. However, we observed that although an individual supply department could perform its tasks efficiently, its work routines did not make the chain efficient unless they were directly linked to current patients’ needs. For example, departments such as central supply, sterile processing, and biomedical engineering restocked what was used by previous patients, but those supplies and equipment did not always match the needs of current patients. We believe the lack of proactive supply was because these departments did not have the clinical information or training to understand what supplies today’s patients needed. This made it difficult for nurses to locate necessary equipment, which may not have been available on the unit. Furthermore, some support departments purposely insulated their work from nursing units so that they wouldn’t be interrupted. Although reducing interruptions could be helpful to the support department’s efficiency, we found that it limited internal supply chain responsiveness. An IT staff person commented, “It’s bad if nurses know our names, because then they bypass the national help number.” Nurses reported spending up to 20 minutes on hold for IT help when they called the national help line. Being away from patients this long was not feasible for nurses, so nurses did not call about IT-related problems and instead relied on workarounds. We also observed a lack of a clear description of the step-by-step process flow of equipment for which many departments had shared responsibility. As a result, nonfunctioning equipment could remain on the unit for weeks with no department taking the initiative to repair it because each department assumed it was someone else’s responsibility.

**Knowledge Translation**

The third action we considered was knowledge translation across department boundaries. Work routines in one department were not always known by the downstream department, making resource handoffs between departments less efficient than they could have been. Consider our observations of the internal supply chain for medications. We observed a nurse spending ten minutes unsuccessfully searching for two bags of intravenous fluid for a patient. She searched in five places for the missing bags before calling the pharmacy for assistance. She was told that the bags had been delivered to the unit, but by the time we left two hours later, she still had not located them. The next day we spoke with the pharmacy technician about the incident and learned that the bags, because of the concentration of an added medication, had been in the unit’s refrigerator the entire time. This was the one place the nurse had not looked. The pharmacy technician explained that medications can be stored in eight different locations depending on a complex algorithm, such as whether the medication is topical or compounded, and if compounded, what the added medication is and its concentration. A technician’s action of delivering medications to the nursing units reveals his or her knowledge of the underlying rules that determine where the bags belong. Because the storage location information...
was of primary importance to the technician’s thought world and because the medication details were visible to nurses in the patient’s electronic medical record, the technician did not think that the phone call about the missing medications was because the nurse did not know where to look, but rather that she hadn’t taken the time to look in the location to see if the bags were there. As a result of this assumption, the technician did not inform the nurse of the storage location just told her that it had been delivered.

This story illustrates how communities of practice unknowingly fail to translate pertinent knowledge because they do not know what others do not know. In our example, the pharmacy knew where the medication was located but didn’t realize that the nurse did not know where it was. Prior research has found that it is especially difficult to transfer knowledge when one community of practice—such as pharmacy—uses that knowledge so extensively that they are unaware that someone (eg, a nurse) might not possess that same knowledge. Thus, it does not even occur to them that the problem could have been caused by someone not knowing a fact that they consider common knowledge.

**Forum for Improvement**

Fourth, mechanisms are needed to foster cross-departmental efforts to monitor and improve internal supply chain performance. In the hospitals we observed, communication about internal supply chain breakdowns, such as the missing intravenous medication bags described above, did not trigger improvement efforts. We propose this is partly because the inconvenience caused by the breakdown is not experienced by the department with the largest ability to remove underlying causes. There was also no structure for internal supply chain members to discuss issues and work together to improve performance. The dimensions of interconnectedness are summarized in Table 4.

Figure 1 depicts the lack of interconnectedness in hospitals’ internal supply chains. The flow of information about a patient’s equipment needs starts with the physician’s orders and passes through the nursing unit to the support department that provides equipment. This flow of information has time lags and goes in the opposite direction from the flow of equipment, which starts with the support department and ends with the patient.

Let us first consider the knowledge about the patient’s equipment needs. Equipment needs are implicit in physician’s orders. However, determining the equipment implications of a physician’s order requires both medical and technological knowledge to translate the medical order into a list of equipment needed to implement that order. The physician has the most knowledge about the patient’s orders and therefore could be the first step in the process to distill the equipment implications of the orders. However, physicians are not responsible for executing medical orders or for supplying equipment to the unit, and therefore they do not know the equipment implications of their patients’ orders. As a result, the equipment needs embedded in an order set are not translated to the support department responsible for

| Table 4. Dimensions of interconnectedness in internal supply chains |
|--------------------------|--------------------------|--------------------------|
| **Aspects**               | **Lack of interconnectedness** | **Quote**                  | **Interconnectedness**               |
| Metrics                  | No measures of internal supply chain performance | I’ve seen people be up to help within an hour. But I’ve also seen broken computers rack up until there’s six out in the lobby. So I don’t know anything about what they really do. Nick, RN | Measures of hospital-level performance |
|                         | Lack of shared rewards      | [Explaining why he did not fully repair a nonfunctional vital signs machine] My department would get charged for it [the attachment]. Biomedical engineer | Shared reward for achieving good performance at the hospital level |
| Process design           | Work not linked to patients’ needs | It’s bad if nurses know our names because then they bypass the national help number. IT engineer | Processes maximize hospital-level performance |
|                         | Lack of clear ownership     | I don’t have time to look for stuff. I let someone else do that. If it’s not behind the yellow line, I don’t go looking. Anna, environmental services technician The environmental services technician should make sure everything is in the room. Crystal, Unit assistant | Clear ownership of process step |
| Knowledge translation    | Knowledge not translated across boundaries | If you could get to see the orders before your patient gets here, that would be really good. Then we could prepare better. Now we are not able to prepare until they actually physically get here. Phoebe, RN | Knowledge translated across boundaries |
| Improvement capacity     | Communication doesn’t trigger improvement efforts | Every patient needs an IV pump, so why there isn’t always one at every bedside in every room is beyond me. We ask for this often. Phoebe, RN | Materiality of problems that surface in downstream departments |
|                         | No mechanisms for cross-departmental improvement | Positive example: The daily “bedhub” meeting between the nursing unit managers and the bed coordinators orchestrated the flow of patients from surgery and the ED to inpatient units. | Mechanisms for making cross-departmental change |

ED = Emergency Department; IT = information technology; IV = intravenous; RN = registered nurse.
We propose that the internal supply chains had low levels of interconnectedness because of how they were designed and managed rather than because of employee error or a shortfall in training. Departments emphasized their own performance, and thus processes were designed to maximize departmental efficiency rather than timeliness of service delivery to patients. Knowledge was not translated across department boundaries, resulting in dropped handoffs of resources between departments. Finally, the managers of the departments in an internal supply chain did not routinely meet to discuss ways to improve chain performance. We assert that mechanisms can be developed to support cross-departmental efforts to monitor and improve internal supply chain performance. Examples would be to create internal supply chain-level measures of performance and to collaboratively design work routines that efficiently move supplies across department boundaries to reach the patient. Although the specific operational failures we observed were likely unique to the two hospitals, the overall finding of a lack of interconnectedness among internal supply departments is a general problem in hospitals.

Our study offers lessons for hospital managers. Workarounds occurred at the interface between supply departments that used predetermined, supply-to-stock routines and nursing units that provided supply-to-order, customized patient care. To avoid workarounds or the need to keep large stocks of materials on the units, caregivers should be able to request and receive patient-specific supplies in a timely fashion. This could be accomplished with technology, such as the use of radio-frequency identification devices for signaling when materials need to be restocked or through dedicated support personnel responsible for frequent restocking on the unit. Although this may seem expensive, it can increase organizational efficiency by avoiding stock outs and reduce compensatory behaviors such as the hoarding of supplies. We believe that the ever-increasing breadth and price of supplies in combination with limited storage space and funds available to nursing units make frequent restocking a more feasible approach.
long-term solution than increasing the quantities of supplies stocked on units. In addition, managers need to create an organizational focus on internal supply chain design and performance. Employees are unlikely to recognize systemic causes of workarounds because they often blame poor performance on the shortcomings of others rather than on poor work-system design. Similarly, uninformned managers might not recognize the need for a hospital-level focus because their hard-working employees are executing required tasks successfully and meeting departmental goals. Unfortunately, such false feedback mechanisms can mask poor hospital-level performance.

Our research suggests that nurses and physicians both possess information that could help improve the performance of internal supply chains. First, up to a quarter of operational failures could be avoided by empowering nursing units to work collaboratively with supply departments to determine optimal stocking of materials and supplies on the units, along with designated storage locations. There would also need to be a system for easily requesting and receiving replenishment when stocks run low, such as the Kanban card system used in manufacturing settings. Second, nurses could codify the equipment and supplies used for high-frequency medication administration and patient care, streamlining equipment or supply needs if equivalent treatment options have differing equipment needs. Building on this database that translates medical orders and patient conditions into equipment needs, a further improvement opportunity could be using historical patient records to forecast seasonal supply needs. This could help supply departments to tailor their work to ensure they can meet predicted patient needs. Finally, it may also be possible to use IT to translate in real time to the supply departments, such as sterile processing and biomedical engineering, the equipment needs of current patients on the basis of their medication orders or surgical procedures.

Future research could expand on this study by determining the costs of operational failures and their impact on patient satisfaction. Such research could help justify investments in improving internal supply chain performance through methods such as those suggested above.

Conclusions

Internal supply chains are important drivers of efficiency, job satisfaction, and quality but are understudied in hospitals. By better leveraging the competencies of the different communities of practices responsible for delivering patient care, hospitals can reduce waste, freeing up staff time to provide care. Achieving this goal will require an explicit emphasis on connecting the routines of the different departments within hospitals.

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18. Spar SJ. Fixing health care from the inside, today. Harv Bus Rev 2005 Sep;83(9):78-91, 158.
The fact that disease is only in part accurately known does not invalidate the scientific method in practice. In the twilight region probabilities are substituted for certainties. There the physician may indeed only surmise, but, most important of all, he knows that he surmises … Investigation and practice are thus one in spirit, method, and object.

— Abraham Flexner, 1866-1959, American educator and publisher and creator of the Flexner Report
We awaken at the same time, enjoying the sound sleep and abundant breakfast ahead. After eating, after taping feet and fitting into boots, after gathering our walking sticks, we join the group, stile after stile. Good company, good conversation, eye-popping scenery, pictures from the past to remember these travels together walking, walking in companionable silence.

Mom does not walk very much these days.

Old age, hips not quite mobile any longer, desire lost to the comfort of a home and good books.

Walking, So long ago. And yet we both share this beautiful vigorous past. An activity done together. Mother, daughter, companionable silence. Who knew there would be a time that silence would include not walking?

Mom doesn’t walk very much these days.

Sharing a love of books, of conversation, of good food and beautiful places for the eyes to drink in. Still mother and daughter but more equals now in companionable silence on the phone.

The daughter continues the legacy of walking in beautiful places, eating great food, and sharing companionable silence with others. But not with Mom, who doesn’t walk very much anymore.

Fear of not walking anymore keeps the walking current each day—gotta walk—not so much for view, good food, and companionship but for walking. It’s the walking that drives the walking, keeping old age at bay. Gotta walk no matter what. Walking for a different reason. Walking to walk. Movement, power, vitality, heart races. Race walking to keep thoughts at bay. To dissipate those fears through walking. Walking that Mom doesn’t do much anymore. Some day. Not at all.
This illustration is a direct interpretation of the story by Dr Runkle. It is mixed media with additional digital manipulation. The artist was searching for a way to depict the melancholy beauty of a solo walk.

Mr Webb is an artist and graphic designer based in Nuremberg, Germany who primarily works in mixed media.
Home Diuretic Protocol for Heart Failure: Partnering with Home Health to Improve Outcomes and Reduce Readmissions

Richard P Veilleux, MPH, MBA; Joseph N Wight, MD; Ann Cannon, RN; Moira Whalen, RN; David Bachman, MD

Abstract

Context: The management of heart failure (HF) is challenging, with high rates of readmission and no single solution. MaineHealth, a health care system serving southern Maine, has shown initial success with home health nurses partnering with physicians in the management of complex patients with HF using the MaineHealth Home Diuretic Protocol (HDP).

Objective: To demonstrate that augmented diuretic therapy, both oral and intravenous, an evidence-based treatment for care of patients with HF experiencing fluid retention, can be delivered safely in the home setting using the HDP and can improve outcomes for recently hospitalized patients with HF.

Design: In late 2011, the MaineHealth HDP was implemented in two hospitals and in the home health agency serving those hospitals. The patient population included recently hospitalized patients with a diagnosis of advanced HF, eligible for home health services and telemonitoring.

Main Outcome Measures: Home health nurses reported data on the patients managed using the protocol, including interventions made, physical findings, lab values, and patient disposition after each episode of care. Questionnaires were used to determine patient and clinician satisfaction.

Results: Sixty patients meeting the criteria above were enrolled between November 2011 and January 2014. The protocol was initiated 84 times for 30 of these patients. Sixteen patients had multiple activations. The readmission rate was 10% and no adverse outcomes were observed. Clinician and patient satisfaction was 97% or greater.

Conclusion: The MaineHealth HDP can be delivered effectively and safely to improve outcomes, reducing readmissions and allowing patients to remain at home.

Introduction

Heart failure (HF) is one of the primary causes of hospitalization and rehospitalization in Maine and the nation.\(^1\,^3\) Care of these patients is complex.\(^4\) After an admission for HF, nearly 25% of patients are readmitted within 30 days, and by 6 months this proportion reaches nearly 50%.\(^5\,^6\)

MaineHealth, a nonprofit health system in Maine, works through its Heart Failure Workgroup (Workgroup) to promote best practices across the care continuum to improve quality, to optimize patient outcomes, and to make the best use of health care resources. Readmission rates serve as indicators of quality. Reducing avoidable readmissions for HF patients is a systemwide improvement objective.

Home health nurses, as members of the Workgroup, identified difficulty obtaining timely physicians’ orders as one contributor to avoidable readmissions. Anecdotal accounts cited frequent instances when the home health nurse believed a patient would benefit from diuresis but instructions from the physician were delayed. In these cases, the patient’s symptoms often progressed, resulting in an Emergency Department visit and hospital readmission. Workgroup consensus was that this scenario was frequently observed and, with approximately 75% of eligible HF patients referred to home health, represented an important opportunity for improvement.\(^7\) The Workgroup further identified that a factor in these cases was timely adjustment of diuretic medications and that these adjustments might be conducted in the home via a standing order, including intravenous (IV) administration when warranted.

In response to this opportunity, the Workgroup developed the MaineHealth Home Diuretic Protocol (HDP), through which home health nurses respond to worsening HF symptoms using predetermined orders for diuretic administration to reduce delays, improve management of fluid retention, improve patient quality of life, and reduce readmissions.

The Workgroup, a quality-improvement forum that includes clinicians, managers, and quality-improvement professionals from across care settings, is led by the Director of the Maine Medical Center Heart Failure Program and a MaineHealth Senior Medical Director. In 2010, the Workgroup established the following objective: to demonstrate that diuretic therapy, including diuretics administered intravenously, can be delivered safely and effectively in the home health setting to address symptoms and signs of decompensation in HF patients using the HDP and standing orders.

Methods

The HDP was derived from existing standards of care for HF. From the patient’s perspective, the treatment they received was routine practice, with no special consent required and no
risks beyond usual care. No patient was denied appropriate treatment. The institutional review board of the Maine Medical Center determined that this was a nonresearch project and not subject to its review.

The project was implemented in two hospitals in the health system (Maine Medical Center and Southern Maine Medical Center) and the primary home health agency serving those hospitals (Home Health Visiting Nurses). The Workgroup created a Home Diuretic Task Force to develop and implement a stepwise protocol. The task force was led by the Director of the Maine Medical Center Heart Failure Program and included a primary care physician, a home health nurse/telehealth coordinator, an inpatient HF nurse, a cardiology nurse practitioner, an emergency physician (the MaineHealth Senior Medical Director), a nurse clinical specialist, and the program manager.

A literature search uncovered five studies from Europe and the US between 1993 and 2010 related to diuretic protocols for HF. Four studies involved a clinic setting whereas one was designed with home diuretic administration by advanced practice nurses. These studies each provided evidence that diuretic protocols can be safe and effective outside the hospital setting despite comorbidities such as renal dysfunction. These studies also demonstrated cost-effectiveness, reduced hospital readmissions, and improved quality-of-life scores.

Starting with these examples, the Task Force developed an algorithm focused on patient safety and best practices for patient care. Hospitalized patients with advanced HF (New York Heart Association Class III/IV) were enrolled in the HDP in conjunction with an order for home nursing and telehealth monitoring. The HDP then remained dormant until the patient met the weight gain threshold, triggering activation of the standing orders. The HDP included monitoring of vital signs and laboratory test values, physician supervision, and a stepwise approach to diuretic therapy. Patient safety was of paramount importance, with physician consultation for abnormal laboratory test results and prompt referral to physician or hospital in any case of progressive symptoms, unstable vital signs, or worsening examination results (Table 1).

Education and training to support implementation of the program included inpatient nurses, discharge planners, cardiologists, hospitalists, home health nurses, and primary care physicians. Presentations were conducted to inform and engage stakeholders and to solicit their feedback on the HDP and its implementation. Training of home health nurses included clinical updates on HF care and implementation of the HDP itself. Detailed information was provided to individual primary care physicians when their patients were enrolled in the HDP.

A primary purpose of evaluation was to demonstrate whether the HDP could be implemented safely. The next question to be answered was whether implementation was feasible without significant modification to existing resources, including staff and equipment. Evaluation was also designed to provide information on the success of HDP at meeting the needs of physicians, nurses, and patients and its impact on readmission rates.

Main outcome measures included the number of patients enrolled, HDP adherence, physical findings, lab values, patient disposition after each episode of care, and patient and clinician satisfaction. The home health telehealth coordinator compiled data provided by the nurses caring for the patient in the home. Vital signs data were recorded, including weight, temperature, blood pressure, pulse, respiratory rate, pulse oximetry, and laboratory values, including serum electrolytes, renal function, and magnesium. Data were also collected on patient symptoms, including dyspnea, orthopnea, rales, peripheral edema, early satiety, abdominal bloating, and chest pain. Actions taken by the home health nurse—direct clinician contact, laboratory testing, and medication administration, as well as patient disposition and outcome—were also recorded. Questionnaires to nurses, patients, and physicians solicited feedback regarding HDP ease.

### Table 1. Overview of MaineHealth Home Diuretic Protocol

<table>
<thead>
<tr>
<th>Enrollment criteria</th>
<th>Heart failure admission</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Advanced heart failure (NYHA Class III/IV)</td>
</tr>
<tr>
<td></td>
<td>Eligible for home health services</td>
</tr>
<tr>
<td></td>
<td>Telehealth monitoring ordered</td>
</tr>
<tr>
<td>Protocol initiation criteria</td>
<td>Weight gain of 2 pounds overnight or 5 pounds in one week</td>
</tr>
<tr>
<td>Day and criteria</td>
<td>Action</td>
</tr>
<tr>
<td>1</td>
<td>If initiation criteria met</td>
</tr>
<tr>
<td></td>
<td>Double oral dose of diuretic</td>
</tr>
<tr>
<td></td>
<td>Check serum electrolytes, renal function, magnesium</td>
</tr>
<tr>
<td></td>
<td>Physical assessment</td>
</tr>
<tr>
<td>2</td>
<td>If patient above baseline weight</td>
</tr>
<tr>
<td></td>
<td>Double oral dose of diuretic</td>
</tr>
<tr>
<td></td>
<td>Administer metolazone</td>
</tr>
<tr>
<td></td>
<td>Check serum electrolytes, renal function, magnesium</td>
</tr>
<tr>
<td></td>
<td>Physical assessment</td>
</tr>
<tr>
<td>3</td>
<td>If patient above baseline weight</td>
</tr>
<tr>
<td></td>
<td>IV administration of diuretic, 1.5 times usual oral dose up to maximum</td>
</tr>
<tr>
<td></td>
<td>Check serum electrolytes, renal function, magnesium</td>
</tr>
<tr>
<td></td>
<td>Physical assessment</td>
</tr>
<tr>
<td>4</td>
<td>If patient above baseline weight</td>
</tr>
<tr>
<td></td>
<td>Immediate physician or hospital referral</td>
</tr>
</tbody>
</table>

* The current version of the protocol itself, along with other supporting materials, can be found at [www.mainhealth.org/home-diuretic](http://www.mainhealth.org/home-diuretic). IV = intravenous; NYHA = New York Heart Association.
of use, opportunities for improvement, patient’s perception of care, impact on patient safety, and responsiveness to patients’ needs. Blinded data were submitted for analysis only in aggregated form. No patient-identifying information was shared with program staff.

**Results**

Sixty patients were enrolled in the HDP between November 2011 and January 2014. The HDP was activated 84 times for 30 of these patients, with multiple activations for 16 patients. In 16 (19%) of the activations, HDP deviations occurred, primarily in the form of physician orders to respond to changes in patients’ status, with 1 patient hospitalized and 1 patient referred to hospice. In 38 (45%) of the 84 activations, the patient’s weight returned to baseline with a doubling of their usual diuretic dose. Baseline weight was achieved 17 times (20%) after doubling the oral diuretic dose combined with metolazone. On 9 (11%) of these 84 activations, the patient’s weight returned to baseline after receiving IV diuretic administration. Overall, a return to baseline weight was achieved in 64 of the 84 HDP activations. Of the 68 activations for which the HDP was followed without deviation, a return to baseline weight occurred in 64 (94%), with only 6 hospitalizations. Two patients were referred for hospice care. A flowchart of these outcomes is provided in Figure 1.

The readmission rate was 10%, with a total of 6 readmissions for the 60 patients enrolled. This compares favorably with the readmission rate among MaineHealth HF patients receiving home health care services (25%) as well as with the Maine Medical Center readmission rate of 20.6% and the national readmission rate of 23% among Medicare patients with a discharge diagnosis of HF. Of the 6 readmissions, 3 were for HF, whereas the other 3 were for pneumonia, chest pain, and complications of diabetes.

One key safety question was whether complex patients with kidney disease could be managed safely under the HDP; therefore, renal function was monitored closely. Creatinine levels were abnormal at baseline in 27 cases. Of these, 13 abnormal creatinine levels worsened whereas 14 improved under the HDP. Abnormal lab values sometimes resulted in modifications of the algorithm to optimize therapeutic effect. These modifications, with close management of these patients to ensure safety, frequently resulted in effective diuretic adjustments and in some cases prompted the scheduling of next-day appointments with physicians, including with a nephrologist. No patient was admitted for renal failure while under the HDP.

The safety and feasibility of IV administration of diuretics in the home environment were questioned by several stakeholders. IV administration of diuretics was relatively infrequent (17%) and was performed by home health nurses without compromising patient safety or quality of care. Most patients did not progress to IV administration, with 67% of patients returning to baseline with oral treatment alone.

Nurses overwhelmingly reported that the HDP was easy to follow and that it helped them respond quickly to patient needs. Patients uniformly indicated that the nurse responded quickly and that the care they received helped them to stay out of the hospital. Only three physicians responded to the request for feedback and each of their responses bears mention here. One physician stated, “This protocol is a nightmare,” expressing concern about excessive phone exchanges regarding changes in the patient status. Further investigation indicated that some of these calls were necessary to safely manage complex patients, whereas other calls reflected a lack of experience with the HDP on the part of home health nurses. This led both to additional training of home health staff and to clarifying expectations among physicians. The message was reframed to stress that, rather than reducing communications about complex patients, this HDP allows physicians to partner with the home health nurse to more effectively manage these patients and to prevent Emergency Department visits and hospital admissions. A second physician expressed the opinion that the protocol improved the patient’s safety as a result of the increased attention inherent in the HDP. The third response declared the HDP “an outstanding program” and a very positive experience for this patient, contributing to keeping the patient out of the hospital.

Medication supply was challenging, with the plan for providing IV medications and supplies requiring several

![Figure 1. Actions and Outcomes on MaineHealth Home Diuretic Protocol.](image)

IV administered a total of 13 times within these 10 activations, with 3 patients receiving IV diuretic on 2 consecutive days.

IV diuretic also administered on two other activations as first step, as noted under “deviations” above. HF = heart failure; IV = intravenous.
improvement cycles. IV medications and supplies were not readily available for patients through community or hospital pharmacies. A strategy involving a regional supplier of infusion services has proved successful, being cost-effective and reliable.

**Discussion**

Controversy continues regarding the true effectiveness of home monitoring in the management of HF. A Cochrane review in 2010 concluded that telemonitoring and structured telephone support do reduce all-cause mortality as well as rehospitalizations, whereas a randomized controlled trial inclusive of 1653 patients published that same year failed to demonstrate any such benefits. Desai similarly questioned the relationship between intensive home monitoring and outcomes, suggesting that emerging technologies may provide opportunities to remotely assess hemodynamic parameters and thereby improve disease management. Konstam, on the other hand, has argued that home monitoring should be considered an integral part of chronic disease management, particularly with HF, given its ever-increasing prevalence and costs.

The recognition that telemonitoring, if it is to be effective, has to be linked to timely intervention led to the development of the MaineHealth HDP. Although clearly a case series description rather than a randomized controlled trial, the HDP results to date suggest that home health nurses empowered with a structured protocol permitting a titrated increase in home diuretic dosages can safely and effectively manage homebound patients with advanced HF. MaineHealth’s integrated approach to improving the care of HF patients provided a structure within which to develop and implement the project. Committed engagement by the home health agency leadership was essential to its success, as was careful oversight by cardiologists and primary care physicians. Essential also was the clinical expertise and continued engagement of the members of the task force. The MaineHealth Heart Failure Program had the structure, staffing, and engagement of HF professionals from across the care continuum to coordinate and support this work well. Specially trained and experienced telehealth nurses played a central role in implementing the HDP.

The most significant limitation of this study is the lack of comparison data for the participant population. Since not all eligible patients were referred and no randomization process was used, it is likely that the discretion of referring physicians resulted in significant variation in the characteristics of patients recruited. Although historic data on the readmission rates for HF patients receiving home health services are available, these data do not differentiate those patients receiving telemonitoring services. Without comparative data for non-HDP patients, the relative impact of the HDP versus the impact of telemonitoring alone cannot be determined. Other limitations include the relatively small number of patients as well as the lack of racial diversity (all White).

From the beginning, patient safety has been the primary consideration and has not been compromised for any study participant. The daily physical examination, close monitoring of signs and symptoms, and laboratory results supported this goal. The effectiveness of the HDP was demonstrated by the return to baseline weight of most patients. The reduction in readmissions was better than anticipated, although no specific target was established for readmission reduction. Fewer patients than anticipated were recruited to the intervention during the study period. Patient recruitment may have been limited by reluctance among physicians to change practice, and by the introduction of a new electronic medical record system in the midst of the study period, creating challenges in the referral process.

The intervention was carried out with existing clinical staff, with no additional resources provided other than the support of quality-improvement staff. There were additional clinical inputs and associated costs, however, including telehealth equipment and home health telehealth coordinator and nursing time, and the extra time required by physicians to actively manage the most complex patients. Going forward, MaineHealth must develop a strategy to account for these additional costs and to allocate resources to scale and sustain the HDP, particularly as the cost savings that result from reduced rates of readmission will probably result in a decrease in revenue. Others considering such an intervention are advised to plan accordingly. This calculus will probably change as more organizations move toward “accountable care” and assume more financial responsibility and risk in providing care for the populations they serve.

Despite the challenges encountered and recognizing the relatively small number of patients enrolled, the MaineHealth HDP has demonstrated that diuretic therapy can be delivered safely and effectively in the home health setting and can improve patient experience outcomes while reducing readmissions. Given its apparent safety and effectiveness, MaineHealth plans to introduce the HDP in additional communities and to adapt it for use in other care settings, most notably skilled and long-term care. Recommendations for further study include using concurrent versus historic comparison data, as well as establishing a patient recruitment process that supports improved comparison of intervention versus control populations.

**Disclosure Statement**

Authors received no assistance in study design, data collection, data analysis, or manuscript preparation. The author(s) have no other potential conflicts of interest to disclose.

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Mary Corrado, ELS, provided editorial assistance.

**References**

Practical Lessons

The most important practical lesson that can be given to nurses is to teach them what to observe—how to observe—what symptoms indicate improvement—what the reverse—which are of importance—which are of none—which are the evidence of neglect—and of what kind of neglect.

—Florence Nightingale, OM, RRC, 1820-1910, celebrated English social reformer and statistician, founder of modern nursing
Great White in Flight
photograph

Bridget Bourgon, PA-C

This photograph of a great egret, or great white heron, was taken at the Bolsa Chica Wetlands in Huntington Beach, CA.

Ms Bourgon is a Physician Assistant in Urgent Care at Kaiser Permanente Orange County in Santa Ana, CA. Photography has been a longtime passion.
Successful Practices in the Use of Secure E-mail

Laura W Johnson, MPH; Terhilda Garrido, MPH; Kate Christensen, MD; Matt Handley, MD

Abstract
Physician use of secure e-mail with patients is anticipated to increase under Stage 2 Meaningful Use requirements, but little is known about how physicians can successfully incorporate it into daily work. We interviewed 27 “super user” physicians at Kaiser Permanente and Group Health who were identified by leaders as being technologically, operationally, and clinically adept and as having high levels of secure e-mail use with patients. They highly valued the use of secure e-mail with patients, despite concerns about a lack of adequate time to respond, and provided tips for using it successfully. They identified benefits that included better care and improved relationships with their patients.

Introduction
In 2004, Kaiser Permanente (KP) implemented an electronic health record (EHR), KP HealthConnect, in all Regions. Beginning the next year, the ability to securely e-mail clinicians became available to all patients registered on kp.org, the personal health record/patient portal integrated with KP HealthConnect that also offers partial records access, appointment scheduling, and online prescription refill services. As of October 2013, more than 15,000 physicians actively used KP HealthConnect, and 4.4 million patients were registered on the patient portal. Annually, kp.org-registered members send more than 14 million secure e-mails to KP clinicians. Group Health (GH) began offering secure e-mail in 2001, before EHR implementation in 2003. As of October 2013, more than 1000 GH physicians actively used EpicCare (Epic Systems Corporation; Verona, WI), and more than 265,000 patients have sent 3.5 million secure e-mails to GH clinicians.

Despite the scale of the KP HealthConnect implementation, secure e-mail is not used evenly across KP. In 2012, the average number of e-mails sent per day by primary care physicians (PCPs) in each Region ranged from 2.0 to 7.3. On average, PCPs across KP send 5.6 secure e-mails to patients each day, but the proportion of PCPs in each Region who send a daily average of 0-1 secure e-mails to patients ranges from 15% to 62%.

The benefits of secure e-mail with patients are well documented. For patients with chronic diseases like diabetes, using secure e-mail positively affects glycemic control and improves patient engagement and patient satisfaction. From the organizational and population health level, secure e-mail use improved Healthcare Effectiveness Data and Information Set (HEDIS) measures for members with diabetes and hypertension in KP Southern California; patients sending 2 or more secure e-mails to PCPs per month had significantly better health outcomes. From the perspective of PCPs, benefits include improved communication and enhanced physician-patient relationships. A 2013 study among Veterans Administration providers found secure e-mail to be a “missing element of complex information ecology” that improves access, communication, and relationships; clinicians reported more direct communication, improved efficiency and convenience, and a reduction in “phone tag.” In another study, 53% of Mayo Clinic physicians reported that secure e-mail using a standardized inbox positively affected their work, and a postimplementation survey revealed that 100% of clinicians reported no negative impact on their work.

Less understood, however, is how to optimize the use of secure e-mail in daily clinical practice or the impact of secure e-mail on workflows and workload. Some studies have documented physician concerns about inadequate time to respond to patient e-mails. A recent study found that most resident physicians feared an increased workload before implementation of a patient portal with secure e-mail. However, after implementation, residents responding to secure e-mail from patients reported that it improved their work and the care they provided. Some concern exists that secure e-mail, among other aspects of physician EHR use, is yet another challenge to physician work-life balance. This is of particular concern at a time when physician burnout is on the rise and we face a growing shortage of PCPs. Additionally, a core objective in Stage 2 of Meaningful Use, which pertains to both specialists and PCPs, is likely to increase the amount of e-mail between physicians and patients over the next few years. Under this objective, to qualify for financial incentives for EHR implementation, eligible clinicians must use secure electronic messaging to communicate relevant health information with at least 5% of their patients seen within the reporting period.

After eight years of organizational experience with secure e-mail, KP’s Health Strategy Governance Group, a senior leadership group overseeing online care delivery, sponsored a study of physician best practices related to using secure e-mail to communicate with patients.
Successful Practices in the Use of Secure E-mail

Methods

We conducted interviews with physician secure e-mail “super users” at KP and GH. We focused on physicians who were highly proficient at using secure e-mail to communicate with patients because we assumed that they would be most experienced at integrating it into their daily workflows and would have developed adaptive strategies that could potentially benefit their less proficient colleagues. Super users were identified by members of the Health Strategy Governance Group and other regional physician leaders as meeting 2 criteria: they were frequent users of secure e-mail and they had extensive technical expertise with the EHR. We interviewed 27 physicians in 7 KP Regions and at GH. Ten participants (37%) practiced internal medicine and 17 (63%) were family physicians. They were primarily men (17, 63%) and practicing full time (24, 89%). Their years in practice ranged from 8 to 41.

We generated 25 interview questions about workflow, e-mail management strategies, physician-patient communication, and concerns and recommendations (see Sidebar: Interview Questions). Responses were recorded during the interviews verbatim onto an Excel spreadsheet (Microsoft; Redmond, WA). Iterative analysis of responses revealed recurring themes, and we used frequency counts to describe patterns across all those interviewed.

Results

Workflow

According to EHR administrative data, super users sent, on average, 17.3 messages a day. Twenty super users (74%) reported that incoming messages went to an inbasket support pool to handle routine administrative messages; 7 (26%) received all e-mail directly from patients. Those using a support pool estimated—and appreciated—that the pool reduced by 20% to 30% the volume of e-mail they needed to respond to by handling more routine administrative messages. Super users most frequently identified registered nurses as staffing inbasket pools; medical assistants also filled this role, although one physician reported that a more limited scope of practice inhibited their effectiveness. Super users directly receiving all secure e-mail from patients strongly preferred this method, describing their approach to patient care as “hands on,” perceiving that it took too long for inbasket staff to forward messages, or disliking a “dumping” phenomenon of receiving multiple messages simultaneously. Three super users (11%) noted that coverage during time off was important to preventing an unmanageable backlog of e-mails; coverage was provided by other physicians or by registered nurses, and one super user noted that standardizing the responsibility of registered nurses for managing inbasket pools would facilitate cross-coverage.

Time Management

Super users estimated that they spent 2 to 3 minutes responding to a single patient secure e-mail, slightly less than a previously documented 3.5 minute response time. Twenty-one interviewees (78%) reported that they lacked dedicated time on their schedules for secure e-mail and consequently squeezed it in at every possible opportunity throughout the day. Twenty participants (74%) completed secure e-mail during working hours, and 7 (26%) handled secure e-mail after hours. One super user (4%) did both.
Response Time

Super users reported two general beliefs about responding to patient-initiated secure e-mail. The first, reported by 6 (22%), was that responding quickly saved time over the long run. These super users cited a response time of less than 24 hours as the gold standard for patient satisfaction and took pride in having a minimal backlog of e-mails. They also expressed concern that a slower response would result in additional e-mails or phone calls. The second, reported by 1 super user (4%), was that a quick response would encourage patients to use secure e-mail. However, a subsequent unpublished analysis found no correlation between average response time and secure e-mail volume.

Secure E-mail vs Phone Calls

Among super users, 5 (19%) expressed a preference for secure e-mail for communicating with patients, compared with phone calls. These users appreciated 3 characteristics of secure e-mail: communication is asynchronous, a known and limited amount of time is required, and it can be easily handled between office visits. In contrast, they described phone calls as open-ended and more likely to evolve into longer discussions on multiple topics; consequently, they returned patient phone calls over lunch or at the end of the day. Super users appreciated the ability to do as much work as possible between patient visits and thought e-mail contributed to this ability whereas phone calls detracted from it. Other super users appreciated secure e-mail but selected telephone communication or secure e-mail according to the patient’s communication preferences and the type of information that needed to be conveyed.

Messaging Tools

Super users typically prioritized secure e-mails at or near the top of all work tasks in their inbasket, the transactional hub of the EHR. The use of “Smart Tools,” such as SmartPhrases (see Sidebar: Sample SmartPhrases Employed by Super Users), was widespread; they provided technical shortcuts for templated notes, descriptions, patient instructions, and clinical details. Twenty-five interviewees (93%) used Smart Tools alone or in combination with free text. Only 2 participants (7%) reported writing e-mails to patients in full without using any technical shortcuts.

Content of E-mail

Nine super users (33%) identified what they perceived as vague, rambling, and multipart patient e-mails as the most challenging types of messages and responded to these messages by asking the patient to schedule a phone or office visit to discuss their concerns. One interviewee (4%) asked patients who sent frequent secure e-mails to keep a daily log of health concerns and send it for review every two weeks.

Tone and Length of Messages

Although we did not ask about writing style, a theme of brevity emerged. Four super users (15%) reported writing succinct messages with a professional, rather than personal, tone. Two participants (7%) described using this approach to model for patients a preferred style of communication. One clinician used system phrases to choose one of several closings and commented that it was possible to be simultaneously brief and personal. However, some super users (3, 11%) appreciated occasional updates from patients on things like family vacations and personal triumphs.

Provider-Initiated Messages

All super users sent secure e-mail without waiting for patients to initiate it. Physician-initiated e-mails included messages containing lab results, despite the fact that most lab results are also automatically made available online to patients when they are available to physicians.

Images

Seven super users (26%) had received clinical pictures from patients via e-mail; all but one appreciated the additional information. One super user reported, “A college student sent me a picture of his throat. I forwarded it to the ENT [ear, nose, and throat specialist] who immediately said the student needed his tonsils out. Surgery was arranged and the student flew home and went straight to the hospital—no need to wait for an appointment.” Of 20 super users (74%) with no experience receiving an image attachment, all were open to it; 15 (56%) thought it would be useful and could aid decision making, especially for dermatologic conditions.

Sample SmartPhrases Employed by Super Users

<table>
<thead>
<tr>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>.pharm = “The medication can be picked up whenever you’d like. The pharmacy is open Monday through Friday, 8:30am to 7:30pm. If you’d like to pick the medication up at a different pharmacy, or have it mailed to you (at no charge) instead, just call xxx-xxxx to speak with a pharmacy representative.”</td>
</tr>
<tr>
<td>.referral = “I have entered the referral—here is the info that you need. Feel free to call the number listed to rebook the appointment if this day/time does not work for you.”</td>
</tr>
<tr>
<td>.appt = “The best way to make an appointment is to call the appointment center at xxx-xxxx at 7 am and request a same-day appointment.”</td>
</tr>
<tr>
<td>.smxraynormal = “The results of your *** have been reviewed and I am happy to report that no significant findings were noted. Let us know if you have any questions.”</td>
</tr>
</tbody>
</table>

Navigating the system

<table>
<thead>
<tr>
<th>Personalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>.signed = “Name of Doctor, MD”</td>
</tr>
<tr>
<td>.happy = “I hope that your winter holidays are wonderful!”</td>
</tr>
<tr>
<td>.wkend = “Have a nice weekend.”</td>
</tr>
</tbody>
</table>

Patient education

| Walking = “Walking is a great way to get exercise. It requires almost no equipment, and can be done rain or shine, any time of year. A good goal is 5x/week, for an average of at least 30 minutes per day—so 150 minutes over the course of a week. There’s a great 9-minute video on the benefits of walking here (URL inserted).” |
Successful Practices in the Use of Secure E-mail

Super User-Reported Benefits of Secure E-Mail

- Improved ability to communicate with patients between visits
- Fast way to follow-up on medication questions
- Pre-examination outreach to identify clinical concerns (which may eliminate need for visit) or order labs ahead of time
- Clarification of visit information not understood or remembered
- Ability to use timed secure e-mail delivery to follow-up with patients they’re concerned about (e.g., new depression diagnosis)
- Ability to communicate more often with senior members who are less mobile

However, half (3 of 6) of the super users who had received images from patients commented on their poor quality. One super user expressed a desire to receive forms, such as logs, from patients as e-mail attachments.

Physician Concerns

When 16 super users were asked what concerned them about secure e-mail, their most frequent responses were e-mail volume (and the related issue of inadequate time for responding) and misuse of e-mail by patients for urgent medical conditions. Of these 16 super users, 5 (31%) identified each issue as a concern. Despite concerns about volume overload, 4 super users (15%) actively encouraged their patients to sign up for kp.org.

Patient Care Successes

Despite the concerns they reported about workload and volume, super users unanimously agreed that patients appreciated secure e-mail. More importantly, they also unanimously agreed that secure e-mail improved patient care quality and extended their ability to care for their patients in ways they had not anticipated. The benefits of secure e-mail reported by super users are contained in the Sidebar: Super User-Reported Benefits of Secure E-Mail. A particularly interesting theme, reported by 3 super users (11%), was that secure e-mail was very helpful in caring for seniors with limited mobility who were adept at communicating electronically. As one super user reported, “I had a patient that I feel like I kept alive and out of the hospital because of e-mail, an older man who didn’t hear very well and had some problems with congestive heart failure. We did a lot of adjustments to his medicines and brought him in for labs, all over e-mail.”

In addition, 17 super users (63%) commented that secure e-mail strengthens the physician-patient relationship because it is an avenue for patients to share problems of a more intimate nature that they may be reluctant to share in a face-to-face encounter.

Encouraging the Use of Secure E-Mail by Colleagues

We asked super users what they thought might inhibit their colleagues from using secure e-mail. Two themes emerged: lack of technical skill (8, 30%) and fear of being overwhelmed by e-mail volume given already heavy clinic schedules (14, 52%). Participants suggested secure e-mail tips (see Sidebar: Secure E-Mail Tips from Super Users).

Discussion

Physician super users were engaged, facile with technology, and proactive in handling secure e-mail. Despite concerns about volume and adequate time for responding to messages, some suggested their members sign up for access to it, wanted to receive images from patients by e-mail, and initiated secure e-mails with patients. Most used available time between seeing patients to respond to secure e-mail from patients, valuing a minimal backlog at the end of the day. Some super users believed that their response time influenced patient secure e-mail behaviors. However, an unpublished internal study of the use of secure e-mail with patients among nearly 3200 KP PCPs separately found that neither a rapid nor a more delayed response pattern was associated with increased e-mail volume.

Our interviews confirm the benefits of secure e-mail reported by others. Super users indicated that it improved the quality of care and contributed to patient satisfaction. They consistently reported that e-mail extended their ability to care for patients in unexpected ways; for example, one super user provided care to a patient who was in Antarctica. Some also appreciated a more personal, nuanced relationship with patients that occurred through e-mail.

Strengths of our study include the fact that it is, to the best of our knowledge, the first to explore how physicians who are highly proficient with e-mail use it to communicate with patients. Limitations include the small size and qualitative nature of our project. Early interviews informed the questions we asked in later ones; we eliminated some questions and added others after the first 15 interviews. As a result, we did not have responses to all items from all participants. The questions we asked throughout all interviews undoubtedly influenced the information super users provided. We did not use patient-centered metrics to confirm participants’ perceptions of the contribution of secure e-mail to patient satisfaction, although a previous study indicates that the use of kp.org, in which secure e-mail is a core functionality, is such a patient pleaser that it is associated with a greater member loyalty. In addition, the analysis of qualitative data is inevitably subjective. Further study is needed to confirm our findings in other settings, to assess varying levels of secure e-mail use with patients among physicians and the extent to which their colleagues who use secure e-mail less experience the benefits reported by super users, and to identify strategies to increase proficient use of secure e-mail by physicians to communicate with patients.

Secure E-Mail Tips from Super Users

- Work on secure e-mails throughout the day to reduce backlog and increase patient satisfaction
- Know how to set limits:
  - Use system templates (SmartPhrases) and limit free text to 2 to 3 sentences
  - Set time limits: eg, today I’ll finish every e-mail/lab etc received before 3 pm
  - Know what you can and can’t do over e-mail and when to ask the patient to come in or have a phone visit
- Master as many technical shortcuts as possible and use them
- Be brief but personal
- Use future e-mail delivery functionality for ticklers
- Ask patients who send long, vague, or complicated messages to schedule a phone or office visit
- Ask patients who e-mail more frequently to keep a daily log and send once every week or two
- Establish good systems to cover physician time off
Our findings lead us to suspect that those strategies may include adequate training, workflow design, and time allocation and management. For instance, improving the technical skills of physicians and their support teams at managing e-mail inbaskets and using SmartPhrases to streamline responses may decrease some barriers to broader use of secure e-mail. Identifying and refining supportive, flexible workflows that leverage the whole health care team to communicate with patients via secure e-mail and establishing standardized e-mail cross-coverage systems for clinicians who are out of the office may also be salient. Effective time management strategies for individual clinicians are likely important. Finally, health care organizations implementing or encouraging the use of secure e-mail under Stage 2 Meaningful Use objectives would do well to consider the value of even a small amount of dedicated time for physicians to use this mode of communication with patients.

Disclosure Statement

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

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References


A Calling

The practice of medicine is an art, not a trade, a calling, not a business, a calling in which your heart will be exercised equally with your head.

— Sir William Osler, 1849-1919, Canadian physician and author
**ORIGINAL RESEARCH & CONTRIBUTIONS**

*Special Report*

**Treatment Progress Indicator: Application of a New Assessment Tool to Objectively Monitor the Therapeutic Progress of Patients With Depression, Anxiety, or Behavioral Health Impairment**

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**Abstract**

Depression, anxiety, and behavioral health impairment are common in the US. Efforts to treat patients with depression, anxiety, and chemical dependency are surmounted by the great demand for psychiatrist and therapist appointments. Unlike other specialties, psychiatry lacks a vital sign or tests (eg, blood pressure for hypertension and hemoglobin A1c for diabetes) to objectively measure a patient’s response to therapy. A new tool called the Treatment Progress Indicator (TPI) appears to offer clinicians an objective approach to assess patients and to monitor therapy over time. The TPI report shows an Expected Treatment Response that allows clinicians to compare their patients’ responses to therapy with those of a cohort of patients with a similar diagnosis and severity. The TPI allows for objective population-level management of disease. This should result in sharing of best practices that will lead to more effective and efficient care plans. Widespread implementation of the TPI has the potential to improve the time required to diagnose conditions and triage patients. As a result, implementation of the tool has the potential to improve behavioral health access and affordability.

**Introduction**

Disorders such as depression, anxiety, and substance abuse are among the most common and disabling health conditions in the US. They often co-occur with chronic medical conditions, and untreated, they can worsen associated health care outcomes. When behavioral health problems are not effectively treated they can be associated with poor health outcomes, increased mortality, decreased work productivity, and an increase in health care costs.

According to Unützer et al, most medical patients with depression, anxiety, and/or chemical dependency may not receive adequate therapy. Efforts to improve the treatment of these disorders in primary care initially focused on screening, education of physicians, development of treatment guidelines, and referral to psychiatry. Although these interventions have not been shown to independently improve care, each area has the potential to contribute to improved mental health outcomes.

Every day clinicians must make decisions about patient care. They must decide whether a patient’s condition warrants treatment, referral, or watchful waiting. If treatment or referral seems appropriate for a patient, the clinician determines if the patient will be treated with medication or individual, group, or combination psychotherapy. After treatment begins, the physician must evaluate whether the patient is responding satisfactorily. All of these decisions pose unique challenges for behavioral health conditions because there are no vital signs, radiologic studies, or blood tests to rely on for diagnosis, treatment planning, and monitoring of the underlying disorder.

Some psychiatrists use one or more psychological tests to assess severity of the disorder and the patient’s progress (eg, Patient Health Questionnaire-9, Beck Depression Inventory, Symptom Checklist 90, Generalized Anxiety Disorder scale). These tests can be very useful but are typically narrowly focused on a single disorder (eg, depression or anxiety). Patients in specialty care commonly report symptoms of multiple disorders. Attempts to establish a broadly acceptable battery of measures have been unsuccessful, owing to differing views of which measures to include, and the length of time required for patients to complete the battery.

Currently, patients with diagnosed depression, anxiety, and/or chemical dependency may be treated in primary care or referred for psychotherapy or to psychiatry. However, most primary care physicians do not have an effective tool to objectively determine if a patient could benefit from a primary care intervention such as a health education class or an appointment with a case manager versus an appointment with a psychiatrist. The patient may wait several days to see a psychiatrist whereas intervention with a frontline case manager or social worker would be immediately available. This delay in care is concerning to patients and may prevent early interventions with the potential to stabilize an acute disorder.

Medical patients are considered to have a positive response to treatment when their symptoms remediate, their life functioning improves, and they feel better. A universally accepted mental health services screening and treatment progress indicator tool may be helpful in providing similar indicators of patient response to treatment for mental health conditions. It could be helpful for visualizing trends in improved functioning and symptom remission over the course of therapy, and in promoting multi-disciplinary collaboration for improved mental health outcomes.

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Treatment Progress Indicator

The Treatment Progress Indicator (TPI) was created to improve access to care and help clinicians get a better assessment of a patient’s overall behavioral health impairment (BHI) and monitor their response to treatment. TPI is a Web-based self-report assessment tool (see Sidebar: Treatment Progress Indicator Self-Assessment Tool). It screens for the most common behavior disorders and measures the severity of the patient’s depression, anxiety, global symptoms, social functioning status, global functioning status, and subjective well-being. These data are combined to derive a global BHI score useful for tracking response to treatment and for risk stratification. The TPI alerts the clinician to severity and presence or absence of indicators of substance abuse, obsessive-compulsive disorder, bipolar disorder, posttraumatic stress disorder, and panic disorder. It includes items for treatment history, use of psychoactive medications, and resilience. It does not assess psychosis, schizophrenia, phobia, or personality disorders.

The TPI system was developed over a decade by Polaris Health Directions (www.polarishealth.com) with extensive involvement of researchers, experts in assessment of mental health treatment outcomes, clinicians, and information technology specialists. The work was sponsored by the National Institute of Mental Health and grounded in a decade of basic research. Measures of the severity of multiple mental health conditions were developed and validated in both medical and mental health settings. Concurrent validation of the depression scale versus clinician evaluations has been established using patient samples from private and public clinics. Foundational research for the TPI also included a series of studies relating “doses” (sessions) of treatment to improvement in behavioral health symptoms and functioning, and in the global BHI score. The TPI was developed using item reduction analysis to reduce the length of the assessment to 29 questions by deleting items that had minimal impact on the reliability of the scales or the correlations of the shorter with the longer versions of the same scale.

Table 1. Treatment Progress Indicator internal consistency reliability

<table>
<thead>
<tr>
<th>Scale</th>
<th>Reliability</th>
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<tbody>
<tr>
<td>Depression</td>
<td>0.82</td>
</tr>
<tr>
<td>Anxiety</td>
<td>0.82</td>
</tr>
<tr>
<td>Symptoms</td>
<td>0.91</td>
</tr>
<tr>
<td>Social impairment</td>
<td>0.77</td>
</tr>
<tr>
<td>Functional impairment</td>
<td>0.85</td>
</tr>
<tr>
<td>Behavioral health impairment</td>
<td>0.86</td>
</tr>
</tbody>
</table>

Table 2. Assessment results for symptom and functioning scales in 2011

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>July</td>
</tr>
<tr>
<td>Overall behavior impairment</td>
<td>77</td>
</tr>
<tr>
<td>All symptoms</td>
<td>48</td>
</tr>
<tr>
<td>Depression (PHQ-9 raw score)</td>
<td>59</td>
</tr>
<tr>
<td></td>
<td>(11)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>54</td>
</tr>
<tr>
<td>Overall functional impairment</td>
<td>80</td>
</tr>
<tr>
<td>Social functional impairment</td>
<td>45</td>
</tr>
</tbody>
</table>

* Low scores are less severe.

PHQ = Patient Health Questionnaire.

Internal consistency reliability is acceptable for all 6 TPI scales and good or excellent for 5 of them (Table 1).

The TPI can be administered using a computer or fax form, typically upon admission to treatment and at clinic-specified intervals throughout an episode of care. The interval between assessments is at the discretion of the clinic. Most commonly it is administered immediately before every treatment session, or at two-week intervals. Assessment reports are available for clinician review immediately upon completion of the computer assessment and within 24 hours for the fax version. Excerpts of assessment reports are shown in Table 2 and Figure 1.

Table 2 shows the percentile score for the overall BHI and subscale percentile scores for depression, anxiety, and functional impairment. In this particular case the data show that the patient improved on all metrics except the social functional impairment metric. Despite this observation the overall Behavioral Impairment (BHI score) percentile improved markedly. Of note is the finding that the BHI score went from 80% to 19% despite only moderate improvement in depression and anxiety scores.

Expected Treatment Response

In addition to providing data for an individual, the TPI chart shown in Figure 1 also provides a graph showing the patient’s actual treatment response compared to the Expected Treatment Response (ETR) for BHI. The ETR algorithm was constructed from TPI data for thousands of patients presenting for treatment at Kaiser Permanente (KP) Southern California psychiatry clinics. The ETR curve was derived through hierarchical linear modeling of change in the patient’s global behavioral health condition as a function of initial severity and other prognostic factors, including treatment history, patient strengths, and expectations.
Treatment Progress Indicator Self-Assessment Tool

<table>
<thead>
<tr>
<th>Question</th>
<th>Response Options</th>
</tr>
</thead>
</table>
| During the last two weeks, how often have you been bothered by feeling bad about yourself—or that you are a failure or have let yourself or your family down? | 1. Not at all  
2. Several days  
3. More than half the days  
4. Nearly every day |
| During the last two weeks, how often have you been bothered by trouble concentrating on things, such as reading the newspaper or watching television? | 1. Not at all  
2. Several days  
3. More than half the days  
4. Nearly every day |
| During the last two weeks, how often have you felt thoughts of harming someone else? | 1. Never  
2. Sometimes  
3. Often |
| In the past two weeks, how often have you felt hopeless or pessimistic about the future? | 1. Never or rarely  
2. Some of the time  
3. Often  
4. All or almost all of the time |
| In the past two weeks, how often have you felt tense or anxious? | 1. Never or rarely  
2. Some of the time  
3. Often  
4. All or almost all of the time |
| In the past two weeks, how often have you worried too much about things? | 1. Never or rarely  
2. Some of the time  
3. Often  
4. All or almost all of the time  
5. No use |
| In the past two weeks, how often have you been able to manage your day-to-day life? | 1. Very well  
2. Fairly well  
3. Fairly poor  
4. Very poor |
| Have you ever been hospitalized for a psychological or emotional problem? | 1. Never  
2. Once  
3. Two or more times |
| How many times have you been in counseling or psychotherapy before now? | 1. Less than two months  
2. Two to three months  
3. Four to six months  
4. More than six months |
| How long have you had the problem(s) for which you are now seeking treatment? | 1. Very poorly  
2. Fairly poorly  
3. Fairly well  
4. Very well |
| Have you ever been able to perform work/school/household tasks? | 1. Very poorly  
2. Fairly poorly  
3. Fairly well  
4. Very well |

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Therefore, the ETR provides a standardized, databased method for monitoring response to therapy for an individual patient compared to similar patients in the database at specific time intervals. The clinician’s decision concerning intervention is guided by projections of the likely course. If the clinician decides to treat, the actual treatment response can be compared with the expected treatment response to determine whether the patient is making adequate progress.

Although few patient trend scores will precisely track the ETR, a series of two or more scores that are substantially less favorable than the ETR may indicate that the patient is not responding as well as expected to therapy (see Figure 1, second assessment actual BHI score). However with treatment adjustment, the actual treatment response may improve more than the ETR for a similar patient profile (see Figure 1, third assessment actual BHI score), indicating that response to therapy is better than expected. This is potentially a very powerful tool as it may help guide therapy and may open the door to identify and spread best practices across the continuum of care.

Treatment Progress Indicator Benefits

By providing a global measure of behavioral health status as well as measures for common disorders and comorbidities, TPI may offer an efficient method for helping clinicians decide whether to treat. If the decision is to treat, TPI can help to determine whether the patient is making satisfactory progress in relation to an evidence-based expectation of progress. Monitoring treatment response may enable clinicians to identify patients who need more intensive therapy, or those that can be safely discharged or stepped down. Treatment approaches that consistently achieve unusually positive outcomes compared to ETR may be identified as best practices and shared.

Traditional evidence-based medicine supports treatment practices that have been shown to improve care. However, no behavioral health treatment is effective for all patients. The TPI enables us to determine whether a patient is receiving the “right” treatment based not upon a specific evidence-supported approach but based upon the answer to the question, “Is the patient making the progress that would be expected on the basis of their initial severity and other factors known to impact the rate and amount of patient improvement?” In clinical practice it is less important to know whether a treatment works in general than to know whether it is working for the patient under care.

The TPI can also be used to identify patients who present in psychiatry clinics who may be candidates for other care pathways. Those with mild, uncomplicated presentations may be candidates for Wellness Coaching or Health Education. Patients with unipolar depression and no significant comorbidities may be candidates for Depression Care Management. Analyses of data for 11,700 patients from 9 KP psychiatry clinics indicates that as many as 15% may be candidates for these less intensive interventions. In addition, having a way to objectively measure BHI sets the stage for triage to occur upstream, even in the primary care setting. Some patients’ care might be shifted to other departments including health education, front line depression case managers, and social workers in primary care. This has the potential to improve access in psychiatry for patients who would most benefit from specialty care (eg. patients with severe bipolar disorders or schizophrenia, and patients at risk for self-harm). The TPI may allow us to assess which patients need to be referred to the Psychiatry Department and “with further research” which patients could be managed in primary care. The TPI’s evidence-based tracking of patients’ responses to therapy should help clinicians identify patients who can safely be returned to primary care. By reducing the need for follow-up appointments in Psychiatry, this could further increase access to new referrals.

The Future for the Treatment Progress Indicator

Every day thousands of patients are treated for depression, anxiety, and functional impairment. Each patient represents potential for learning and performance improvement. Our goal as clinicians is to better understand which types of interventions are most effective for which types of patients. Because there is currently no objective way to measure a patient’s emotional vital sign in the behavioral health setting, there is no optimal way to identify and to share standardized best practices among clinicians. The TPI is designed to harvest data to allow clinicians to better understand what works and for whom.

The utility of ETR curves will continually increase as new patient data are added to the TPI database. The capacity to routinely capture and make use of the treatment histories of real patients constitutes a learning system and a potential milestone for behavioral health. Large patient volume gives organizations like KP a unique opportunity to use the TPI to establish and to continually refine ETRs for all treatment modalities. ETRs can be established for group psychotherapy, individual psychotherapy, medication management, and combinations of the three (eg, medication and individual psychotherapy).

Numerous measures exist for detecting individual disorders such as depression, but there are very few instruments that measure all components assessed by the TPI or do so efficiently. TPI compares well with alternative tools when practical issues such as the number of items, time required for completion, mode of administration, complexity of scoring, customizability, and special training requirements are considered. The scope of the TPI is important because patients often report multiple problem areas. The ability of the TPI to monitor treatment response for patients with multiple problems is therefore important, and could be further strengthened when ETRs are derived for specific treatment modalities.

Detecting depression, anxiety, chemical dependency, suicidality, and functional status would be helpful both for the behavioral health specialists as well as primary care physicians. In each setting, determination of appropriate care pathways is best for the patient and for improving access to the most intensive treatments. In both settings, evidence-based tracking of patient response to treatment is critical. If a patient is responding to therapy, improvement can be documented using the TPI instead of relying on subjective, nonquantitative documentation in the patient chart. The TPI gives us the ability to identify best treatment strategies that could be shared with other physicians. The TPI would allow identification of psychiatry clinic patients who...
Treatment Progress Indicator: Application of a New Assessment Tool to Objectively Monitor the Therapeutic Progress of Patients With Depression, Anxiety, or Behavioral Health Impairment

improve with therapy and who could return to their primary care physician. If symptoms recur, the TPI could be administered to determine if the patient needs to be referred back to behavioral health medicine. Return to the primary care physician will help increase access to behavioral health medicine.

Finally, the TPI can be used to quickly identify patients who are not responding to therapy. As a result, treatment plans can be reviewed and adjusted (eg, check for adherence to medication prescription, appropriate dosage of medication, or intensity of psychotherapy). A simple self-administered measure to complete either in the clinic, by secure messaging, online, or by telephone administration would be an efficient means to assess the nature and severity of conditions screened for by the TPI.

Conclusion

Physicians prefer to quantify a disorder when possible. The TPI might be considered a type of laboratory test or an emotional vital sign. Like blood glucose readings, the TPI may serve as an entry point for patients with behavioral issues and their physicians to communicate about disease control, decide among treatment options (including “watch and wait”), monitor progress, and, when appropriate, adjust therapy.

Multisymptom screening together with brevity, reliability, and construct and criterion validity makes the TPI tool an attractive dual-purpose instrument for making diagnoses and assessing severity of depression, anxiety, and chemical dependency disorders, particularly in the busy setting of clinical practice.

Disclosure Statement

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

Acknowledgment

Leslie Parker, ELS, provided editorial assistance.

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Some of All

Is the clinician a biochemist, a biophysicist, a biologist, a pathologist, a psychologist, a psychiatrist, a social scientist, a statistician? In my view, he is none of these and at the same time he must be something of all of them.

— John Romano, MD, 1908-1994, American physician, psychiatrist, and educator
FaceTime
photograph

Sally J Cullen, MD

This photograph was taken while on tour in Egypt in 2009. The natural world is full of wonder—we need only step outside.

After more than 32 years practicing medicine, Dr Cullen retired in 2012 as Assistant Chief of Pediatrics at Kaiser Permanente Folsom in CA. She is passionate about protecting national parks and public spaces and uses photography to encourage others to celebrate our natural world. More of her photography can be viewed at: www.myparkphotos.com/property/SallyCullen.html.
Thoracic Endometriosis Syndrome: Case Report and Review of the Literature

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Abstract

Thoracic endometriosis syndrome is the presence of endometrial tissue in or around the lung. Thoracic endometriosis syndrome consists of four distinct clinical entities: catamenial pneumothorax, catamenial hemothorax, hemoptysis, and pulmonary nodules. Thoracic endometriosis syndrome is a rare and complex condition, and diagnosis is often delayed or missed by clinicians, which can result in recurrent hospitalizations and other complications. Current treatments include hormone therapy and, where warranted, surgical intervention. We report the case of a 48-year-old woman with endometriosis causing bowel obstruction and concurrent catamenial pneumothorax.

Case Report

A 48-year-old woman was sent to the Emergency Department for further evaluation after being examined in the after-hours medical clinic. She had presented with one week of left-sided cramping abdominal pain with nonbloody, non-bilious emesis, and then developed diarrhea alternating with constipation. She denied fevers, chills, shortness of breath, chest pain, or urinary symptoms, and she reported regular menstrual cycles. She denied using cigarettes, alcohol, or recreational drugs and had no prior abdominal surgeries. Her family history was unremarkable. On examination she had tachycardia with diffuse abdominal tenderness and distention. Seven months before her presentation she was evaluated for right upper quadrant abdominal pain. An abdominal ultrasound at that time was normal, and the pain eventually resolved spontaneously.

In the Emergency Department, her temperature was 37.1°C, blood pressure was 147/108 mm Hg, pulse was 97 beats/min, respiratory rate was 17 breaths/min, and oxygen saturation was 99% on ambient air. She was alert and oriented and was in no distress. Her physical examination was notable for a mildly distended abdomen with high-pitched bowel sounds. She had equal breath sounds bilaterally. Her complete blood count was unremarkable other than a mild elevation in her platelet count of 573K/µL. Her chemistry panel demonstrated an increased anion gap metabolic acidosis (measured CO₂, 19 mEq/L; anion gap, 19). Her lactic acid was normal. Renal and liver function tests were normal.

A computed tomography (CT) scan of the abdomen and pelvis demonstrated small bowel and colonic dilation, with concern for an obstructing lesion at the distal sigmoid colon (Figure 1A). A small right pneumothorax (Figure 1B) was also identified. A nasogastric tube was placed for decompression. She underwent a colonoscopy to evaluate the etiology of her bowel obstruction, which revealed extrinsic compression causing sigmoid narrowing. The patient subsequently underwent a diagnostic laparoscopy and right chest tube placement. Laparoscopy revealed extensive peritoneal masses with concentric narrowing at the rectosigmoid junction with adhesions in the pelvis. Visualization was limited owing to the dilated bowel, so the decision was made to do exploratory laparotomy. She underwent rectosigmoid resection, appendectomy, diverting loop ileostomy, and total abdominal hysterectomy with bilateral salpingo-oophorectomy. Pathology results were consistent with implantation of endometrial tissue (Figures 2A and 2B). Given the extensive endometriosis, it was presumed that the pneumothorax was likely catamenial in nature. The chest tube was removed on postoperative day 2. Her diet was slowly advanced and she was discharged in good condition 6 days after her surgery.
General Overview

Endometriosis is the condition wherein endometrial tissue is present outside of the uterine cavity. It is encountered most commonly in pelvic structures such as the ovary, uterine ligaments, pelvic peritoneum, cervix, labia, and vagina. Thoracic endometriosis syndrome (TES) is the presence of endometrial tissue in or around the lung. TES consists of 4 distinct clinical entities: catamenial pneumothorax (CP), catamenial hemothorax (CHx), hemoptysis, and pulmonary nodules. Although endometriosis in general can affect up to 15% of women in their reproductive years, TES remains an exceedingly rare condition.

Described as early as 1912 by Hart, endometriosis is documented as causing pulmonary lesions consisting of endometrial glands and stroma. In 1938, Schwartz described a woman with inguinal node endometriosis with hemoptysis with a “lung tumor” that bled with every menstrual cycle. Since then, endometriosis has been documented in the lung, bronchi, pleura, and diaphragm. In the past 100 years, there has been improved understanding of the prevalence, clinical manifestations, diagnosis, and treatment of TES. The two largest retrospective studies in this period noted the peak incidence of TES occurs between ages 30 to 35 years, with CP the most common presentation of TES.

It remains unclear how endometrial tissue migrates to the thoracic cavity. In 1927, the concept of retrograde menstruation, or the reflux of endometrial tissue from the uterus to the peritoneum via the fallopian tubes, was introduced as the etiology of peritoneal endometriosis. This is thought to occur during the menstrual cycle when the cervical mucus plug is absent. Alternatively, these fenestrations were believed to be either congenital or the result of direct erosion by endometrial implants and could be as large as four inches in diameter.

Alternative theories for the presence of endometrial tissue in the lungs have been presented, including coelomic metaplasia, or the transformation of peritoneal/plural epithelium into endometrial tissue under the influence of physiologic stimuli. This theory explains the presence of endometrial tissue in patients without a uterus including men on prolonged estrogen therapy. However, it fails to explain the right-sided thorax predominance seen in most TES cases. An additional theory is that endometrial transplantation occurs through lymphatic/vascular microembolization, explaining the presence of both intrapulmonary and other extra-uterine sites of implantation.

TES occurs almost exclusively in the right hemithorax (approximately 95% of cases). There are several potential reasons for this laterality. Physiologically, peritoneal fluid moves in a clockwise fashion from the pelvis along the right paracolic gutter to the subphrenic space. Endometrial tissue located within the peritoneum likely follows the same directional flow, landing more commonly on the right hemidiaphragm. Once there, the falciform ligament prevents further travel of tissue to the left. Additionally, interperitoneal pressure variation with respiration causes the right hemidiaphragm to contract against the liver, known as the “piston effect,” which potentially allows for endometrial implantation and/or migration across the diaphragm. Finally, although congenital diaphragmatic hernias are far more common on the left side, congenital diaphragmatic defects, particularly fenestrations, are known to occur more commonly on the right, leading to the right-sided predominance of TES.

Specific Clinical Entities

Catamenial Pneumothorax

CP is responsible for only 2.5% to 5% of cases of women with spontaneous pneumothorax even though it accounts for 73% of the cases of TES. The first case of CP was described by Maurer et al in 1958, but the term catamenial pneumothorax was not introduced until 1972. CP is typically defined as spontaneous and recurrent pneumothorax occurring within 72 hours from the onset of menstruation. According to Karpel et al, the number of recurrent pneumothoraces can range from 2 to 42 per patient.

Three theories have developed to explain this entity. The first is transdiaphragmatic passage, or movement, of air from the vagina to the peritoneum via the fallopian tubes, and subsequently to the thorax via diaphragmatic fenestrations. This is thought to occur during the menstrual cycle when the cervical mucus plug is absent. The second is air leakage triggered by sloughing of the endometrial implants located on the pleura. The third proposes a hormonally mediated mechanism in which high levels of
prostaglandin from thoracic endometrial implants cause vascular and bronchiolar vasoconstriction, leading to ischemic injury and ultimately causing alveolar rupture and subsequent air leakage. The etiology of CP is likely multifactorial given that none of these theories alone accounts for the varied clinical presentations of CP.

Patients with CP most often report right-sided pleuritic chest pain and dyspnea. One study found that right scapular pain was highly specific for the diagnosis of CP. Accurate diagnosis is enhanced by heightened clinical suspicion regarding women in their reproductive years who present with chest pain or spontaneous pneumothorax.

**Catamenial Hemorrhage**

CHx accounts for approximately 14% of cases of TES but overall is a very rare cause of pleural effusions. As with CP, the right hemithorax is involved in most cases, although both bilateral and left-sided CHx have been described. Clinical presentation typically includes acute onset of chest pain and dyspnea. Diagnostic imaging reveals pleural effusions ranging from 200 mL to 2000 mL in size. CHx is associated with pelvic/pleural endometrial implants and diaphragmatic defects seen on thorascopy, indicating that the pathogenesis likely involves migration of endometrial tissue from the pelvis to the thorax, consistent with the theory of retrograde menstruation.

**Catamenial Hemoptysis**

Catamenial hemoptysis (CHy) is an uncommon manifestation of TES, accounting for only 7% of cases, and is rarely mentioned in the general differential diagnosis of hemoptysis. Unlike other forms of TES, pleuritic chest pain is not a common clinical presentation. Symptoms may not occur with every menstrual cycle although they can still occur frequently throughout a person’s lifetime. One woman was reported to have hemoptysis with more than 200 menstrual cycles. It is presumed to be caused by endobronchial or parenchymal endometrial tissue deposits, the presence of which is best explained by the microembolization theory. In a small retrospective study of patients with CHy in South Korea, 16 of 19 study subjects had a history of obstetric or gynecologic procedures before developing hemoptysis. Interestingly, this supports the notion that trauma and uterine manipulation are predisposing factors for microembolization. Although no deaths from CHy have been reported, it may be life threatening owing to its associated risk of asphyxiation.

**Pulmonary Nodules**

Pulmonary nodules are a rare effect of TES, accounting for approximately 6% of cases of TES. As such, TES is almost never mentioned as a possible cause of a newly discovered pulmonary nodule. The most common clinical manifestation of TES lung nodules is hemoptysis, because the proliferating endometrial implant(s) may communicate with a nearby bronchus, but the nodules are often asymptomatic. Pulmonary nodules appear to occur more frequently in older women (mean age, 38 to 39 years) compared with the other manifestations of TES (mean age, 34 years). The endometrial implants may be surrounded by fibrinous tissue and therefore can present as a mass or infiltration on lung imaging that can be mistaken for malignancy. In one report, a pulmonary nodule appeared as a well-demarcated subpleural ovoid tumor with cavitation. Symptoms do not necessarily correlate with menses, which may delay diagnosis.

**Diagnosis**

Heightened clinical suspicion is the key to diagnosis of TES. A woman in her reproductive years who reports chest pain, dyspnea, or cough around the time of her menstrual cycle should clue the physician to the possibility of TES. Diagnosis is facilitated by the use of imaging studies. Radiographic imaging may be sufficient to identify pleural effusions or pulmonary nodules. However, magnetic resonance imaging is more sensitive and specific for identifying endometrial implants. Magnetic resonance imaging also has the advantage of being noninvasive and can be repeated as needed. Bronchoscopy may be useful in the diagnosis of pulmonary endometriosis by cytologic examination of bronchial washings, although earlier studies indicated that the diagnostic yield of bronchial brushings or washings is very low. Additionally, bronchoscopy may play a role in the localization of a bleeding site or in planning surgical intervention.

**Treatment**

The cornerstone of TES management is the suppression of ovarian estrogen secretion, commonly with oral contraceptives, progesterone agents, danazol, or gonadotropin-releasing hormone (GnRH) agonists. Since 1994, the latter 2 have been used the most frequently. GnRH analogs cause GnRH receptor down-regulation, creating reversible hypogonadotropic hypogonadism, making it the treatment of choice for women wishing to preserve fertility. Although it is conveniently administered via monthly intramuscular depot injections, it is expensive and requires a long duration of therapy to achieve control. Danazol directly prevents the midcycle luteinizing hormone surge, resulting in anovulation.
and thereby decreasing the secretion of estradiol. The optimal duration of both therapies is uncertain. Unfortunately, treatment with hormonal therapy alone is associated with a recurrence rate exceeding 50% within 6 months after treatment was stopped. Because there has been no demonstrated difference in efficacy between these drugs, the drug cost, patient preference, and side effects such as hot flashes, depression, and osteoporosis may dictate which agent to use.

Hysterectomy with bilateral salpingo-oophorectomy, although effective, results in permanent infertility and does not address dormant endometrial implants that may become active with administration of exogenous estrogen. Patients for whom hormonal therapy has failed may benefit from surgical treatment. This is best accomplished by video-assisted thorascopic surgery, which allows multiple treatment modalities to be implemented: 1) resection of areas of the lung and diaphragm where endometriotic implants are present, 2) closure of diaphragmatic fenestrations with mechanical staplers, sutures, or placement of a diaphragmatic patch, and 3) abrasive mechanical pleurodesis and chemical pleurodesis with tetracycline, minocycline, or talc. Ikeda et al found that the use of polyglactin mesh on the lung and diaphragm where endometrial implants were present (causing fibrotic adhesions) was successful in treating 4 patients with CP, all of whom remained symptom free for 5 years after surgery. According to Härkö et al, the ideal surgical approach would entail maximizing pleural adhesion to the thoracic wall, removing any potential space for pathologic features. Because of its ability to address most of the intrathoracic pathologic features, a surgical approach has been suggested to be superior to hormonal therapy alone. However, it has also been shown that surgical treatment followed by hormonal therapy was associated with no recurrence in a follow-up period as long as 45 months, and therefore, a combination of surgical and hormonal therapy may be the preferred approach for treatment and prevention.

Of note, once the diagnosis of TES is established, it is prudent to have proper gynecologic follow-up for these patients because TES can be a marker of concomitant severe pelvic endometriosis, which potentially has serious implications on a woman's fertility and overall health.

**Conclusion**

Because TES is a rare and complex condition, diagnosis is often delayed or missed by clinicians. To avoid such issues and implement appropriate treatment, a high index of suspicion is essential in any woman of reproductive age or receiving hormone replacement therapy who is experiencing cyclical chest pain, dyspnea, and/or hemothorax. Hormone therapy is a suitable first-line treatment because it is less invasive and can preserve fertility. However, surgical intervention is available for women for whom medical therapy fails or who have a high burden of disease.

**Disclosure Statement**

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

**Acknowledgment**

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Thoracic Endometriosis Syndrome: Case Report and Review of the Literature


Journey

From childhood to maturity
And youth to age;
From innocence to knowing;
From foolishness to discretion,
And then, perhaps, to wisdom;
From weakness to strength—
And often back again;
From health to sickness,
And back, we pray to health again …

Birth is a beginning
And death is a destination
And life is a journey.

— Jewish prayer as recited in Synagogue
Comparative Health Systems Research among Kaiser Permanente and Other Integrated Delivery Systems: A Systematic Literature Review

Jared Lane K Maeda, PhD, MPH; Karen M Lee; Michael Horberg, MD, MAS

Abstract

Context: Because of rising health care costs, wide variations in quality, and increased patient complexity, the US health care system is undergoing rapid changes that include payment reform and movement toward integrated delivery systems. Well-established integrated delivery systems, such as Kaiser Permanente (KP), should work to identify the specific system-level factors that result in superior patient outcomes in response to policymakers’ concerns. Comparative health systems research can provide insights into which particular aspects of the integrated delivery system result in improved care delivery.

Objective: To provide a baseline understanding of comparative health systems research related to integrated delivery systems and KP.

Design: Systematic literature review.

Methods: We conducted a literature search on PubMed and the KP Publications Library. Studies that compared KP as a system or organization with other health care systems or across KP facilities internally were included. The literature search identified 1605 articles, of which 65 met the study inclusion criteria and were examined by 3 reviewers.

Results: Most comparative health systems studies focused on intra-KP comparisons (n = 42). Fewer studies compared KP with other US (n = 15) or international (n = 12) health care systems. Several themes emerged from the literature as possible factors that may contribute to improved care delivery in integrated delivery systems.

Conclusions: Of all studies published by or about KP, only a small proportion of articles (4%) was identified as being comparative health systems research. Additional empirical studies that compare the specific factors of the integrated delivery system model with other systems of care are needed to better understand the “system-level” factors that result in improved and/or diminished care delivery.

Introduction

Rising health care costs, wide variations in quality, and increased patient complexity led to passage of the Affordable Care Act, which has resulted in the US health care system undergoing rapid changes. These changes include payment reform (ie, value-based purchasing, bundled payments) and movement toward integrated delivery systems, such as accountable care organizations and patient-centered medical homes. Because the current US health care system performs poorly relative to those of other countries, alternative models of care delivery have been proposed.

Some of the inefficiencies of the current US health care delivery system stem from the growth of new and expensive medical technologies and the fee-for-service payment of physicians. Although physicians aim to provide patient care on the basis of scientific evidence, financial considerations may influence their treatment decisions. Replacement of fee-for-service with capitated payment has been proposed as one way to improve the efficiency of health care delivery. However, changing the physician payment structure by itself may not be enough to achieve the desired outcome. Previous research has shown that although prospective payment has slowed the growth of health care spending at the medical group level, similar results have not been achieved among individual or small practices.

Physician practices therefore may need to be reorganized and integrated across multispecialty groups and hospitals to be responsive to new payment methods. Thus, health care reform efforts also may need to focus on redesigning integrated systems of care.

Integrated delivery systems are a model of health care involving an organized, coordinated, and collaborative network that brings together various physicians to deliver coordinated care and a continuum of services to a given patient population. Integrated delivery systems are clinically and fiscally accountable for the health status and outcomes for the population served, and they have systems to manage and to improve clinical outcomes. Key attributes of successful integrated delivery systems have been suggested. These attributes include: 1) shared values and goals, 2) patient-centeredness and a focus on population health, 3) coordination of care across a continuum of health care services and settings, 4) physician financial incentives that are aligned with patients’ goals, 5) use of evidence-based practices, 6) electronic health records (EHR) that are accessible and shared by all physicians to track patients across a continuum, 7) the right mix of primary care and specialist physicians and appropriate medical equipment to serve the given population, and 8) continuous

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innovation and learning to improve the value of care.

A previous report highlighted that tightly integrated delivery systems with their own health plan may serve as a potential model of high-performing health care systems because the insurance function of these systems allows for greater flexibility and aligned incentives, and helps deliver high-value care. More specifically, Kaiser Permanente (KP), the largest nonprofit integrated delivery system in the US, may serve as a model of a high-performing health care system because of several unique aspects. KP serves various geographic populations in the US, including California, Colorado, District of Columbia, Georgia, Hawaii, Maryland, Oregon, Virginia, and Washington, with more than nine million active members in 2013. Patients in the KP system receive comprehensive, multidisciplinary health care, including all medical and surgical specialties as well as pharmacy, radiology, and laboratory services. In many geographic Regions, KP owns its hospitals; in the other Regions, KP has contracts with preferred hospitals. The population in KP is representative of the states they serve; data indicate that members overall are similar to the general population regarding age, sex, and race/ethnicity, with only slight underrepresentation of those in lower and higher income and education categories. Despite these key features, important questions remain about the “best practices” of integrated delivery systems that achieve superior outcomes. Policymakers are increasingly demanding high-quality research regarding which specific aspects of the integrated delivery model result in superior patient outcomes. For example, there are essential questions regarding how integrated systems are able to coordinate care among different specialties and how the use of information technology and clinical decision support systems are able to support transformational care delivery. Consequently, well-established integrated delivery systems, such as KP, should work to identify the specific system-level factors or confluence of factors that improves such services, as well as access, quality, and other such outcomes in an integrated delivery system. The answer to these fundamental questions may serve as a platform to inform and to guide emerging models of care delivery such as accountable care organizations and patient-centered medical homes.

Through a better understanding for which key systems and processes in integrated delivery systems work and the mechanisms by which they function, this knowledge may be translated and disseminated to the larger US health care delivery system. Comparative health systems research involves a comparison of the different approaches used by systems to organize and deliver health care services for a given population. Thus, comparative health systems is one area of research that may be able to provide valuable insights to policymakers and practitioners regarding which particular aspects of the integrated delivery system model result in improved care delivery and patient outcomes.

In response to policymakers’ growing interest in this area, KP has embarked on a research agenda for comparative health systems. Therefore, the objective of this literature review was to examine the existing published studies on comparative health systems that relate to integrated delivery systems and KP, to obtain a baseline understanding of the state of comparative health systems research that can provide foundational insights and recommendations.
knowledge. We also sought to identify, to quantify, and to classify the literature in this area.

**Methods**

To gain an understanding of the universe of research studies published on comparative health systems, we conducted a literature search on PubMed and the internal KP Publications Library. The KP Publications Library is a unique, full text searchable database of publications authored or coauthored by KP staff, including investigators, clinicians, and administrators, regardless of journal. The database contains 10,000 records describing journal articles, book chapters, books, letters, and commentaries. The library does not include posters, presentations, or published abstracts. In both literature searches, we sought to include existing studies that compared KP as a system or organization with other health care systems or organizations, or across KP facilities internally, in any topic area. We defined comparative health systems research as any study that compared KP as a system with another health system; any study that compared KP’s performance with a state or national benchmark; and any study that compared KP’s innovations in care delivery with old or previous models of care. We also included intra-KP studies that compared a system of care in or between another KP Region or in or between KP facilities. Any such types of these comparisons between different systems or models of care were defined as the systems of comparison. The search was inclusive of all subject areas, ranging from quality to information technology. We looked for explicit comparisons between KP and similar health care systems. Studies that included aggregated data from KP and other health care systems were excluded because there were no direct system-level comparisons that would allow us to disentangle the different health care systems.

In PubMed, the MeSH (Medical Subject Headings) search terms included Kaiser Permanente and comparative health services (n = 258), comparative health systems (n = 34), comparative integrated systems (n = 14), health services benchmarking (n = 10), health system benchmarking (n = 7), and quality benchmarking (n = 7; Table 1). From the 330 publications, we identified 16 studies involving direct system comparisons, which we categorized into KP to Other US, KP to Other International, and KP to KP (interregional or intraregional KP comparisons). The PubMed search yielded 16 relevant articles that met the criteria of comparative health systems research involving KP (Figure 1).

On the basis of PubMed results and additional refinement, we expanded our search to 20 keywords and topics to discover both external and internal comparisons from our KP Publications Library. The KP Publications Library search was used to find additional articles that may have been missed through the PubMed search because of differences in tagged words or keywords, articles that are not indexed, or delays in indexing.

We limited the final results from the KP Publications Library to the following criteria: 1) publication type: journal article only (no editorials, letters, and commentaries); 2) abstract: no publications without an abstract unless published in the last two months; and 3) date: no publications before 1995 because of the likelihood of lesser relevance.

The comprehensive search using the same 20 search terms in the KP Publications Library generated 1271 unique citations (Table 1). After limiting the search set to the previously stated criteria, 1132 citations required closer review. These studies were manually reviewed, and articles that were previously identified from PubMed were removed. We examined the results, first considering the study title and abstract and then reviewing the full text article, if necessary, to make a determination of appropriateness. Our examination of 1117 KP abstracts and full publications yielded 45 more publications relevant to the topic of comparative health systems research. We also identified 4 publications that were not found through our literature search (because they did not have a KP author listed or had no keyword hits from our search sets) and were

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<th>Table 1. Search terms used in review of Kaiser Permanente Publications Library</th>
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Symbols: Asterisk = wildcard search; brackets = field searched; [all fields] = searching the full text of the publication; braces (at end of rows) = Publications Library total number of articles; and quotation marks = phrase search.
Table 2. Studies by systems of comparison

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<th>Author, Year</th>
<th>Systems of comparison</th>
<th>Topical area</th>
<th>Condition</th>
<th>Outcomes</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thorner, 1978</td>
<td>KP to US military health care system</td>
<td>Resource use</td>
<td>NA</td>
<td>Ambulatory care and hospital utilization rates among civilian beneficiaries of the military health care system, members of KP, and noninstitutionalized population</td>
<td>Civilian beneficiaries of the military health care system were generally not found to be taking full advantage of their entitlement to health care.</td>
</tr>
<tr>
<td>Rubenstein, 2002</td>
<td>KP to VA</td>
<td>Quality</td>
<td>MHSA</td>
<td>Team success in developing depression care improvement programs</td>
<td>A high degree of local support and expertise was needed from primary care and mental health clinicians for the local team’s approach to quality improvement. However, the central team approach was more likely to succeed than the local team’s approach when local practice conditions were not optimal.</td>
</tr>
<tr>
<td>Kerr, 2004</td>
<td>KP to VA and other HMO</td>
<td>Quality</td>
<td>Diabetes mellitus</td>
<td>Quality of diabetes mellitus care</td>
<td>Diabetes processes of care and 2 of 3 intermediate outcomes were better for patients in the VA system than for patients in commercial managed care, but both VA and commercial managed care had room for improvement.</td>
</tr>
<tr>
<td>Magid, 2011</td>
<td>KP to VA and US</td>
<td>Quality</td>
<td>CVD</td>
<td>BP control among patients with uncontrolled BP</td>
<td>A multimodal intervention of patient education, home BP monitoring, BP measurement reporting to an interactive voice response system, and clinical pharmacist follow-up achieved greater reductions in BP compared with usual care.</td>
</tr>
<tr>
<td>Fishman, 2004</td>
<td>KP to US</td>
<td>Health system performance; resource use; quality</td>
<td>NA</td>
<td>Cost, quality, and effectiveness of US health care system</td>
<td>There needs to be a revision in how health services research approaches analyses of cost, production, and output, and one must consider alternative notions of final goods. Also, there needs to be a review of the availability and quality of data necessary to conduct this research.</td>
</tr>
<tr>
<td>Kim, 2004</td>
<td>KP to US</td>
<td>Health system performance</td>
<td>Diabetes mellitus</td>
<td>Diabetes mellitus processes of care</td>
<td>Group/network models provided better diabetes processes of care than did independent practice association (IPA) models. This may be caused by the clinical infrastructure available in group models that is not available in IPA models.</td>
</tr>
<tr>
<td>Stiefel, 2008</td>
<td>KP to US</td>
<td>Resource use</td>
<td>NA</td>
<td>Hospital and hospice use for end-of-life care</td>
<td>Geographic variation in hospital use in KP appears to be correlated with variation in the surrounding communities; this suggests that KP resource use may be influenced, at least in part, by broader community practices.</td>
</tr>
<tr>
<td>Horberg, 2011</td>
<td>KP to US</td>
<td>Quality</td>
<td>HIV</td>
<td>Quality performance for patients with HIV</td>
<td>KP’s results compared favorably with those of other organizations.</td>
</tr>
<tr>
<td>Wisdom, 2011</td>
<td>KP to US</td>
<td>Data management</td>
<td>MHSA</td>
<td>Data management capacity at substance abuse treatment programs</td>
<td>An infusion of expertise, training, and funding is needed to improve substance abuse treatment programs’ IT-related systems and data management processes.</td>
</tr>
<tr>
<td>Schroeder, 2012</td>
<td>KP to US</td>
<td>Quality</td>
<td>Diabetes mellitus, CVD</td>
<td>Simultaneous control of diabetes mellitus, hypertension, and hyperlipidemia</td>
<td>Individuals who simultaneously achieve multiple treatment goals may provide insight into self-care strategies for individuals with comorbid health conditions.</td>
</tr>
<tr>
<td>Hazelhurst, 2012</td>
<td>KP to US FQHCs</td>
<td>Quality, HIT</td>
<td>Asthma</td>
<td>Asthma care quality</td>
<td>Automated measures of asthma care quality performed well in the HMO, where practice is more standardized.</td>
</tr>
<tr>
<td>DeCoste, 1997</td>
<td>KP to Manitoba, Canada, and US</td>
<td>Resource use</td>
<td>NA</td>
<td>Ambulatory care visit rates and procedure rates for 3 surgical procedures</td>
<td>For the surgical procedures studied, US rates were higher than those in either KP or Manitoba. US system led to more surgical intervention, and removal of financial barriers led to higher use of primary care services, where more preventive and ameliorative care can occur.</td>
</tr>
<tr>
<td>Smith, 2006</td>
<td>KP to Canada and US</td>
<td>HIT/EHR/ CPOE/CDS/ patient safety</td>
<td>NA</td>
<td>Potentially contraindicated agents in elderly patients</td>
<td>Alerts in an outpatient EHR aimed at decreasing prescribing of medications in elderly persons may be an effective method of reducing prescribing of contraindicated medications.</td>
</tr>
<tr>
<td>Ham, 2003</td>
<td>KP to UK NHS and US Medicare program</td>
<td>Resource use</td>
<td>NA</td>
<td>Hospital utilization of different health systems</td>
<td>NHS can learn from KP’s integrated approach, the focus on chronic diseases, effective management, the emphasis placed on self-care, the role of intermediate care, and the leadership provided by physicians in developing and supporting this model of care.</td>
</tr>
</tbody>
</table>
### Comparative Health Systems Research among Kaiser Permanente and Other Integrated Delivery Systems: A Systematic Literature Review

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<table>
<thead>
<tr>
<th>Study</th>
<th>Comparison</th>
<th>Methodology</th>
<th>Outcomes</th>
</tr>
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</table>
| Prof,
  2006 | KP to UK and US | Resource use; premature infants | Gestational age at discharge among moderately premature infants |
| Towill,
  2006 | KP to UK NHS | Health system performance | Health care supply chain performance |
| Feachem,
  2002 | KP to UK NHS | Resource use; health system performance | Cost and health system performance |
| Séror,
  2002 | KP to UK NHS | HIT | Ideologic differences in health care market infrastructure |
| Frelich,
  2008 | KP to Danish Health Care System | Health system performance | Utilization, quality, and costs of different health systems |
| Strandberg-Larsen,
  2010 | KP to Danish Health Care Service | Clinical integration | Primary care clinicians’ perceptions of clinical integration in two health care systems |
| Schiøtz,
  2011 | KP to Danish Health Care System | Health system performance | Preventable hospitalizations and readmissions for ambulatory-care-sensitive conditions and chronic conditions |
| Schiøtz,
  2012 | KP to Danish Health Care System | Quality | Self-management behaviors among patients with Type 2 diabetes mellitus |
| Paxton,
  2011 | KP to Norway | Registries; quality | Choice of implants, techniques, and outcomes for knee arthroplasty |
| Domurat,
  1999 | Intra-KP comparison | Disease management; HIT/EHR; quality | Laboratory and BP screening rates for patients with diabetes mellitus |
| Horberg,
  1999 | Intra-KP comparison | Care delivery/coordination; health system performance | Antiretroviral therapy adherence for HIV-positive patients |
| Brown,
  2000 | Intra-KP comparison | Disease management | Mortality, change in comorbidity, rate of uptake of preventive measures, use of pharmaceuticals, and hospital utilization for patients with diabetes mellitus |
| Johnston,
  2000 | Intra-KP comparison | Home health; HIT/telemedicine; quality; resource use | Effectiveness of remote video technology in home health care setting |
| Merenich,
  2000 | Intra-KP comparison | Disease management | Lipid screening and treatment rate, patient satisfaction among patients with CVD |

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<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Comparison</th>
<th>Setting</th>
<th>Outcome Measures</th>
<th>Findings/Interpretations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nichols</td>
<td>2000</td>
<td>Intra-KP</td>
<td>Quality</td>
<td>Diabetes mellitus</td>
<td>Busy clinicians with heavy workloads can improve their management of diabetes by identifying patients whose glycemic control could be improved through a change in medication or simple adjustment in dosage.</td>
</tr>
<tr>
<td>Perry</td>
<td>2000</td>
<td>Intra-KP</td>
<td>Quality</td>
<td>Cancer</td>
<td>Several innovations demonstrated the ability to integrate improved care management into evolving service delivery at KP, such as use of call center technologies and redesign of primary care delivery.</td>
</tr>
<tr>
<td>Lorig</td>
<td>2001</td>
<td>Intra-KP</td>
<td>Self-care</td>
<td>Chronic diseases</td>
<td>One year after exposure to a chronic disease self-management program, most patients experienced statistically significant improvements in a variety of health outcomes and had fewer ED visits.</td>
</tr>
<tr>
<td>Thompson</td>
<td>2001</td>
<td>Intra-KP</td>
<td>Quality</td>
<td>NA</td>
<td>Group visit attendees stood out as experiencing the greatest benefits and were especially likely to report avoiding a telephone call or visit to their physician by using a self-care handbook.</td>
</tr>
<tr>
<td>Vollmer</td>
<td>2001</td>
<td>Intra-KP</td>
<td>HIT, medication</td>
<td>Asthma</td>
<td>An HIT-based adherence intervention showed potential for supporting medication adherence in patients with chronic diseases such as asthma.</td>
</tr>
<tr>
<td>Shafer</td>
<td>2002</td>
<td>Intra-KP</td>
<td>Quality; team</td>
<td>Chlamydia infection</td>
<td>Implementation of a clinical practice intervention in a large HMO significantly increased the C. trachomatis screening rates for sexually active adolescent girls during routine checkups.</td>
</tr>
<tr>
<td>Yuan</td>
<td>2003</td>
<td>Intra-KP</td>
<td>Resource use;</td>
<td>NA</td>
<td>Intensive outpatient consultation with a pharmacist targeting high-risk patients would improve survival and decrease hospitalization rates.</td>
</tr>
<tr>
<td>Taylor</td>
<td>2003</td>
<td>Intra-KP</td>
<td>Disease</td>
<td>Diabetes mellitus</td>
<td>A nurse care management program can significantly improve some medical outcomes in patients with complicated diabetes without increasing the number of physician visits.</td>
</tr>
<tr>
<td>Finley</td>
<td>2003</td>
<td>Intra-KP</td>
<td>Care coordination</td>
<td>MHSA</td>
<td>Clinical pharmacists had a favorable effect on multiple aspects of patient care.</td>
</tr>
<tr>
<td>Garrido</td>
<td>2005</td>
<td>Intra-KP</td>
<td>HIT/EHR; quality</td>
<td>NA</td>
<td>Readily available, comprehensive, integrated clinical information reduced use of ambulatory care while maintaining quality and allowed physicians to replace some office visits with telephone contacts.</td>
</tr>
<tr>
<td>Patel</td>
<td>2005</td>
<td>Intra-KP</td>
<td>Interdisciplinary</td>
<td>NA</td>
<td>Implementation of a team assignment system in an ED was associated with reduced time to physician assessment, a reduced percentage of patients who left without being seen, and improved patient satisfaction.</td>
</tr>
<tr>
<td>Lorig</td>
<td>2005</td>
<td>Intra-KP</td>
<td>Self-care</td>
<td>Chronic diseases</td>
<td>Six years after the beginning of the dissemination process, the peer-led chronic disease self-management program was integrated into most of the KP Regions and was being offered to several thousand patients each year.</td>
</tr>
<tr>
<td>Stubbings</td>
<td>2005</td>
<td>Intra-KP</td>
<td>HIT/telepharmacy</td>
<td>NA</td>
<td>Clinical pharmacy call center has used telephonic, electronic, and other means of communication in an effort to reduce costs and improve the quality of care.</td>
</tr>
<tr>
<td>Grypma</td>
<td>2006</td>
<td>Intra-KP</td>
<td>Quality</td>
<td>MHSA</td>
<td>An adapted version of the Improving Mood-Promoting Access to Collaborative Treatment (IMPACT) program implemented at a large HMO achieved similar clinical improvements in depression as the clinical trial despite a lower number of intervention contacts.</td>
</tr>
<tr>
<td>McFarland</td>
<td>2006</td>
<td>Intra-KP</td>
<td>Resource use</td>
<td>MHSA</td>
<td>State Medicaid policies may make it difficult for clients to obtain suitable chemical dependency treatment services.</td>
</tr>
</tbody>
</table>

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### Comparative Health Systems Research among Kaiser Permanente and Other Integrated Delivery Systems: A Systematic Literature Review

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<table>
<thead>
<tr>
<th>Study</th>
<th>Type of Comparison</th>
<th>HIT/EHR Use</th>
<th>Disease Management</th>
<th>CVD</th>
<th>Quality</th>
<th>Effectiveness of Diabetes Mellitus Care Management</th>
<th>Patient Satisfaction and Service Quality of a Call Center Technology</th>
<th>Total Health Care Expenditures after Incident Acute Cardiovascular Event</th>
<th>Validity of Race and Ethnicity Data from Health Plan Administrative Records</th>
<th>Secure Messaging has been Associated with a Decrease in Office Visits, an Increase in Measurable Quality Outcomes (at Least in Primary Care), and Excellent Patient Satisfaction.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palen,23 2006</td>
<td>Intra-KP comparison</td>
<td>HIT/CPOE/ CDS; patient safety</td>
<td>NA</td>
<td>Physician compliance with guidelines for laboratory monitoring at time of therapy initiation</td>
<td>There was no significant difference between the control and intervention group physicians (CPOE reminders) in the overall rate of compliance with ordering the recommended laboratory monitoring for patients prescribed study medications.</td>
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<tr>
<td>Simon,24 2006</td>
<td>Intra-KP comparison</td>
<td>HIT/CDS; patient safety</td>
<td>NA</td>
<td>Rates of dispensing potentially inappropriate medications in older adults</td>
<td>Age-specific alerts sustained the effectiveness of drug-specific alerts to reduce potentially inappropriate prescribing in older people and resulted in a considerably decreased burden of the alerts.</td>
<td></td>
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</tr>
<tr>
<td>Vollmer,25 2006</td>
<td>Intra-KP comparison</td>
<td>HIT; resource use; quality</td>
<td>Asthma</td>
<td>Acute health care utilization and quality of life among asthmatics</td>
<td>This study did not find improved health outcomes between patients who received an automated telephone outreach or usual care.</td>
<td></td>
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</tr>
<tr>
<td>McConnell,26 2006</td>
<td>Intra-KP comparison</td>
<td>Disease management; quality</td>
<td>CVD</td>
<td>Hypertension control among patients with CVD</td>
<td>A pharmacist-managed, physician-supervised population management approach in patients with coronary artery disease significantly improved BP control.</td>
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</tr>
<tr>
<td>Hornbrook,27 2007</td>
<td>Intra-KP comparison</td>
<td>HIT</td>
<td>Pregnancy</td>
<td>Detection of pregnancy episodes and maternal morbidities using automated data</td>
<td>A pregnancy episode grouper algorithm takes advantage of databases readily available in IDSs and has important applications for health system management and clinical care.</td>
<td></td>
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</tr>
<tr>
<td>Humphries,28 2007</td>
<td>Intra-KP comparison</td>
<td>HIT/CDS; patient safety</td>
<td>NA</td>
<td>Rate of codispensing of critically interacting drug combinations</td>
<td>Employment of an intervention system that limits electronic alerts regarding drug interactions to those deemed critical but that also requires pharmacist intervention and collaboration with the prescriber decreased the number of critical drug interactions dispensed.</td>
<td></td>
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</tr>
<tr>
<td>McGaw,29 2007</td>
<td>Intra-KP comparison</td>
<td>Care coordination; patient safety</td>
<td>Chronic diseases</td>
<td>Reductions in medical errors, follow-up with care plans</td>
<td>Identification of unintended medication discrepancies and potential drug-related problems and increased follow-up during care transitions can improve patient safety and quality of care while saving health care resources.</td>
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</tr>
<tr>
<td>Merenich,30 2007</td>
<td>Intra-KP comparison</td>
<td>Disease management; quality</td>
<td>CVD</td>
<td>All-cause mortality in patients with CVD</td>
<td>Compared with those not enrolled in the comprehensive cardiac care (CCC) program, patients enrolled in the early CCC program were 89% less likely to die.</td>
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</tr>
<tr>
<td>Neuwirth,31 2007</td>
<td>Intra-KP comparison</td>
<td>HIT, quality, resource use</td>
<td>NA</td>
<td>Impact of panel management on patients, physicians, and staff</td>
<td>Spread of panel management should be informed by lessons and findings from early adopters and should include continued monitoring of the impact of this rapidly developing approach on quality, patient satisfaction, primary care sustainability, and cost.</td>
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<tr>
<td>Raebel,32 2007</td>
<td>Intra-KP comparison</td>
<td>HIT/CDS; patient safety</td>
<td>NA</td>
<td>Proportion of ambulatory elderly patients prescribed potentially inappropriate medications</td>
<td>Coupling data available from information systems with the knowledge and skills of physicians and pharmacists can improve safety of prescribing for patients aged 65 years and older.</td>
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</tr>
<tr>
<td>Graetz,33 2009</td>
<td>Intra-KP comparison</td>
<td>Care coordination; HIT/EHR</td>
<td>NA</td>
<td>Clinicians' perceptions of care coordination</td>
<td>EHR use is associated with aspects of care coordination involving information transfer and communication of treatment goals.</td>
<td></td>
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</tr>
<tr>
<td>Schmittdiel,34 2009</td>
<td>Intra-KP comparison</td>
<td>Quality</td>
<td>Diabetes mellitus</td>
<td>Effectiveness of diabetes mellitus care management</td>
<td>In a population with improving control of risk factors, patients entering diabetes care management experienced slightly greater improvement.</td>
<td></td>
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</tr>
<tr>
<td>Sterling,35 2009</td>
<td>Intra-KP comparison</td>
<td>Quality; care delivery</td>
<td>MHS</td>
<td>Chemical dependency and mental health treatment outcomes among adolescents</td>
<td>A chemical dependency treatment episode resulting in good 1-year chemical dependency outcomes may contribute significantly to both chemical dependency and mental health outcomes 3 years later.</td>
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</tr>
<tr>
<td>Bowman,36 2010</td>
<td>Intra-KP comparison</td>
<td>HIT/EHR; quality</td>
<td>NA</td>
<td>Patient satisfaction and service quality of a call center technology</td>
<td>DirectConnect system has resulted in statistically significant improvement in key service quality measures.</td>
<td></td>
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</tr>
<tr>
<td>Delate,37 2010</td>
<td>Intra-KP comparison</td>
<td>Disease management; resource use</td>
<td>CVD</td>
<td>Total health care expenditures after incident acute cardiovascular event</td>
<td>Comprehensive and aggressive implementation of secondary cardiac prevention strategies and close monitoring and follow-up of patients with coronary artery disease provided by the Collaborative Cardiac Care Service were associated with reduced health care expenditures.</td>
<td></td>
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</tr>
<tr>
<td>Smith,38 2010</td>
<td>Intra-KP comparison</td>
<td>Resource use; disparities; HIT/EHR</td>
<td>NA</td>
<td>Validity of race and ethnicity data from Health Plan administrative records</td>
<td>Quality of racial information obtained from administrative records may benefit from additional supplementation by birth certificate data.</td>
<td></td>
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</tr>
<tr>
<td>Baer,39 2011</td>
<td>Intra-KP comparison</td>
<td>HIT/EHR</td>
<td>NA</td>
<td>Office visit utilization, quality of care, and patient satisfaction with secure message</td>
<td>Secure messaging has been associated with a decrease in office visits, an increase in measurable quality outcomes (at least in primary care), and excellent patient satisfaction.</td>
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</tbody>
</table>
provided to us by KP authors or identified through press releases because they were found to be relevant to the overall topic. We reviewed the final set of articles for agreement on inclusion.

**Results**

In total, the literature search from the 2 comprehensive databases, in addition to publications identified outside our systematic review, resulted in 65 publications for inclusion in this analysis. Table 2 summarizes the included studies of comparative health systems. For each of the studies reviewed, we evaluated the system of comparison, topical area, and condition type. The topical area was the areas of comparison, the condition type was the disease or diseases of study, and the outcomes were the system outputs. The following topical areas were examined: resource use (ie, cost of care, utilization, length of stay); quality (ie, quality-improvement programs, quality performance, processes of care, patient outcomes of care, patient satisfaction); health information technology (ie, management of health information across computer systems); EHR (ie, electronic health information about patients); clinical decision support (ie, system that assists physicians with decision making related to patients); computerized physician order entry (ie, electronic entry of physician treatment orders); telemedicine (ie, telecommunications systems that provide health care across distances); health system performance (ie, health system delivery of care); self-care (ie, patient self-management of condition); disease management (ie, interventions to help patients cope with a condition); pharmacy consultation (ie, pharmacist counseling of patients regarding their medications); care delivery/care coordination (ie, provision and coordination of health care services); registries (ie, collection of data on patients with a specific condition); clinical integration (ie, integration of clinical information and health care services from different entities); patient safety (ie, prevention of medical errors); medication adherence (ie, patients taking medications as prescribed); and team performance (ie, team functioning).

Of all studies published by or about KP, only 4% of articles were identified as being comparative health systems research. The comparative health systems studies that were reviewed tended to focus mostly on quality of care (n = 30) and health information technology/EHR/clinical decision support/telemedicine (n = 18). Diabetes mellitus was also a common focus of the studies reviewed (n = 11).

Most studies identified in the literature search that met the criteria of comparative health systems research were intra-KP studies (interregional or intraregional that were in or between different KP Regions; n = 42). These studies either compared one KP Region with another for a particular care topic or compared a system of care in a KP Region that had heterogeneous processes among its different medical centers. Fewer studies (n = 15) were identified that compared KP with another US health care system (ie, fee-for-service, health maintenance organization, and/or Veterans Affairs). In addition, there were 12 studies that compared KP with international health care systems. Among the different topical areas that the comparative health systems studies covered, the most frequently studied topic was quality of care (n = 30) and articles that related to health information technology/EHR/clinical decision support/telemedicine (n = 18). Other
commonly studied topics included resource use (cost/utilization; n = 16),¹ health systems performance (n = 7),¹⁴,50,61,70,72,73,76 and disease management (n = 7).¹⁴,15,17,25,30,46,47

On the basis of disease or type of condition, diabetes mellitus was the most frequently studied (n = 11).⁴ Other conditions that were commonly studied included cardiovascular disease (n = 7),¹⁰,17,30,46,47,66,69 mental health and substance abuse (n = 6),²⁰,30,52,45,57,67 and asthma/chronic obstructive pulmonary disease (n = 4).¹⁰,22,35,68

Several themes emerged from the literature as possible factors that may contribute to improved care delivery in integrated delivery systems. Seven studies suggested clinical integration as a possible reason for better performance.¹⁰,¹⁷,50,61,62,70,74

The use of technology (ie, electronic alerts, health information technology, EHR, secure messaging, remote video technology) was another common attribute cited across studies.⁹ Last, a comprehensive approach to care delivery (ie, multidisciplinary care teams, comprehensive care management, interdisciplinary treatment, multimodal interventions) and self-management were other themes highlighted as possibly improving patient outcomes.¹

**Clinical integration, the use of technology, comprehensive care, and patient self-management were consistent themes identified as being associated with improved care delivery.**

**Discussion**

In our review of the literature on comparative health systems research involving one or more KP entities, we found that most studies to date have focused primarily on intra-KP comparisons. Fewer studies compared KP with other US health care systems or international health care systems. One possible reason for this gap in the literature could be the lack of recognition of an integrated delivery system’s ability to deliver high-quality services, the paucity of comparative performance data, and the unwillingness of organizations to share performance data. Furthermore, because most of the US health care system operates under a fee-for-service model, there are a limited number of other similar integrated delivery systems with a health plan component that may serve as suitable comparisons to KP. As a result, there remains much room for growth and additional research in comparative health systems that compare the KP model of care with other US health care systems, including more traditional fee-for-service care models, academic medical centers, Veterans Affairs medical centers, other integrated delivery systems (ie, Intermountain Healthcare based in Salt Lake City, UT; Geisinger Health System headquartered in Danville, PA; Group Health in Seattle, WA), the safety net (federally qualified health centers, community health centers, and free clinics), and international health care systems. Additional research in this area could examine which systems or processes work in improving care delivery and how different systems are able to achieve these outcomes. Improved performance is evidence that key processes contribute to better care. Further investigations into the types of best practices would lead to a more comprehensive understanding of which models or systems of care are most effective.

We also found that the comparative health systems studies we reviewed tended to focus on quality of care and health information technology/EHR/clinical decision support/telemedicine. In addition, some key attributes of integrated delivery systems emerged from the literature as possibly contributing to a higher performance. Clinical integration, the use of technology, comprehensive care, and patient self-management were consistent themes identified as being associated with improved care delivery. These have been areas of emphasis in practice and research in KP, and thus such findings are not surprising. The EHR and population health management programs are considered essential elements of an integrated approach to care that promotes a consistent and reliable care experience.⁷⁹

However, additional research that examines other factors hypothesized to lead to a higher health system performance, such as physician financial incentives, patient-centeredness, and continuous innovation, should be further investigated. Our finding by type of condition revealed that diabetes mellitus and cardiovascular disease were the most commonly studied, likely because these are common and prevalent conditions and areas of research emphasis. Because most of the comparative health systems studies tended to focus on a limited number of condition types, studies that examine other common types of conditions, such as cancer, gastrointestinal diseases, and joint diseases, would further contribute to the body of literature.

There are a few limitations to this systematic review. First, our review of the literature from the KP Publications Library was restricted to studies published after 1995 until the most currently available at the time of the literature search. There may have been additional studies that were published before our study period or after our literature search was conducted. Second, we focused only on studies of comparative health systems that compared KP with other systems of care. There may be other comparative health systems studies that did not explicitly include KP as a comparator. We excluded studies that aggregated KP data with other health systems. Despite our best efforts, we acknowledge that we may have missed some articles in our literature search. However, we also asked other researchers at KP, as part of our systematic review, to ensure a complete and comprehensive literature search. Furthermore, this literature review did not attempt to examine or compare the outcomes of the comparative health systems studies. Rather, we sought only to identify, to classify, and to quantify the studies to help guide future research among large integrated delivery systems.

**Conclusion**

We found that studies published by or about KP rarely included comparative health systems research. Given the changing health care landscape and movement toward integrated care, additional empirical studies that compare the specific factors of the integrated delivery system model with other systems of care (or in KP if there is heterogeneity of such care) may identify the system-level factors that result in more efficient care delivery. Additionally, more work must be done...
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in partnership with similar health care organizations to demonstrate the benefits of integration toward quality, affordability, accessibility, and effectiveness. Such investigations could seek to understand how systems work to improve clinical outcomes and examine what are the key characteristics of successful systems. By developing the capacity to conduct and communicate the outcomes of comparative health systems research, the health care industry will be able to disseminate and translate the best practices that are able to address issues of quality, affordability, access, and effectiveness. It is important for all to gain organizational commitment to address the research questions that compare each different system's performance with rigor and transparency.

The knowledge gained from comparative health systems research will enable the dissemination and translation of best practices that can be adopted by the larger US health care delivery system and ensure high-quality, effective care for all.

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References

A Superior Form of Service

Group medicine is a superior form of service. The best way to make full use of the present technology of medicine is to organize medical groups, teams that will practice in health centers. These must be close to the people, in industrial centers, residential neighborhoods, or farms.

— Henry E Sigerist, MD, 1891-1957, medical historian and social visionary
CASE STUDY

Special Medical Conditions Associated with Catatonia in the Internal Medicine Setting: Hyponatremia-Inducing Psychosis and Subsequent Catatonia

Andrei A Novac, MD; Daniela Bota, MD, PhD; Joanne Witkowski, MD; Jorge Lipiz, MD; Robert G Bota, MD, MSG

Abstract

Diagnosis and treatment of catatonia in the psychiatry consultation service is not infrequent. Usually, the patient either presents to the Emergency Department or develops catatonia on the medical floor. This condition manifests with significant behavioral changes (from mildly decreased speech output to complete mutism) that interfere with the ability to communicate. After structural brain disorders are excluded, one of the diagnoses that always should be considered is catatonia. However, the causes of catatonia are numerous, ranging from psychiatric causes to a plethora of medical illnesses. Therefore, it is not surprising that there are many proposed underlying mechanisms of catatonia and that controversy persists about the etiology of specific cases.

There are only 6 reports of hyponatremia-induced catatonia and psychosis in the literature. Here, we present the case of a 30-year-old woman with catatonia and psychosis induced by hyponatremia, and we use this report to exemplify the multitude of biologic causes of catatonia and to propose a new way to look at the neuroanatomical basis of processing, particularly the vertical processing systems we believe are involved in catatonia.

Introduction

Catatonia is a frequently diagnosed disorder in psychiatry. The following scenarios are the most common: the patient arrives at the Emergency Department with behavioral changes that interfere with communication, or on the medical floor the patient develops significant behavioral changes that interfere with communication. The main features of catatonia are the same, regardless of the cause, and the clinical picture is dominated by three or more of the following symptoms: stupor, cataplexy, waxy flexibility, negativism, mutism, posturing, mannerism, stereotypy, agitation, grimacing, echolalia, and echopraxia.

The differential diagnostic should include illnesses that mimic catatonia, such as akinetic Parkinson disease, malignant hyperthermia, stiff-person syndrome, conversion disorder, selective mutism (selective mutism is a social anxiety disorder in which people who can speak normally in some situations cannot speak in other situations—especially in performance scenarios), locked-in syndrome, and other hypokinetic and hyperkinetic states. Selective mutism, as seen in manifestations of personality disorders, malingering disorder, or factitious disorder, does not share the other features of catatonia and is relatively easily excluded.

After the patient is seen by the neurology and the psychiatry service and structural brain damage (such as stroke, tumor, or abscess) in the dominant hemisphere as well as severe dementia or delirium are excluded, the next line of differential diagnosis will include other medical conditions, including metabolic, neurologic, and substance-induced disorders. According to a review of 261 cases of catatonia, mental illness contributed to only up to 25% of those cases.

Historically, catatonia is related to schizophrenia and other mental illnesses, such as severe depression, bipolar disorder, and psychosis. However, the causes of catatonia are numerous, ranging from psychiatric to medical illnesses. Therefore, it is not surprising that there are several proposed underlying mechanisms of catatonia—including top-down modulation, cholinergic and serotoninergic rebound hyperactivity, sudden and massive blockade of dopamine, and hyperactivity of glutamate.

One theory suggests that catatonia involves a “top-down modulation” in self-related processing of basal ganglia resulting from a deficiency of gamma aminobutyric acid (GABA). Top-down modulation is described as a bidirectional process that determines our ability to focus on stimuli relevant to our needs and to ignore background information. Therefore, successful interplay between the enhancement and suppression of the neuronal activity generates the contrast necessary for successful representation of relevant information. Benzodiazepines bind to a specific site on a GABA receptor, making it more efficient. As a result there is an increase in chloride ions that leads to an increase in polarization of postsynaptic neurons, therefore making them less excitable and more able to filter the relevant stimuli. One report states that malignant catatonia can occur in the setting of benzodiazepine withdrawal. Other research suggests that hyperactivity of glutamate can be another underlying chemical dysfunction, especially at the decrease in N-methyl D-aspartate receptor.

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Catatonia can also happen in clozapine withdrawal. The proposed mechanism for clozapine-withdrawal-induced catatonia very likely happens owing to cholinergic and serotoninergic rebound hyperactivity.3,10 Significant dopamine blockade can also cause catatonia. England et al11 reported that first-generation antipsychotic medications caused worsening catatonia symptoms. However, second-generation antipsychotic medication on several occasions did treat the symptoms of catatonia.12 In addition, there are many reports that strongly suggest that stimulant medication can treat catatonia symptoms in patients with bipolar disorder13 or depression.14 Imaging results are different in various stages of catatonia. For example, in a patient with very-late-onset schizophrenia, hypoperfusion in the thalamus and striatum and hyperperfusion in the left lateral frontal cortex and left temporal cortex during the catatonia was reported. This scan was compared with the scan after the treatment.15 In another report,16 the imaging results of a patient with schizoaffective disorder in the acute phase of catatonia showed dramatic decrease in perfusion in the left parietal and motor cortex that reversed to normal after resolution of the episode. In addition, in cases of chronic catatonia, functional imaging identified abnormalities that happen bilaterally in the thalamus and frontal lobes.17 It is always interesting to look at the evolutionary perspective—is this part of a survival mechanism, when perceived impending doom leads to catatonia? And do the mechanisms presented above overlap with those circuits leading to what we morphologically assess as catatonia?18

Case Presentation
Ms A was a 30-year-old single woman living by herself and working as a factory operator for clean room production. She was born in the Philippines, came to the US as an infant, and was raised in San Diego, CA. She had an intact family and was the second of three children. Her father was in the military and was strict and a disciplinarian. He was occasionally physically abusive with her and her siblings. The patient was very close to her siblings and her mother.

In grammar school, she was a very good student. As a teen, she became more rebellious. She said the only way she was able to finish. She dated, and her last relationship ended abruptly six months before she came in to the Emergency Department. Ms A was depressed as a result of that loss and received therapy through church counseling. Her depression improved without medications.

Her medical history was significant for papillary thyroid cancer, which was diagnosed 14 years before this incident and was successfully treated but had recurred recently. A few months after her recurrence of cancer, she received iodine-131 therapy for metastatic papillary thyroid cancer, and one day later she became confused and was found to have severe hyponatremia (Figure 1). At the same time she was taking the following medications: levothyroxine 125 mcg every morning, enoxaparin 40 mg subcutaneous every 24 hours, atenolol 50 mg daily, and docusate sodium 100 mg twice a day. On the second day of hospitalization, her confusion worsened, and the next day she developed auditory hallucinations, hearing Britney Spears sing. The patient was dancing: taking small steps, rotating 180 degrees, and repeating this about a dozen times. Then, she would touch the perfusion pole, approximately in the same place, and would repeat the sequence over a period of several hours. She would answer with one or two words to selective questions. When asked to hold a paper, she did and continued to hold it for the next 10 minutes. The psychiatrist ordered clonazepam 0.5 mg orally three times a day and risperidone 0.5 mg orally three times a day.

The following day she was able to sit in a chair, stereotypic activity resolved, and she was able to recognize the psychiatrist. She answered most questions with complete sentences. When asked what happened the day before, she replied, “I had a mild concussion … which is severe … because it is a concussion.” In the following days she recovered entirely. Medications were stopped 3 months after her full recovery. There have been no similar psychiatric symptoms 18 months after her recovery.

Discussion
There have been some reports of hyponatremia following radio-contrast iodine therapy.15 The etiology is thought to be caused by a low-iodine diet and withdrawal of thyroxine therapy, which leads to a hypothyroid state.20,21 In this case, the iodine-131 protocol was followed, and she had no other changes in her medications or diet shortly before admission. In the absence of other identified confounding factors, we are suggesting that hyponatremia was caused by the radio-contrast iodine therapy.

Hyponatremia is defined as a decrease in serum sodium concentration below 135 mmol/L, and it can occur with high, normal, or low plasma tonicity.22 In hypervolemic hyponatremia, the body has too much water; this is generally caused by kidney, heart, or liver failure. Euvolemic hyponatremia (normovolemic state) is commonly caused by chronic health conditions including cancer (as in this case) or certain medications; it is often seen in syndrome of inappropriate antidiuretic hormone but also with primary polydipsia and low dietary solute intake. In hypovolemic hyponatremia, there is too little water; this can happen in certain
Case Study

Catatonia is a clinical presentation that is similar regardless of the precipitating or causing factors. When a clinical presentation is deemed a catatonic symptom and resolved the emerged psychosis over the next eight days.

Conclusion

Catatonia is a condition frequently identified in medical settings. It is often induced by organic etiopathies. Even though the symptoms are not specific, the treatment for catatonia is considered to be effective. The authors suggest that the observed abnormalities in catatonia are due to a disturbed vertical processing system that involves the thalamus and the frontal lobe. This is supported by the evidence that the observed abnormalities in catatonia are due to a disturbed vertical processing system that involves the thalamus and the frontal lobe.

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Dr. Daniela Bota is on the Advisory Board of Genentech; is on the Advisory Board of Hauzer; and is a Consultant to Novo Nordisk. The author(s) have no other potential conflict of interest to disclose.
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Best Clinical Practices for Male Adult Survivors of Childhood Sexual Abuse: “Do No Harm”

Les Gallo-Silver, MSW, LCSW-R; Christopher M Anderson; Jaime Romo, EdD

Abstract
The health care literature describes treatment challenges and recommended alterations in practice procedures for female survivors of childhood sexual abuse, a subtype of adverse childhood experiences. Currently, there are no concomitant recommendations for best clinical practices for male survivors of childhood sexual abuse or other adverse clinical experiences. Anecdotal information suggests ways physicians can address the needs of adult male survivors of childhood sexual abuse by changes in communication, locus of control, and consent/permission before and during physical examinations and procedures. The intent of this article is to act as a catalyst for improved patient care and more research focused on the identification and optimal responses to the needs of men with adverse childhood experiences in the health care setting.

Introduction
One in 6 men are survivors of childhood sexual abuse, according to the literature.13 The legal, mental health, and research definitions of childhood sexual abuse are not the same. This article uses the legal definitions of childhood sexual abuse that includes vaginal, anal, and oral penetration; child prostitution; participation in pornography; repeated and purposeful exposure to adult sexual acts including viewing pornography; and excessive adult nudity and gratuitous showing of genitals to children.9 In the US, 1 in 71 men (1.4%) reports having been raped, with 27.8% of these men indicating their first experience of rape by age 10 years or younger.5

On the basis of 2010 US Census figures for the male population (n = 151,781,326), there could be more than 24 million male survivors of childhood sexual abuse in the US.6 The number of potentially affected men indicates a need to educate physicians on best clinical practices for this at-risk population. Extensive research indicates that a history of childhood sexual abuse can have a major, long-term negative impact on the survivor’s health, well-being, and life expectancy.7

Kaiser Permanente Medical Services and the Centers for Disease Control and Prevention in Atlanta, GA, sponsored the Adverse Childhood Experiences (ACEs) Study, which assessed a large population of adult survivors from among 17,337 health maintenance organization members receiving health care services. This study identified a sample of 2310 women and 127% men who met the criteria for self-acknowledged physical childhood sexual abuse involving physical contact, and it used a multivariate logistic regression analysis to predict what would or would not occur to the men and women in the sample.7 In addition, the researchers found that the presence of 1 type of child abuse made the potential for other types of child abuse more likely. The accumulation of abuse resulted in extraordinary increases in the risk factors to attempt suicide compared with those without any child abuse experiences, and an increased risk of alcoholism and illicit drug use as well as marital and family problems. The study demonstrated that the psychological, social, and behavioral outcomes of ACEs were identical for men and women.

Multiple studies of ACEs indicate the interplay between mental health and medical health. The psychological impact of an ACE may result in behaviors that diminish the overall health, exacerbate stress-sensitive conditions, and diminish a person’s willingness to seek timely treatment for medical problems.8-10

Even though this research4-10 indicates that the extent and impact of trauma for female and male survivors of childhood sexual abuse are the same, there continues to be a gender gap in the health care literature that focuses on the care of the male survivor. The literature in breast cancer and in obstetrics and gynecology addresses the issues of providing health care services to a sexually abused female patient. Physicians in these specialties perform genital examinations and related invasive procedures. The recommendations for physicians in these studies indicate the need to slow down the examination process to enable more communication with the patient as well as asking the patient for permission to proceed with the examination.11-14 Medical internists and urologists examine men in a manner proximate to a gynecologist’s examination of women. Yet, no recommendations exist to address the issue of childhood sexual abuse and its potential impact on adult male patients.

Health Issues Affecting Adult Survivors of Childhood Sexual Abuse
Health care clinicians have identified that childhood sexual abuse raises the risk of a number of medical conditions and illnesses sometimes labeled “diseases of trauma.”15-18 These health problems, studied in both sexes, include asthma, chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, migraines, and chronic pain, among others.4,15,16,19

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Therefore, physicians in numerous specialties are likely to have patients with a history of sexual abuse. Male survivors of all forms of severe childhood psychological, emotional, or physical abuse resist disclosure of physical and psychological symptoms. In addition, men are more reluctant to report sexual abuse than are female survivors. A contributing factor to nondisclosure may be that men knew the abuser before the abuse, as suggested by literature reporting that the child usually knows the abuser a priori. In these cases, the abuser is a parent, sibling, other family member, family friend, coach, teacher, clergy, or other familiar person. This increases feelings of shame and betrayal. Adherence to the guidelines we propose when interacting with male patients with histories of trauma can be a powerful tool for helping deliver more beneficial health care to all men.

**Triggers and Triggering**

Research has shown that although only a small fraction of physicians routinely inquire about historical traumatic incidents, most patients report that they would actually favor such inquiries. Although it is beyond the scope of this article to address the complexity of posttraumatic stress disorder, four symptom groups are conceptualized: reexperiencing the trauma, avoiding situations that remind one of the trauma, alteration of thoughts and mood stability, and increased sensitivity to stimuli/increased reactivity to stimuli. For survivors of sexual abuse, feelings of powerlessness can be pivotal. The power differential between the physician and patient, added to the anxiety and fear a person may have about one’s medical condition and symptoms, can render the health care environment particularly stressful to a person who feels emotionally and physically vulnerable in most environments.

Volunteers from two peer support organizations (MaleSurvivor and Males for Trauma Recovery) provided vignettes of their distressing experiences receiving health care services. The men in these vignettes found certain aspects of their medical care “triggering,” which is an aspect of the increased sensitivity to stimuli and increased reactivity to stimuli. A trigger is any sound, word, smell, sight, taste, physical or emotional feeling, and/or other stimulus that evokes some aspect of a previous trauma, in this case childhood sexual abuse. Because of the obvious intimate nature of medical care, any number of triggers exists, among them the request to undress, physical contact, and positioning the patient’s body. As the literature indicates and the following first four vignettes describe, male survivors’ issues of trust, expectation of betrayal, and negative associations to touch may result in the reactivation of the trauma with potentially harmful effects.

Communication privacy management theory developed a way of understanding how people evaluate the amount and type of privacy they need or want in interpersonal relationships and the ramifications of decision making about disclosure. This theory suggests that when the patient discloses a history of sexual abuse to the physician, the patient may initially feel less comfortable with the physician. This then renders the physician’s response to the information as essential to establishing an optimal physician-patient relationship.

**Vignette 1**

“With my last heart attack, I almost did not call 911 because I was so afraid they would insert an IV [intravenous catheter] into my groin. I had told my cardiologist of my problem. When I was...”

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**Recommendations for Best Clinical Practices with Male Survivors of Childhood Sexual Abuse and Adverse Childhood Experiences**

**Communication cluster**

1. As part of history taking, ask about adverse childhood experiences of physical and/or sexual abuse, and family violence.
2. Listen to the patient and stop doing any other nonemergency activity.
3. Ask your patient about concerns and preferences in the biologic sex of his physicians. If there are gender concerns, allow the patient to discuss them.

**Control cluster**

4. If your patient indicates he is fearful, ask your patient about how to increase his feelings of safety.
5. For invasive procedures, ensure your patient understands informed consent and that he can change his mind at any point before sedation or anesthesia.
6. Help your patient anticipate the stressors of next steps before you order further tests or procedures.
7. Review procedures with your patient that involve undressing and touching.

**Permission cluster**

8. Inform your patient before touching and explain the specific purpose of touching.
9. Inform your patient at the beginning of the examination that you will request body positioning before making that request.
10. Take a “sounding” from your patient during invasive examination procedures (“How are you doing? Do you need me to...?”).
on the table in the operating room with IV Valium [diazepam] and morphine, I still, somehow deep in my brain, realized that there was a needle stuck in my groin (for heart catheterization and implanting a stent). I started flailing about in a full-blown panic attack. The doctor called for a crash team and bad people held me down while they administered restraints and got an anesthetist to put me completely under.

Vignette 2

"Reluctantly I agreed to go to a gastroenterologist for a colonoscopy recommended by my internist because of blood in my stool. I had conscious sedation for the procedure. I told the doctor that I am a survivor of incest. During the procedure, I woke up feeling the scope inside my body and someone holding the cheeks of my behind open. I called out to the doctor that I was awake. I heard him tell the anesthesiologist to give me more sedation. Once I was in recovery, I knew what had happened, but the doctor did not mention it and acted as if nothing happened. Just like my dad after he would rape me, it was not mentioned, as if it never happened."

Vignette 3

"My internal medicine doctor referred me to a sleep study, and I knew it would bring up issues of my sexual abuse. The abuse frequently happened at night once my parents had fallen asleep. The thought of someone watching me sleep brought up a little apprehension, yet the thought of possibly dying in my sleep (because of obstructive sleep apnea) overrode my anxiety, at least in the beginning of this medical procedure. I was lying on the bed, when the nurse put the instrument that measures the breath through the nostrils, my understanding of the procedure and all the coping techniques I had went out the window. The instrument placed in my nostrils triggered my rape response. It was as if the perpetrator was there placing his hands over my mouth and nose all over again.

"When I left the facility I was holding back the tears the best I could for as far through the building as I could. I felt like vomiting, but nothing came out. I went home and just blanked out for a while, then fell asleep. The office never called my primary doctor to explain what happened."

Vignette 4

"I went to a urologist due to prostate symptoms. I was not able to find a woman urologist that would see adult male patients. I told the urologist about the sexual abuse when I was a kid, but he seemed not to get it. He told me to "drop 'em" (meaning pull down my pants) when he wanted to examine me. When he did the digital rectal examination, I winced due to the discomfort, and he joked: "And I didn't even buy you a nice dinner."

In contrast to these four vignettes, the following two vignettes demonstrate more effective physician responses to a patient’s disclosure of a history of childhood sexual abuse.

Vignette 5

"I passed out in the street and cut my face up when I hit the pavement. I woke up in the emergency room, and I was very scared. The thorough examination included a rectal exam. I began to shiver; I guess I was nervous, and I refused the examination. The ER [emergency room] doctor explained that he needed to see if I was bleeding and if that was why I passed out. Crying, I told him that my brother forced me to have anal intercourse when I was a kid. He was really cool. He said it was my choice to be examined. He told me if I agreed I would feel some pressure but he would be very brief. So I agreed. After, he asked me if I was okay and if I wanted to talk to a social worker."

Vignette 6

"I had trouble swallowing and I was losing lots of weight. My regular doctor told me I needed to have a ‘scope’ [endoscopic examination] and sent me to another doctor for it. The new doctor told me what the scope was all about, and I freaked. I told him no way is anything going in my mouth and down my throat. He asked me if I had this test before or some other similar examination that upset me. I thought a moment and I said what the hell. I told [him] when I was nine, my hockey coach would get me drunk on beer and then I had to perform oral sex on him! The doctor looked shocked and sad. He told me I really needed this scope and he understood why I was upset about it. I knew he was right so I agreed to do it. The day of the scope, the doctor was very kind to me. He talked to me a lot about the scope and what he would be doing while I was sedated."

Communication privacy management theory indicates that disclosure of private information, such as a history of sexual abuse or other ACEs, relies on privacy rules. Privacy rules focus on the issue of under what conditions disclosure occurs, such as the pluses or minuses of sharing private information in a specific situation or context. The men in these vignettes decided to disclose, which then altered the relationship with the physician. We suggest that the decision to disclose by a male survivor of childhood sexual abuse relates to the “triggering” discomfort/distress caused by the increased sensitivity/reactivity to stimuli. The success of the changed relationship requires an empathic physician response that recognizes the importance of the shared information for the patient and the patient’s distress. The physicians in Vignettes 1 through 4 responded without empathy. The resulting physician-patient relationship was unsuccessful in that the patients reported a negative experience. The physicians in Vignettes 5 and 6 responded empathically. The resulting physician-patient relationship was successful in that the patients reported a positive experience. These six vignettes are neither representative nor an objective sample. Therefore, one cannot generalize from anecdotal information nor prove a cause-effect relationship. Yet, if physicians ignore, minimize, or deny the psychological debris of childhood sexual abuse for male survivors, they can inadvertently reinforce a survivor’s unwillingness to seek appropriate help, comfort, or support. In this way, medical care risks being a reenactment of the sexual abuse that was characterized by similar abusers of power. The physicians who recognized their patients’ distress and responded in empathic ways did not reinforce or reenact the patients’ abuse experiences.
Best Clinical Practices for Male Adult Survivors of Childhood Sexual Abuse: “Do No Harm”

**Recommendations**

We have identified ten recommendations for best clinical practice in providing health care to male survivors of childhood sexual abuse (see Sidebar: Recommendations for Best Clinical Practices with Male Survivors of Childhood Sexual Abuse and Adverse Childhood Experiences). These recommendations cluster around issues of communication, control, and permission. The communications cluster focuses on asking about the man’s sexual abuse history and, if one is present, the interpersonal aspects of processing the information as part of physician-patient relationship building. Part of the control cluster focuses on integrating the process of anticipatation of potentially triggering aspects of a medical examination, tests, and treatments. The permission cluster focuses on the interpersonal interchange that needs to take place before intrusive and intimate aspects of medical care begin. The gradual progression of a physical examination, which includes talking the patient through the process, is a way of pacing the examination at the speed the patient is most comfortable.

Communication between physician and patient is a crucial foundation of good medical care and cannot be limited to the physician asking questions of the patient and recording the answers. The typical busy medical practice poses a challenge to optimal communication. In addition, the electronic medical record can make it easy for a physician to gaze at the computer screen or the keyboard rather than actually face and interact with the patient. Most important is the physician understanding how to respond to the disclosure of a history of childhood sexual abuse empathically. The physician’s empathic response enhances the relationship with the patient who has taken the risk of disclosure. This requires eye contact, not introducing another question, and not changing the subject but presenting concern and a willingness to learn more if the patient wants to continue to share (see Sidebar: Empathic Communication Techniques with Men Disclosing Histories of Childhood Sexual Abuse and Adverse Childhood Experiences). Asking a follow-up question is not an empathic response to disclosure; rather, it prevents the patient from sharing important information of how to proceed with his care. Following an empathic response to the disclosure of child sexual abuse, it tends to comfort the patient to ask how his experience of childhood sexual abuse affects him now.

The locus of control in the health care of the male survivor needs to be with and not the physician. It is common, even in this era of consumer-oriented medicine, for a patient to be overwhelmed or intimidated during interaction with physicians. For some patients, physicians are an authority figure, and it is important for physicians to keep in mind that the abuser was often an authority figure as well. Consent is a moment in time, yet a male survivor is the type of patient who might believe that once he has agreed to a procedure or treatment, there is no other recourse but to acquiesce even if he has changed his mind. Pacing is a way of approaching things in a gradual rather than in a propulsive manner. A physician may proceed with an examination from body part to body part or organ system to organ system in a routine familiar and typical for the physician but unusual and extraordinary for the patient. Physicians need to continue to take a “sounding” from their male survivor patient to maintain an ongoing dialogue about

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**Empathic Communication Techniques with Men Disclosing Histories of Childhood Sexual Abuse and Adverse Childhood Experiences**

1. Physicians need to hear the patient’s words but also to listen to the patient’s feelings through tone of voice.
2. Although not all cultural groups value or are comfortable with direct eye contact, most people of any culture believe a person is not paying attention to them if s/he is writing or keyboarding while talking. Physicians should pause (put down the pen, remove hands from the keyboard) and listen before recording the patient’s answers.
3. Physicians can demonstrate empathy and understanding by responding to the patient’s answers before going on to the next question.
4. Sounds of compassion and soft tones of voice also convey empathy.
5. Reflecting back using the words the patient has used in sharing information with you is a basic way to accomplish empathy.
6. The physician who hears a patient’s disclosure of childhood sexual abuse is placed in the role of a witness. The physician’s response needs to demonstrate respect of the importance of what the patient has shared.
7. A response with the word “okay” is easy to misunderstand because the word can have any number of meanings, some of which are insensitive and thoughtless.
8. Avoid using “placeholder” responses such as “I see,” “Got it,” “Really,” or “I understand” because these can sound particularly callous or insincere to these patients.
9. Empower survivors to tell you how best to move forward with them. For example, the question “Thank you for sharing that. How can I work differently, given what you have shared?” can be an effective way to interact with a patient who has disclosed childhood sexual abuse.
10. Avoid physical contact with a patient in the immediate moments after disclosure. Even well-intentioned contact can be potentially triggering and upsetting.
the patient’s comfort with the decisions he has made. A “sounding” is a clear, concrete request for information about a patient’s experience and coping ability in the moment.

Permission is perhaps the most important aspect of the physician-patient relationship. We recommend that physicians specifically ask for permission. For particularly invasive procedures (eg, digital rectal examinations, testes examinations, retraction of the foreskin of the penis), it is best to specifically engage the patient in a “sounding” on how the patient is coping in the moment. As indicated by the first four vignettes and the introductory case material, the male survivors were not able to articulate their distress as it related to their abuse. A physician may believe that s/he has the patient’s permission to examine him simply because the patient is in the examination room and complying with the physician’s requests. Even if physicians inform a patient of what they will do during an examination or procedure, in the context of the physician as the authority, it implies the patient has no choice. This can easily replicate the patient’s history of sexual abuse, in which his body ceases to be his own and the abuser uses his body in various ways.

Conclusions
Childhood sexual abuse affects a substantial number of men, making it imperative that physicians engaged in male health issues alter their practice to meet their patients’ needs. Childhood sexual abuse has adverse long-term effects on the physical and mental health of survivors. In particular, childhood sexual abuse disrupts interpersonal relationships and can manifest itself in mistrust, fear, avoidance, and suspiciousness of authority figures in their lives. Best clinical practices with male survivors of childhood sexual abuse include physicians considering changes in the way they initially identify this patient population, communicate, respond, listen to, involve, examine, and plan for effective and empowering interactions with them. The male survivor population as a health care consumer group requires rigorous scientific research similar to the research that exists on women survivors. This could ultimately improve the medical care of male survivors.

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

Acknowledgment
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The Art

Too often is it forgotten that the science of medicine finds expression only in the application of the art.

— Denslow Lewis, MD, 1857-1913, American gynecologist and author
COMMENTARY

Prediabetes and Lifestyle Modification: Time to Prevent a Preventable Disease

Phillip Tuso, MD, FACP, FASN

Abstract

More than 100 million Americans have prediabetes or diabetes. Prediabetes is a condition in which individuals have blood glucose levels higher than normal but not high enough to be classified as diabetes. People with prediabetes have an increased risk of Type 2 diabetes. An estimated 34% of adults have prediabetes. Prediabetes is now recognized as a reversible condition that increases an individual’s risk for development of diabetes. Lifestyle risk factors for prediabetes include overweight and physical inactivity.

Increasing awareness and risk stratification of individuals with prediabetes may help physicians understand potential interventions that may help decrease the percentage of patients in their panels in whom diabetes develops. If untreated, 37% of the individuals with prediabetes may have diabetes in 4 years. Lifestyle intervention may decrease the percentage of prediabetic patients in whom diabetes develops to 20%.

Long-term data also suggest that lifestyle intervention may decrease the risk of prediabetes progressing to diabetes for as long as 10 years. To prevent 1 case of diabetes during a 3-year period, 6.9 persons would have to participate in the lifestyle intervention program. In addition, recent data suggest that the difference in direct and indirect costs to care for a patient with prediabetes vs a patient with diabetes may be as much as $7000 per year. Investment in a diabetes prevention program now may have a substantial return on investment in the future and help prevent a preventable disease.

Introduction

In the US, 79 million adults have prediabetes,1 a prevalence approximately 3 times that of diabetes.1 Prediabetes is defined as a condition in which people have higher than normal blood glucose levels but not high enough for a diagnosis of diabetes.1 According to the American Diabetes Association, the diagnostic criteria for prediabetes is an elevated fasting plasma glucose level (100 mg/dL-125 mg/dL), a glycated hemoglobin (HbA1c) value of 5.7% to 6.4%, or an elevated plasma glucose level after an oral glucose tolerance test (140-199 mg/dL).2 The diagnostic criteria for prediabetes and diabetes are shown in Table 1.

Findings of the population-based US National Health and Nutrition Examination Survey suggest that 35% of US adults older than 20 years and 50% of those older than age 65 years have prediabetes.1 Around 5% to 10% of people with prediabetes become diabetic every year.1 The American Diabetes Association recommends that diabetes testing start at age 45 years for all adults who are overweight (body mass index [BMI] ≥ 25 kg/m2) and have any of the following additional risk factors:4

- physical inactivity
- hypertension or history of cardiovascular disease
- low levels of high-density lipoprotein cholesterol and high triglycerides
- first-degree relative with diabetes
- history of previous elevated blood glucose level or HbA1c measurement
- women with polycystic ovarian syndrome
- history of gestational diabetes or giving birth to a baby weighing more than 4.082 kg (9 lb)
- member of an ethnic or minority racial group.

Kaiser Permanente (KP), with approximately 8.5 million members, may be a microcosmic representation of the national data. It is estimated that KP has 852,031 patients who currently meet the criteria for prediabetes by laboratory testing (Table 2). Not all patients with prediabetes are overweight or obese. Data in Table 2 show that 81% of these patients in the Antelope Valley and Kern Service Areas are overweight or obese (BMI ≥ 25) and 19% are normal weight (BMI < 25).

A systematic review of prospective studies confirms a strong, continuous association between HbA1c level and subsequent diabetes risk.3 Persons with an HbA1c value of 6.0% or above had a high risk for development of clinically defined diabetes. The 5-year risk of diabetes if the baseline HbA1c value was at least 6% ranged from 25% to 50%. The relative risk of diabetes was 20 times higher if the HbA1c was greater than or equal to 6% compared with an HbA1c of 5% or less. Persons with an HbA1c value between 5.5% and 6.0% also had a substantially increased risk of diabetes, with 5-year incidences ranging from 9% to 25%. The authors conclude that the level of HbA1c appears to have a continuous association with diabetes risk. According to an American Diabetes Association expert panel, up to 70% of individuals with prediabetes will eventually have diabetes. If current trends continue, 1 in 3 adults will have diabetes by 2050.6

The total estimated cost of diagnosed diabetes in 2012 is $245 billion. This included $176 billion in direct medical costs and $69 billion in indirect costs. The largest components of direct medical costs were hospital inpatient care and prescription medications. People with diagnosed diabetes incur average medical expenditures of about $13,700 per year, of which approximately $7900 is attributed to diabetes. The largest component of indirect costs was increased absenteeism and reduced productivity while at work.5

Phillip Tuso, MD, FACP, FASN, is the Care Management Institute Physician Lead for Total Health. E-mail: phillip.j.tuso@kp.org.
### Table 1. American Diabetic Association diagnostic criteria for normal glucose, prediabetes, and diabetes

<table>
<thead>
<tr>
<th>Diabetes test</th>
<th>Normal</th>
<th>Prediabetes</th>
<th>Diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin A1c, %</td>
<td>&lt; 5.7</td>
<td>5.7-6.4</td>
<td>≥ 6.5</td>
</tr>
<tr>
<td>Fasting blood glucose, mg/dL</td>
<td>&lt; 100</td>
<td>100-125</td>
<td>&gt; 125</td>
</tr>
<tr>
<td>Oral glucose tolerance, mg/dL</td>
<td>&lt; 140</td>
<td>140-199</td>
<td>&gt; 199</td>
</tr>
</tbody>
</table>

### Table 2. Estimate of active members in Kaiser Permanente who screened “positive” for prediabetes in 2012

<table>
<thead>
<tr>
<th>Region</th>
<th>Active members in diabetes risk cohort</th>
<th>Percentage of membership age 10 to 75 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado</td>
<td>32,973</td>
<td>7</td>
</tr>
<tr>
<td>Georgia</td>
<td>11,234</td>
<td>5</td>
</tr>
<tr>
<td>Hawaii</td>
<td>34,997</td>
<td>18</td>
</tr>
<tr>
<td>Northern California</td>
<td>327,845</td>
<td>12</td>
</tr>
<tr>
<td>Northwest</td>
<td>54,466</td>
<td>13</td>
</tr>
<tr>
<td>Ohio</td>
<td>4969</td>
<td>7</td>
</tr>
<tr>
<td>Southern California</td>
<td>385,547</td>
<td>13</td>
</tr>
<tr>
<td>Kaiser Permanente</td>
<td>852,031</td>
<td>12</td>
</tr>
</tbody>
</table>

4 Data specifications reflect an interregional diabetes risk cohort to be used for measurement purposes only and is not intended to inform clinical practice guidelines. Measurement period for membership data was January 1, 2012, through September 30, 2012. Measurement time for diagnoses and laboratory test results was January 1, 2006, through September 30, 2012. Data sources were Geographically Enriched Member Socio-demographics (GEMS) for Kaiser Permanente (KP) members and Clarity for diagnoses and laboratory test results.

5 Cohort excludes Mid-Atlantic data.

6 Inclusion criteria were active KP members age 10 through 75 years, including members with a diagnosis of gestational diabetes but no diagnosis of diabetes who had laboratory values in the prediabetes range; 2 laboratory values for fasting plasma glucose of 100 to 125 mg/dL, or 1 laboratory value for hemoglobin A1C of 5.7% to 6.4%. Exclusion criteria were deceased members, non-KP members, and members with a diagnosis of diabetes (Type 1 or 2) or laboratory values in the range for diabetes.

### Commentary

National annual medical costs of prediabetes in 2007 exceeded $25 billion, or an additional $443 for each adult with prediabetes.4 Several studies suggest that the long-term damage of organ associations with diabetes may start in prediabetes.5–10 In 2012, United Healthcare reported in Health Affairs that adults with diabetes have an average annual health care expenditure of $11,700 per person, whereas adults without diabetes have an average annual expenditure per person of $4,400.11

### Treatment

#### Lifestyle Intervention

Treatment of diabetes prevents some of its devastating complications but does not usually restore normal blood glucose levels.12–13 The diagnosis of diabetes is often delayed until complications are present.14 Because current methods of treating diabetes do not prevent all the complications associated with the condition, prevention of diabetes and even prediabetes is preferable. The Diabetes Prevention Program Research Group has published several studies showing that Type 2 diabetes may be preventable by diet and exercise.15–18

In 2002, Knowler et al19 hypothesized that lifestyle intervention would prevent or delay the development of diabetes. Researchers randomly assigned patients with prediabetes to receive a placebo or a lifestyle modification program with the goals of at least a 7% weight loss and at least 150 minutes of physical activity per week. The mean age of the participants was 51 years, and the BMI was 34.0 kg/m². The average follow-up was 2.8 years. The incidence of diabetes was 11.0 and 4.8 cases per 100 person-years in the placebo and lifestyle groups, respectively. The lifestyle intervention reduced the incidence by 58% compared with placebo. Participants assigned to the lifestyle intervention had more weight loss and greater increase in physical activity than did participants in the placebo group.

The average weight loss was 0.1 kg and 5.6 kg in the placebo and lifestyle intervention groups, respectively (p < 0.001). Further analysis of the study showed that if patients with prediabetes received no intervention, diabetes would develop in approximately 57% in 4 years. The lifestyle modification program decreased the percentage of persons with prediabetes in whom diabetes developed in 4 years to approximately 20% (Figure 1).

Unless people with prediabetes change their lifestyle, most will have Type 2 diabetes within the next 10 years, according to the National Institute of Diabetes and Digestive and Kidney Diseases.19 Lifestyle changes such as weight loss (7% of body weight) and moderate physical activity (150 minutes per week) can reduce the risk of diabetes by as much as 58%.20 To prevent 1 case of diabetes during a 3-year period, 6.9 persons would have to participate in the lifestyle intervention program.21

The Finnish Diabetes Prevention Study published in 200322 evaluated the effects of a lifestyle intervention on short-term and long-term changes in diet and exercise behavior, and the effect of the intervention on glucose and lipid metabolism. In the study, 522 middle-aged, overweight

![Figure 1. Cumulative incidence of diabetes during a four-year period in patients with prediabetes who engaged in a lifestyle modification program versus no lifestyle modification program (placebo).](image)
subjects with impaired glucose tolerance were randomly assigned to receive either usual care or an intensive lifestyle intervention. The control group received general advice about diet and exercise at baseline and had an annual physician’s examination. The subjects in the intervention group received additional individualized dietary counseling from a nutritionist. They were also offered circuit-type resistance training sessions and advised to increase overall physical activity. The intervention was the most intensive during the first year, followed by a maintenance period. The intervention goals were to reduce body weight, reduce intake of dietary and saturated fat, and increase physical activity and dietary fiber intake. The authors found that intensive lifestyle intervention produced long-term beneficial changes in diet, physical activity, and clinical and biochemical parameters and reduced diabetes risk. The incidence of diabetes was related to weight loss. The incidence of converting from prediabetes to diabetes was approximately 2% for subjects who lost at least 5% of their body weight vs about 8% for subjects who gained more than 2.5% of their body weight (p < 0.002).

In 2009, Knowler et al and the Diabetes Prevention Program Research Group17 investigated the persistence of the effects in the long term on the patients described in the study published by the same group in 2002. In this follow-up study, 88% of patients enrolled for a median additional follow-up of 5.7 years. On the basis of benefits from the intensive lifestyle intervention in the first study, all 3 groups were offered group-implmented lifestyle intervention. During the 10-year follow-up since randomization, the original lifestyle group lost, then partly regained weight. Diabetes incidence rates in this follow-up study were similar between treatment groups: 5.9 per 100 person-years for lifestyle intervention and 5.6 for placebo. Diabetes incidence in the 10 years since randomization was reduced by 34% in the lifestyle group compared with the placebo group. The authors concluded that prevention or delay of diabetes with lifestyle intervention could persist for at least 10 years.

In 2012, Perreault et al19 reported that patients with prediabetes that did not progress to diabetes after they completed an intensive lifestyle intervention were still at high risk for the development of diabetes. They also discovered that reversion to normal glucose levels, even transiently, was associated with a 56% reduced risk of future diabetes.

In 2013, Schellenberg et al20 compared the effectiveness of lifestyle interventions to standard care on minimizing progression of prediabetes to diabetes or reducing all-cause mortality in diabetes. This meta-analysis study identified 9 randomized, controlled trials with prediabetic patients who were at risk of diabetes and 11 randomized, controlled trials with patients who had diabetes. Seven of the 9 studies looking at patients who were at risk of diabetes reported that lifestyle interventions decreased the risk of diabetes up to 10 years after a lifestyle intervention.

Results of multiple trials support a long-term reduction in diabetes risk or a delay in onset of the disease as a result of lifestyle and drug-based intervention.21,22 In the 20-year follow-up of the Da Qing Diabetes Prevention Study, those receiving a lifestyle intervention had a 51% lower incidence of diabetes.23 Group-based lifestyle interventions over 6 years can prevent or delay diabetes for up to 14 years after the active intervention.

In 2011, Gong et al24 reported a study started in 1986 when 577 adults with impaired glucose tolerance from Da Qing, China, were randomly assigned by clinic to a control group or 1 of 3 lifestyle intervention groups (diet, exercise, and diet plus exercise). In 2006, the researchers conducted a 20-year follow-up study of the original participants to compare the incidence of retinopathy, nephropathy, and neuropathy in the intervention group vs the control group. Follow-up information was obtained on 542 (94%) of the original participants. After adjusting for clinic and age, the incidence of severe retinopathy was 57% lower in the intervention group than the control group. No significant differences were found in the incidence of severe nephropathy or in the prevalence of neuropathy.25

### Pharmacologic and Surgical Intervention

Evidence of potential benefits from pharmacotherapy to prevent diabetes in patients with prediabetes was reported by Knowler et al26 in 2002. Biguanides, such as metformin, were shown by the investigators to decrease the incidence of diabetes but not as much as lifestyle interventions. Metformin, which has a good safety profile, has beneficial effects on BMI and lipid concentrations.20 In 2010, Lilly and Godwin27 concluded after a systematic review of the literature and meta-analysis that metformin lowers risk of Type 2 diabetes by 45%. The number needed to treat was between 7 and 14.27 The beneficial effects of metformin were greater in people who were prediabetic with a higher baseline BMI than in the individuals with a lower BMI.14

Thiazolidinediones (troglitazone, rosiglitazone, and pioglitazone) have been shown to reduce the incidence of diabetes in patients at risk of diabetes. However, risks of this medication, which may include hepatotoxicity, weight gain, edema, and heart failure, outweigh the benefit in preventing prediabetes from progressing to diabetes.28,29 For example, troglitazone was withdrawn from the market in 2000 because of serious idiosyncratic hepatotoxicity.30

Although inhibitors of the renin-angiotensin-aldosterone system may have a beneficial effect on reducing complications of prediabetes and diabetes, there is no evidence that they help in preventing prediabetes from progressing to diabetes. In morbidly obese people, bariatric surgery is associated with sustained weight loss and a substantial reduction in the two-year and ten-year incidence of diabetes.31,32

### Discussion

By screening and risk-stratifying individuals as prediabetic, we may be able to develop a strategy to prevent prediabetes

---

**Table 3. Distribution of members with prediabetes by body mass index for Kaiser Permanente Southern California Antelope Valley and Kern Service Areas**

<table>
<thead>
<tr>
<th>Body mass index, kg/m²</th>
<th>Antelope Valley, no. (%)</th>
<th>Kern, no. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 30</td>
<td>4403 (54)</td>
<td>3534 (51)</td>
</tr>
<tr>
<td>25-29</td>
<td>2192 (27)</td>
<td>2098 (30)</td>
</tr>
<tr>
<td>&lt; 25</td>
<td>1510 (19)</td>
<td>1335 (19)</td>
</tr>
<tr>
<td>Total</td>
<td>8105 (100)</td>
<td>6967 (100)</td>
</tr>
<tr>
<td>≥ 25</td>
<td>6595 (81)</td>
<td>5632 (81)</td>
</tr>
</tbody>
</table>
from progressing to diabetes. Clinical evidence suggests that we should not accept a prediabetic state but should actually try to convert prediabetes to a normal glucose state. Lifestyle and pharmacologic interventions by themselves may not help prevent long-term microvascular or macrovascular complications of prediabetes. Only by achieving a normal glucose state can we prevent complications of prediabetes and diabetes.

The identification and treatment of prediabetic individuals is therefore crucial to our efforts to make health care more affordable, prevent preventable disease, and save lives. Recent evidence presented in this article suggests that prevention of progression of prediabetes to diabetes and conversion of prediabetes to a normal glucose state is possible. On the basis of a literature review and published meta-analyses, we recommend that physicians screen and risk-stratify individuals with prediabetes. By doing so, we may be able to develop interventions that focus on the risk of the patient with prediabetes.

As shown in Table 4, it may be possible to risk-stratify individuals with prediabetes by HbA1c and BMI. All patients with prediabetes should complete the following goals: 1) lifestyle modification training, 2) 150 minutes per week of physical activity, and 3) 7% weight loss if BMI exceeds 25 kg/m2. For high-risk individuals with high BMI, pharmacologic and surgical interventions may be considered if these goals are not achieved. Metformin appears to have a good safety record and may help with weight and lipid management. Other antidiabetes medications may have risks that prohibit their use at this time.19

Economic considerations are important for health care groups because the cost to care for individuals with diabetes far exceeds the cost to care for patients with prediabetes or normal glucose levels. Most studies support the notion that lifestyle change should be the cornerstone for diabetes prevention. On the basis of results published by Knowler et al20 in 2002 and others,21 it may make financial sense to invest in the treatment of prediabetes. Knowler et al20 estimated that 37% of individuals with prediabetes would have diabetes in 4 years without intervention. If individuals with prediabetes complete a lifestyle intervention program, their risk of diabetes developing in 4 years decreases to about 20%. Studies were not performed to determine if interventions to promote healthy eating and active living over many years could help reduce the percentage of people whose prediabetes progresses to diabetes to less than 20% (Figure 1). The difference in direct and indirect costs to treat a patient with prediabetes vs diabetes is estimated to be about $7000 per year.22

KP estimates having at least 852,031 patients with prediabetes (Table 2). If we do nothing, diabetes may develop in 4 years in approximately one-third, or 284,010 patients. If we were able to persuade the 852,031 prediabetic members to participate in and complete a lifestyle management program, the number in whom diabetes develops might decrease to approximately 170,406, or 113,604 patients saved from development of diabetes. The estimated cost savings per year would be costs saved from treating thousands of patients with diabetes minus the cost to implement an effective screening and lifestyle management program for all patients with prediabetes.

In 2012, Health Affairs published an article looking at the economics of screening and treating individuals with prediabetes.23 Using a simulation model, the authors projected the costs and benefits of a nationwide community-based lifestyle intervention program for preventing Type 2 diabetes. In the hypothetical intervention program, nearly 100 million Americans aged 18 to 84 years would be screened over the next 25 years and nearly 23 million of those would have prediabetes. Another 13 million would be expected to be enrolled in a lifestyle intervention. The researchers projected that over the 25-year simulation period the hypothetical program would prevent or delay 885,000 new cases of Type 2 diabetes and result in a gain of 952,000 life-years and 669,000 quality-adjusted life-years. The researchers projected that the program would result in $29.8 billion in downstream savings for those in whom diabetes and diabetes-related complications may have developed without intervention.24

Of concern are recent data showing that an intensive lifestyle intervention focusing on weight loss did not reduce the rate of cardiovascular events in overweight or obese adults with Type 2 diabetes.37 The finding suggests there is a window of opportunity in patients with prediabetes to save lives that may not occur in patients with diabetes. However, in another study, lifestyle modification was exceptionally effective in preventing diabetes in older individuals, and this finding was largely explained by greater weight loss and an increase in physical activity.25 These data suggest that even older adults may benefit from behavior-change interventions aimed at preventing diabetes and its complications. Recent data suggest that lifestyle interventions to prevent diabetes may overcome the genetic risk of diabetes.26 This information may be helpful to

### Table 4. Proposed risk stratification and treatment strategies for prediabetes

<table>
<thead>
<tr>
<th>Risks and treatments</th>
<th>Low risk</th>
<th>Medium risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin A1c %</td>
<td>5.7-5.8</td>
<td>5.9-6.1</td>
<td>6.2-6.49</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Lifestyle modification, 16-week course</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Physical activity of at least 150 minutes per week</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Weight loss of 7% of body weight if BMI ≥ 25 kg/m²</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Hemoglobin A1c &lt; 5.7%</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Metformin therapy for patients with BMI ≥ 25 kg/m² if no weight loss after 16-week lifestyle modification course</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastric bypass surgery for patients with BMI &gt; 35 kg/m² per guidelines for treating obesity and/or if no weight loss after lifestyle modification and/or metformin therapy</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BMI = body mass index; ✓ = yes.
parents of children with a strong family history of diabetes.

Finally, because most of the direct costs for diabetes are associated with treating complications of diabetes, a managed care organization like KP, which is not dependent on fee-for-service reimbursement, may be in a unique position to help implement upstream programs in schools and community programs now to prevent prediabetes, diabetes, and complications of diabetes.41

Conclusions

The time is right to develop a proactive approach to prediabetes. This approach may include the following recommendations for practice:

1. Develop a business case for screening for and for treating prediabetes. This will involve estimating the cost savings resulting from preventing hundreds of thousands of patients from diabetes minus the estimated cost to screen all patients at risk of diabetes and the estimated cost for implementing an effective lifestyle modification program to all patients with prediabetes.

2. Develop clinical guidelines for physicians on how to identify and manage patients with prediabetes, as outlined in Table 4. The guidelines will help us determine a standardized approach to treating prediabetes and allow us to develop measurable outcomes to determine if all patients with prediabetes are completing a lifestyle modification program and achieving weight loss, HbA1c, and physical activity goals, as shown in Table 4.


20. Schellenberg ES, Dryden DM, Vandermeer B, Ha C, Korowyn C. Lifestyle interven-


A Commentary on “Comparative Health Systems Research among Kaiser Permanente and Other Integrated Delivery Systems: A Systematic Literature Review”

Thomas E Kottke, MD, MSPH; Patrick T Courneya, MD

The occurrence of occupational organization ... constitutes a dimension quite as distinct and fully as important as its knowledge."

In this issue of The Permanente Journal, Maeda et al1 enumerate the relative frequency at which articles on comparative health systems research are published about Kaiser Permanente (KP) and other integrated delivery systems. Searching PubMed and the KP Publications Library, they found that a mere 4% of publications met their criteria. This is unfortunate because well-organized systems are the foundation of effective health services delivery, and comparative health systems research to create these systems can greatly increase the value that Americans receive from their health care.

After observing that the physicians he studied tended to practice very much like their colleagues despite differences in training and upbringing, Eliot Freidson1 concluded that “occupational organization ... constitutes a dimension quite as distinct and fully as important as its knowledge ... .” Having practiced medicine at many different sites over our careers, we have found that the organization of care in a particular location determined the services that we could offer the patient, the efficiency with which we provided those services, and the patient’s experience with the care that s/he received from us. Therefore, we would have to agree with Freidson—organizational context is a powerful determinant of clinical performance. The paucity of comparative health systems research relative to the overall investment in research represents a missed opportunity for research to contribute to the Triple Aim.

Despite contributing nearly one-third of the international investment in biomedical research and spending more on health care than any other country, Americans receive a poor return on their investment. Americans die sooner and experience more illness than do residents of many other countries.3-4 In 2007, life expectancy at birth for US males was 17th of 17 peer countries; life expectancy for US females was 16th of 17 countries.3 We believe that these poor results are due, in part, to the paucity of comparative organizational research aimed at improving outcomes for individual patients and entire populations.

This paucity also contributes to the persistence of inequitable care in America. Colorectal cancer screening rates are markedly lower for individuals of low economic and educational status.5 Additionally, in a large cohort of whites and African Americans, follow-up of colorectal abnormalities was significantly lower among the African Americans.6 Inequalities of care like these contribute to large differences in life expectancy, even in single metropolitan areas. In the Twin Cities, MN, for example, age-standardized mortality rates for American Indians are six times as high as they are for Asians.7 Life expectancy in some Twin Cities zip codes is equal to that of Armenia, Estonia, and Jordan, and it is exceeded by life expectancy in the Gaza Strip in the Middle East, in Romania, and in China.8

However, poor health outcomes and disparities do not need to be a part of American life. In a recent issue of The Permanente Journal, Tuso et al9 reported their analysis of the care processes that reduced the risk of readmission because of heart failure. They found that a complex case conference, along with a visit from a home health nurse and a follow-up visit with the patient’s physician reduced the risk of readmission by about 45%. Among the 21 patients for whom complete data were available and who were treated around the time of the study, there were 81 admissions in the 6 months before and 22 admissions in the 6 months after the complex case management conference was implemented, a reduction of 68%.

HealthPartners in St Paul, MN, has used comparative health systems research to significantly reduce disparities in care while addressing screening targets for all patients. The tools that we have used include collecting language preference and racial identification from our patients, identifying and reporting the levels of care disparities, diagnosing the sources of the disparities, developing initiatives that address the particular causes of the disparities, and continuously monitoring the results with monthly report cards to assure ourselves that the new system is outperforming the prior system.

For example, the gap in mammography rates between white women and women of color was 12.3 percentage points in 2007, and appointment no-show rates for women of color were high. We met with women in the community and learned that returning to the clinic for a second visit was a major barrier to mammography. We instituted a same-day mammography program and were able to decrease the disparity rate to 6.1 points by 20109 and 3.2 points by the fourth quarter of 2013 (unpublished written data available on request). Likewise, by offering multiple options for colorectal cancer screening (eg, fecal immunochemical test or colonoscopy) and actively promoting screening to patients of color, we have been able to reduce the

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References

gap in colorectal cancer screening between white patients and patients of color from 26.2 points during the first quarter of 2009 to 12.0 points in July 2013 (unpublished written data available on request). While decreasing health disparities, we have also increased screening rates for both colorectal cancer and breast cancer for all groups of patients.

By using the organizational tools described earlier and employing an East African community health worker to follow-up with patients in the community, HealthPartners clinicians at one clinic were able to reduce the disparity in optimal diabetes care for patients of color—to just 4.4 points in February 2014 (unpublished written data available on request). The rate of optimal diabetes care for patients of color—45.4%—is 7 points above the average for medical groups reporting to Minnesota Community Measurement, a nonprofit organization whose mission is to accelerate the improvement of health by publicly reporting health care information.11

We believe that creating an environment that comprises five activities has allowed us to achieve the goals described above: 1) a set of mutual, measurable goals; 2) public reporting of the extent to which the goals are being achieved; 3) sufficient resources to achieve the goals; 4) alignment of stakeholder incentives, imperatives, and sanctions with the goals; and 5) leadership among all stakeholders to endorse and promote the goals.12

In the past, the high cost of obtaining claims data and clinical data was a legitimate barrier to comparative health systems research. However, with the implementation of electronic billing and electronic health records, large group practices like KP, and medical group consortia such as the Health Maintenance Organization Research Network with its Virtual Data Warehouse,13 comparative health systems research is now economically feasible. Although the impact of participation in care improvement collaboratives is limited in many cases,14 we believe that participation in the Institute for HealthCare Improvement’s programs helps health care organizations improve their care through self-evaluation and shared learning. To stimulate care improvement, HealthPartners has published clinic performance reports on selected indicators for many years.15 These reports have been associated with meaningful improvements in performance by clinical groups that treat HealthPartners members. Public reporting of health system performance by national organizations such as the Healthcare Effectiveness Data and Information Set (HEDIS),16 Hospital Compare,17 and the Leapfrog Group18 might also be expected to drive competition for outcomes improvement by groups that are not formally affiliated. Although improving monthly performance reports should be considered adequate evidence of goal attainment, a stepped-wedge randomized evaluation design would also be a powerful and efficient evaluation tool that, in most cases, would satisfy the exigent circumstances of care delivery system development.19

“Knowing is not enough; we must apply. Willing is not enough; we must do.” This credo, attributed to Johann W von Goethe, appears on the frontispiece of all Institute of Medicine reports and underscores the fact that biomedical research and health care are social investments that are expected to create value for the public. More than 40 years ago, Freidson20 recognized that an effective care delivery system is the substrate that creates value from knowledge. Maeda et al have done the research documenting the paucity of research designed to develop this substrate.

It is now time for the health care research and practice communities to collaborate, increase comparative health systems research activity, and give Americans the value in health care that they deserve.21

Acknowledgment

Kathleen Louden, ELS, of Louden Health Communications provided editorial assistance.

References

A Novel Use of Foley Catheters to Prevent Injury to the Pelvic Viscera During Stereotactic Radiosurgery for Undifferentiated Pleomorphic Sarcoma of the Sacrum

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Abstract
The use of a Foley catheter to protect the small and large bowel from radiation injury during stereotactic radiosurgery to the spine has not previously been described in the surgical literature. Many spine tumors should be treated with stereotactic radiosurgery as opposed to external beam therapy, yet the proximity of visceral organs may preclude adequate target delivery of radiation. We describe the novel use of Foley catheters placed intraoperatively to displace the bowel during stereotactic radiosurgery, allowing for a full radiation dose to be safely delivered to the tumor. The advantages of this technique are the low cost, the ability to place multiple catheters intraoperatively, and the ability to withdraw all the catheters after radiation without the need for reoperation.

Case Report
The patient was a 56-year-old woman with a history of T1N0M0 rectal adenocarcinoma treated with transanal excision followed by adjuvant chemoradiation 5 years before presentation. The patient had lymphovascular invasion, and she received 45.00 Gy to the whole pelvis and a boost of 55.60 Gy to the tumor bed, without subsequent local or distant recurrence. One year before presentation, she developed numbness of the lower left foot and leg; a magnetic resonance image (MRI) of the pelvis revealed a 4.2 cm × 1.8 cm mass compressing the left S1 nerve root, initially thought to represent a peripheral nerve sheath tumor (Figure 1). Fine needle aspiration of the mass demonstrated an unclassified spindle cell neoplasm but could not diagnose the mass as malignant, and a subsequent core needle biopsy again demonstrated a spindle cell neoplasm. Thus, the working diagnosis was nerve sheath tumor. The patient was very symptomatic from radiculopathy, and her treatment options included observation, radiation, or surgery. Conventional external beam radiation therapy was not possible because of the patient’s history of radiation therapy, and the bowel had already received the maximal dose of radiation. The patient elected surgery and underwent a left S1 laminectomy for presumed schwannoma.

The pathology report demonstrated a grade 2 pleomorphic undifferentiated sarcoma with osteoclast-like giant cells, likely representing a radiation-induced tumor. The patient’s new tumor was pathologically unrelated to the prior tumor, was located within the prior radiation field, and had evolved over an interval of several years after radiation. A postoperative MRI demonstrated a residual mass in the S1-S2 neural foramina with tumor extending into the pelvis, and resection for this
ventral component was not achievable by a posterior approach. The patient thus underwent an exploratory laparotomy for removal of this anterior component of the tumor. The pathology report from this procedure demonstrated a pleomorphic undifferentiated sarcoma with osteoclast-like giant cells and a lymph node with clear margins. Subtotal resection was achieved.

A postoperative MRI of the pelvis demonstrated a mass-like rind of enhancing material in the anterolateral margin of the left S1 neural foramen, suspected to be a residual tumor. Stereotactic radiosurgery (SRS) was planned to treat the residual tumor, but the patient was given time to recover from her surgical procedures. One month later, a repeat MRI demonstrated tumor progression. The patient’s case was presented at tumor board, and it was felt that further anterior debulking was critical. However, it was not feasible to achieve this via an anterior laparotomy because of the sacral promontory obstructing the approach. Thus, a revision via the posterior approach would be necessary. However, a gross total resection would not be possible because of the previous subtotal resection, and SRS was critical for control of the residual tumor. Preoperative evaluation demonstrated that the adjacent bowel was too close to the tumor for safe delivery of adequate dosing to the tumor by SRS. Thus, the preoperative planning included a method to keep the bowel away from the sacrum during SRS and to subsequently allow the bowel to return to its normal anatomic position next to the sacrum after SRS.

The initial preoperative plan was to use aortic angioplasty catheters to create a space that would displace the bowel, which could subsequently be deflated and withdrawn easily. The patient underwent a revision via the posterior approach to remove the tumor and to attempt placement of the angioplasty catheters. Bilateral ureteral stents were placed, the small bowel and rectum were dissected off the anterior surface of the sacrum, and a revision S1-S2 laminectomy, partial resection of the sacrum, and resection of the left S1 nerve root were performed. The tumor that could be safely removed from a posterior approach was resected, but clearly the anatomic limitations precluded a gross, total resection. The stiff and relatively sharp tips of the angioplasty catheters prevented safe and accurate placement. In addition, upon inflation of the balloon, the construct was very stiff and not malleable, precluding proper placement of the balloons. Thus, the strategy of placing these angioplasty balloons was abandoned.

Intraoperatively, the discussion turned to identifying alternate catheters that were soft, malleable, and already equipped with a balloon, leading to the selection of a large-volume-balloon Foley catheter. Two Foley catheters, with balloon volumes of 30 cc each, were obtained and placed ventral to the sacral defect. The tips of the Foley catheters were trimmed to prevent iatrogenic injury or erosion into native structures during postoperative radiation therapy. Because a single catheter would not stay in place, a second catheter was placed dorsal to the first to prevent it from migrating (Figure 2). They were placed manually and then inflated with barium mixed with saline. An intraoperative O-arm image (lower-resolution intraoperative computed tomography) confirmed satisfactory position of the catheters and adequate distance between the sacrum and the bowel (Figure 2).

Because the manufacturer’s instructions recommend saline as the appropriate fluid for balloon inflation, two new Foley catheters were then placed directly through the sacral wound and inflated with saline. The two drains were placed adjacent to each other in a buttressing manner and were not secured to each other. They were then tunneled laterally through the subcutaneous tissues and secured to the skin exit sites with non-absorbable sutures. The skin was closed primarily over the surgical incision, and the sacrum provided the barrier to prevent Foley catheter migration posteriorly. The patient was discharged on postoperative day 4 and subsequently received an SRS boost totaling 30.00 Gy in 5 fractions, with minimal dose to the adjacent bowel. The Foley catheters remained in situ for the duration of radiation therapy. They were removed in the outpatient clinic in the standard manner, as with other intraabdominal drains, after premedication with oral narcotics on the final day of radiation treatment, 3 weeks postoperatively. The balloons were inspected and were without leakage.

The final pathology report was of a grade 2 pleomorphic undifferentiated sarcoma with osteoclast-like giant cells.
CASE STUDY

Immunohistochemical staining revealed a moderate to high mitotic index with an MIB-1 labeling index of 15%. Patchy CD31 staining of the tumor raised the remote possibility of an atypical angiosarcoma, but staining for vascular markers including Fli1, thrombomodulin, and factor VIIIa was negative. The tumor was negative for melanoma markers (S-100, HMB-45, and Melan-A), as well as keratin, arguing against sarcomatoid carcinoma (which is the more common presentation of recurrence of a rectal carcinoma). The staging classification was T1N0M0.

The patient subsequently completed an electron boost dose of 12.50 Gy in 5 fractions with 6 MV electrons directed to the postoperative bed and 5 cycles of adjuvant chemotherapy with ifosfamide and epirubicin. She presented with symptoms of a possible closed-loop small bowel obstruction 10 months after her last operation. She was brought to the operating room promptly and no bowel resection, and she did undergo lysis of adhesions with the operating room promptly and no bowel resection, and she did undergo lysis of adhesions with that strategy when we recognized that we could not orient the inflexible catheters in the presacral space without risking injury to the intestine. Another more recent novel strategy is the use of an air-filled breast prosthesis to exclude small bowel from the pelvis; this was performed following resection of recurrent adenocarcina of the ascending bowel. The disadvantage of this approach is the need for reoperation to remove the prosthesis once the radiation therapy has been completed. Katsoulakis et al reported a similar technique using saline bags placed by interventional radiology, but a standard Foley catheter was not used in these ten cases. Sezeur et al also described a similar technique, but again, they used prosthetics, not standard Foley catheters.

In patients such as ours with a previous history of external beam radiation, SRS is an important option, but it carries an increased risk of injury to the adjacent small bowel and rectum. For those patients who have exceeded the normal-tissue maximum tolerated dose of external beam therapy in the treatment of unrelated malignancies, alternate treatment strategies are necessary. In the current case, because of anatomic constraints, interventional radiology to either place a physical barrier or to infiltrate the presacral space with saline to displace the bowel anteriorly before radiation treatment was deemed unsuitable. We initially considered an operative approach involving theuse of an angioplasty catheter but intraoperatively chose not to proceed with that strategy when we recognized that we could not orient the inflexible catheters in the presacral space without risking injury to the intestine.

The only other therapeutic alternative would have been to use intraoperative radiation therapy. However, because the sacral nerve roots had already received maximal radiation, intraoperative radiation therapy could not be safely delivered. Ultimately, the novel use of a Foley catheter enabled the patient to undergo successful treatment, with successful removal at the completion of treatment.
A Novel Use of Foley Catheters to Prevent Injury to the Pelvic Viscera During Stereotactic Radiosurgery for Undifferentiated Pleomorphic Sarcoma of the Sacrum

**Case Study**

**Conclusion**

To reduce the risk of radiation injury to the small bowel and rectum during stereotactic radiosurgery for tumors of the sacrum, a large-volume Foley catheter can be positioned intraoperatively in the pelvis to temporarily displace the visceral organs. The advantages of this approach are the low cost, the ability to place multiple catheters to displace the bowel, and the ability to remove the catheters without the need for reoperation.

**Disclosure Statement**

Dr. Chou reported receiving honoraria from Medtronic and Depuy; he is also a consultant for Globus and Orthofix. Dr. Maa is on the Board of Directors of the American Heart Association and the San Francisco Medical Society. Dr. Jahan reported receiving grant support from Pfizer, Adaro Pharmaceuticals, Morphotek, OSI/Roche, and Medimmune; he is also a consultant for Clovis Pharmaceuticals and Novartis. No other conflicts of interest were disclosed.

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**References**


CME Evaluation Program

Section A.

Article 1. (page 4) An Adaptation of Family-Based Behavioral Pediatric Obesity Treatment for a Primary Care Setting: Group Health Family Wellness Program Pilot

Compared with baseline, children who completed the behavioral obesity program ended the treatment period with, on average:
- a. lower BMI Z-Score
- b. higher parent-reported quality of life
- c. both a and b
- d. neither a nor b

Interviews with parents who took part in the group-based program revealed that most parents felt that the process of their child developing healthy behaviors for eating and physical activity was:
- a. a private matter that parents take on without much interaction with or input from friends and family
- b. a medical treatment that involves frequent physician visits
- c. an opportunity for their child to succeed without parent involvement
- d. a social experience that is made easier when parents get support from friends and family and made harder when they feel undermined or discredited

Article 2. (page 11) Temporal Trends in Mortality after Coronary Artery Revascularization in Patients with End-Stage Renal Disease

In comparison with the reference time period of 1996-1999, the relative risk of 3-year mortality in the revascularization period between 2004-2008 was:
- a. 34% lower
- b. 42% lower
- c. 66% lower

The statistical analysis used to understand temporal trends of coronary revascularization procedures in patients on chronic dialysis was:
- a. linear regression
- b. time-to-event analysis
- c. logistic regression

Section C.

What other changes, if any, do you plan to make in your practice as a result of reading these articles?

Section D. (Please print)

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